Upcoming Evidence Committee Meeting

From: "Shapiro, Elizabeth (CIV)" <(b) (6)>
To: "Gardner, Joshua E (CIV)" <(b) (6)>, "Byron, H. Thomas (CIV)" <(b) (6)>, "Reno, Tammy (USAEO)" <(b) (6)>, "Montague, Rich (CIV)" <(b) (6)>, "Bain, Adam (CIV)" <(b) (6)>, "Dintzer, Kenneth (ATR)" <(b) (6)>, "Huntley, Colin (CIV)" <(b) (6)>, "McVeigh, Peter (ENRD)" <(b) (6)>, "Blaha, Amber (ENRD)" <(b) (6)>, "Benson, Barry (CIV)" <(b) (6)>, "Goldberg, Stuart M. (TAX)" <(b) (6)>, "Himmelhoch, Sarah (ENRD)" <(b) (6)>, "Stemler, Patty (CRM)" <(b)(6); (b)(7)(C) per CRM>, "Wroblewski, Jonathan (CRM)" <(b)(6); (b)(7)(C) per CRM>, "Gardner, Joshua E (CIV)" <(b) (6)>, "Smith, David L. (USAEO)" <(b) (6)>, "Lyons, Samuel R (TAX)" <(b) (6)>, "Fountain, Dorothy (ATR)" <(b) (6)>
Cc: "Hunt, Ted (ODAG)" <(b) (6)>, "Goldsmith, Andrew (ODAG)" <(b) (6)>
Date: Thu, 29 Oct 2020 21:59:04 -0400
Attachments: agenda_book_for_evidence_rules_committee_meeting_november_13_2020final_0.pdf (11.11 MB)

All,

The Evidence Rules Advisory Committee is meeng on Frida y, November 13. This is the first meeng in o ver a year, since (b)(5) per CIV agenda book for reference. It's outrageously long, and impossible to read cover to cover. I have included the relevant page numbers in the discussion below, so you can hone in on the relevant topics.

This is will the third year that we are discussing possible amendments to FRE 702. (b)(5) per CIV (b)(5) per CIV very welcome. In parcular , I would be intereste (b)(5) per CIV amendments (with their proposed notes) could (b)(5) per CIV .

Second: We are also years into a discussion of FRE 106. (Tab 3 of the Agenda Book, beginning on page 538). Amendment is being considered in order to resolve a circuit split, wherein some circuits the rule of compleon trump s (b)(5) per CIV former committee chair (Judge Livingston) at the last meeng pr oposed a third possibility, which is to allow the compleng (hear say) statement to come in for the non-hearsay purpose of context. Four possible amendment , on pages 588-596. (b)(5) per CIV . I would welcome th (b)(5) per CIV .

Third: Rule 615, on excluding witnesses, is the last major agenda item. Amendment was proposed because the text of Rule 615 is limited to excluding witnesses from the courtroom, but it doesn't technically prohibit a prospecy e witness e the courtroom. The proposed amendment would (b)(5) per CIV . The committee also discussed the consequences o g a prohibion on access t o tesmon y, includ Drafting suggeson begins a t page 660. (b)(5) per CIV . But please weigh in if you see an problems or have suggesons.

Thanks to everyone for taking the me t o look at the materials and provide your views. (To refresh memories, I've also included below the summary that I circulated on these items from a year and a half ago.)
All best,
Betsy

****
(b)(5) per CIV

ADVISORY COMMITTEE
ON
RULES OF EVIDENCE

November 13, 2020

THIS PAGE INTENTIONALLY BLANK

ADVISORY COMMITTEE ON EVIDENCE RULES

AGENDA FOR COMMITTEE MEETING

November 13, 2020

I. Committee Meeting --- Opening Business

Opening business includes:

- Introduction of new Chair, Hon. Patrick Schiltz
- Approval of the minutes of the Fall, 2019 meeting.
- Report on the June, 2020 meeting of the Standing Committee.

II. Rule 702

The Committee has been considering two possible changes to Rule 702: 1) an amendment regulating overstatement of expert conclusions (directed toward, but not only toward, forensic experts); and 2) an amendment (or Committee Note) that the admissibility requirements set forth in the rule --- most especially sufficiency of basis and reliability of application --- are matters that must be decided by the court by a preponderance of the evidence under Rule 104(a). The Reporter's memorandum on these possible changes is behind Tab 3.

Immediately behind the Reporter's memo are three attachments:

1. A case digest prepared by the Reporter on forensic expert testimony;

2. Judge Schroeder's recently published article in the Notre Dame Law Review on the Rule 104(a)/104(b) question.

3. Letters and Reports to the Committee from the defense bar in support of an amendment to Rule 702.

III. Rule 106

The Committee has been considering a proposal to amend Rule 106, the rule of completeness, for two purposes: 1. to specify that completing evidence is not barred by the hearsay rule; and 2. to extend its coverage to oral statements. The Reporter's memorandum on the subject is behind Tab 3.

Immediately behind the Reporter's memo is a report prepared by Professor Richter on case law in the states that allow completion with unrecorded oral statements.

IV. Rule 615

The Committee is considering whether the Rule should be amended to provide that a Rule 615 order extends to prohibiting excluded witnesses from obtaining or from being provided trial testimony while they are excluded from the courtroom. The Reporter's memorandum on Rule 615 is behind Tab 4.

V. Emergency Rule

The Committee was asked to consider whether the Evidence Rules should be amended to provide for different rules in an emergency such as the pandemic. The Reporter's memorandum on the subject is behind Tab 5.

VI. Circuit Splits

The Reporter has prepared a memorandum on circuit splits on the meaning of certain Federal Rules of Evidence. This is being submitted to assess the interest of the Committee in considering amendments to rectify some of these circuit splits. The memorandum is behind Tab 6.

VII. *Crawford* Outline

The Reporter's updated outline on cases applying the Supreme Court's Confrontation Clause jurisprudence is behind Tab 7.

TAB 1

TAB 1A

Committee on Rules of Practice and Procedure
(Standing Committee)

Chair

Honorable John D. Bates
United States District Court
E. Barrett Prettyman U.S. Courthouse
333 Constitution Avenue, N.W.
Washington, DC 20001

Reporter

Professor Catherine T. Struve
University of Pennsylvania Law School
3501 Sansom Street
Philadelphia, PA 19104

Secretary

Rebecca A. Womeldorf, Esq.
Secretary, Standing Committee and
Rules Committee Chief Counsel
Administrative Office of the U.S. Courts
Thurgood Marshall Federal Judiciary Building
One Columbus Circle, N.E., Room 7-300
Washington, DC 20544

Advisory Committee on Appellate Rules

Chair

Honorable Jay S. Bybee
United States Court of Appeals
Lloyd D. George U.S. Courthouse
333 Las Vegas Boulevard South, Suite 7080
Las Vegas, NV 89101-7065

Reporter

Professor Edward Hartnett
Richard J. Hughes Professor of Law
Seton Hall University School of Law
One Newark Center
Newark, NJ 07102

Advisory Committee on Bankruptcy Rules

Chair

Honorable Dennis R. Dow
United States Bankruptcy Court
Charles Evans Whittaker U.S. Courthouse
400 East Ninth Street, Room 6562
Kansas City, MO 64106

Reporter

Professor S. Elizabeth Gibson
University of North Carolina at Chapel Hill
5073 Van Hecke-Wettach Hall, C.B. #3380
Chapel Hill, NC 27599-3380

Associate Reporter

Professor Laura B. Bartell
Wayne State University Law School
471 W. Palmer
Detroit, MI 48202

Advisory Committee on Civil Rules

Chair

Honorable Robert M. Dow, Jr.
United States District Court
Everett McKinley Dirksen U.S. Courthouse
219 South Dearborn Street, Room 1978
Chicago, IL 60604

Reporter

Professor Edward H. Cooper
University of Michigan Law School
312 Hutchins Hall
Ann Arbor, MI 48109-1215

Associate Reporter

Professor Richard L. Marcus
University of California
Hastings College of the Law
200 McAllister Street
San Francisco, CA 94102-4978

Advisory Committee on Criminal Rules

Chair

Honorable Raymond M. Kethledge
United States Court of Appeals
Federal Building
200 East Liberty Street, Suite 224
Ann Arbor, MI 48104

Reporter

Professor Sara Sun Beale
Duke Law School
210 Science Drive
Durham, NC 27708-0360

Associate Reporter

Professor Nancy J. King
Vanderbilt University Law School
131 21st Avenue South, Room 248
Nashville, TN 37203-1181

Advisory Committee on Evidence Rules

Chair

Honorable Patrick J. Schiltz
United States District Court
United States Courthouse
300 South Fourth Street, Room 14E
Minneapolis, MN 55415

Reporter

Professor Daniel J. Capra
Fordham University
School of Law
150 West 62nd Street
New York, NY 10023

Chair	Reporter
Honorable Patrick J. Schiltz United States District Court United States Courthouse 300 South Fourth Street, Room 14E Minneapolis, MN 55415	Professor Daniel J. Capra Fordham University School of Law 150 West 62nd Street New York, NY 10023

Members

Honorable James P. Bassett
Associate Justice
New Hampshire Supreme Court
One Charles Doe Drive
Concord, NH 03301

Honorable Shelly Dick
United States District Court
Russell B. Long Federal Building
777 Florida Street, Room 301
Baton Rouge, LA 70801

Honorable Seth DuCharme*
Acting Principal Associate Deputy
Attorney General (ex officio)
Office of the Deputy Attorney General
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

Traci L. Lovitt, Esq.
Jones Day
100 High Street, 21st Floor
Boston, MA 02110-1781

* Alternate Representative:
Elizabeth J. Shapiro, Esq.
Deputy Director, Civil Division
United States Department of Justice
1100 L Street, N.W., Room 12100
Washington, DC 20530

Honorable Tom Marten
United States District Court
401 North Market Street, Room 232
Wichita, KS 67202-2000

Kathryn N. Nester, Esq.
Federal Defenders of San Diego, Inc.
225 Broadway, Suite 900
San Diego, CA 92101

Honorable Thomas D. Schroeder
United States District Court
Hiram H. Ward Federal Building
251 North Main Street, Room 231
Winston Salem, NC 27101-7101

Consultants

Professor Liesa Richter
University of Oklahoma School of Law
300 Timberdell Road
Norman, OK 73019

Liaisons

Honorable James C. Dever III
(*Criminal*)
United States District Court
Terry Sanford Federal Building
310 New Bern Avenue, Room 716
Raleigh, NC 27601-1418

Honorable Carolyn B. Kuhl
(*Standing*)
Superior Court of the State of California
312 North Spring Street, Department 12
Los Angeles, CA 90012

Honorable Sara Lioi
(*Civil*)
United States District Court
John F. Seiberling Federal Building
Two South Main Street, Room 526
Akron, OH 44308

Secretary, Standing Committee and Rules Committee Chief Counsel

Rebecca A. Womeldorf, Esq.
Administrative Office of the U.S. Courts
One Columbus Circle, N.E., Room 7-300
Washington, DC 20544

Advisory Committee on Evidence Rules

Members	Position	District/Circuit	Start Date		End Date
Patrick J. Schiltz	D	Minnesota	Chair:	2020	2023
James P. Bassett	JUST	New Hampshire		2016	2022
Shelly Dick	D	Louisiana (Middle)		2017	2020
Traci L. Lovitt	ESQ	Massachusetts		2016	2022
Tom Marten	D	Kansas		2014	2020
Kathryn Nester	FPD	California (Southern) (CDO)		2018	2021
Seth DuCharme*	DOJ	Washington, DC		----	Open
Thomas D. Schroeder	D	North Carolina (Middle)		2017	2020
Daniel J. Capra Reporter	ACAD	New York		1996	Open

Principal Staff: Rebecca Womeldorf (b)(6) per EOUSA

Bridget Healy (b)(6) per EOUSA

_____

* Ex-officio - Acting Principal Associate Deputy Attorney General

Liaisons for the Advisory Committee on Appellate Rules	Hon. Frank M. Hull *(Standing)* Hon. Bernice B. Donald *(Bankruptcy)*
Liaison for the Advisory Committee on Bankruptcy Rules	Hon. William J. Kayatta, Jr. *(Standing)*
Liaisons for the Advisory Committee on Civil Rules	Peter D. Keisler, Esq. *(Standing)* Hon. A. Benjamin Goldgar *(Bankruptcy)*
Liaison for the Advisory Committee on Criminal Rules	Hon. Jesse M. Furman *(Standing)*
Liaisons for the Advisory Committee on Evidence Rules	Hon. James C. Dever III *(Criminal)* Hon. Carolyn B. Kuhl *(Standing)* Hon. Sara Lioi *(Civil)*

Rebecca A. Womeldorf, Esq.
Chief Counsel
Administrative Office of the U.S. Courts
Office of General Counsel – Rules Committee Staff
Thurgood Marshall Federal Judiciary Building
One Columbus Circle, N.E., Room 7-300
Washington, DC 20544

Bridget M. Healy, Esq.
Counsel
(Appellate, Bankruptcy, Evidence)

S. Scott Myers, Esq.
Counsel
(Bankruptcy, Standing)

Julie M. Wilson, Esq.
Counsel
(Civil, Criminal, Standing)

Brittany Bunting
Administrative Analyst

Shelly Cox
Management Analyst

Hon. John S. Cooke
Director
Federal Judicial Center
Thurgood Marshall Federal Judiciary Building
One Columbus Circle, N.E., Room 6-100
Washington, DC 20544

Laural L. Hooper, Esq.
Senior Research Associate
(Criminal)

Marie Leary, Esq.
Senior Research Associate
(Appellate)

Molly T. Johnson, Esq.
Senior Research Associate
(Bankruptcy)

Dr. Emery G. Lee
Senior Research Associate
(Civil)

Timothy T. Lau, Esq.
Research Associate
(Evidence)

Tim Reagan, Esq.
Senior Research Associate
(Standing)

TAB 1B

Effective December 1, 2019

REA History:

- No contrary action by Congress
- Adopted by Supreme Court and transmitted to Congress (Apr 2019)
- Approved by Judicial Conference (Sept 2018) and transmitted to Supreme Court (Oct 2018)

Rule	Summary of Proposal	Related or Coordinated Amendments
AP 3, 13	Changed the word "mail" to "send" or "sends" in both rules, although not in the second sentence of Rule 13.	
AP 26.1, 28, 32	Rule 26.1 amended to change the disclosure requirements, and Rules 28 and 32 amended to change the term "corporate disclosure statement" to "disclosure statement" to match the wording used in amended Rule 26.1.	
AP 25(d)(1)	Eliminated unnecessary proofs of service in light of electronic filing.	
AP 5.21, 26, 32, 39	Technical amendment that removed the term "proof of service."	AP 25
BK 9036	Amended to allow the clerk or any other person to notice or serve registered users by use of the court's electronic filing system and to serve or notice other persons by electronic means that the person consented to in writing.	
BK 4001	Amended to add subdivision (c) governing the process for obtaining post-petition credit in a bankruptcy case, inapplicable to chapter 13 cases.	
BK 6007	Amended subsection (b) to track language of subsection (a) and clarified the procedure for third-party motions brought under § 554(b) of the Bankruptcy Code.	
BK 9037	Amended to add subdivision (h) providing a procedure for redacting personal identifiers in documents that were previously filed without complying with the rule's redaction requirements.	
CR 16.1 (new)	New rule regarding pretrial discovery and disclosure. Subsection (a) requires that, no more than 14 days after the arraignment, the attorneys are to confer and agree on the timing and procedures for disclosure in every case. Subsection (b) emphasizes that the parties may seek a determination or modification from the court to facilitate preparation for trial.	
EV 807	Residual exception to the hearsay rule; clarifies the standard of trustworthiness.	
2254 R 5	Makes clear that petitioner has an absolute right to file a reply.	
2255 R 5	Makes clear that movant has an absolute right to file a reply.	

Effective February 19, 2020

The Interim Rules listed below were published for comment in the fall of 2019 outside the normal REA process and approved by the Judicial Conference for distribution to Bankruptcy Courts to be adopted as local rules to conform procedure to changes in the Bankruptcy Code – adding a subchapter V to chapter 11 – made by the Small Business Reorganization Act of 2019

Rule	Summary of Proposal	Related or Coordinated Amendments
BK 1007	The amendments exclude a small business debtor in subchapter V case from the requirements of the rule.	
BK 1020	The amendments require a small business debtor electing to proceed on the subchapter V to state its intention on the bankruptcy petition or within 14 days after the order for relief is entered.	
BK 2009	2009(a) and (b) are amended to exclude subchapter V debtors and 2009(c) is amended to add subchapter V debtors.	
BK 2012	2012(a) is amended to include chapter V cases in which the debtor is removed as the debtor in possession.	
BK 2015	The rule is revised to describe the duties of a debtor in possession, the trustee, and the debtor in a subchapter V case.	
BK 3010	The rule is amended to include subchapter V cases.	
BK 3011	The rule is amended to include subchapter V cases.	
BK 3014	The rule is amended to provide a deadline for making an election under 1111(b) of the Bankruptcy Code in a subchapter V case.	
BK 3016	The rule is amended to reflect that a disclosure statement is generally not required in a subchapter V case, and that official forms are available for a reorganization plan and - if required by the court - a disclosure statement.	
BK 3017.1	The rule is amended to apply to subchapter V cases where the court has ordered that the provisions of 1125 of the Bankruptcy Code applies.	
BK 3017.2	This is a new rule that fixes dates in subchapter V cases where there is no disclosure statement.	
BK 3018	The rule is amended to take account of the court's authority to set times under Rules 3017.1 and 3017.2 in small business cases and subchapter V cases.	
BK 3019	Subdivision (c) is added to the rule to govern requests to modify a plan after confirmation in a subchapter V case under 1193(b) or (c) of the Bankruptcy Code.	

Effective (no earlier than) December 1, 2020

Current Step in REA Process:

- Adopted by Supreme Court and transmitted to Congress (Apr 2020)

REA History:

- Approved by Judicial Conference (Sept 2019) and transmitted to Supreme Court (Oct 2019)
- Approved by Standing Committee (June 2019)
- Approved by relevant advisory committee (Spring 2019)
- Published for public comment (unless otherwise noted, Aug 2018-Feb 2019)
- Approved by Standing Committee for publication (unless otherwise noted, June 2018)

Rule	Summary of Proposal	Related or Coordinated Amendments
AP 35, 40	Proposed amendment clarifies that length limits apply to responses to petitions for rehearing plus minor wording changes.	
BK 2002	Proposed amendment would: (1) require giving notice of the entry of an order confirming a chapter 13 plan; (2) limit the need to provide notice to creditors that do not file timely proofs of claim in chapter 12 and chapter 13 cases; and (3) add a cross-reference in response to the relocation of the provision specifying the deadline for objecting to confirmation of a chapter 13 plan.	
BK 2004	Amends subdivision (c) to refer specifically to electronically stored information and to harmonize its subpoena provisions with the current provisions of Civil Rule 45, which is made applicable in bankruptcy cases by Bankruptcy Rule 9016.	CV 45
BK 8012	Conforms Bankruptcy Rule 8012 to proposed amendments to Appellate Rule 26.1 that were published in Aug 2017.	AP 26.1
BK 8013, 8015, and 8021	Unpublished. Eliminates or qualifies the term "proof of service" when documents are served through the court's electronic-filing system conforming to pending changes in 2019 to AP Rules 5, 21, 26, 32, and 39.	AP 5, 21, 26, 32, and 39
CV 30	Proposed amendment to subdivision (b)(6), the rule that addresses deposition notices or subpoenas directed to an organization, would require the parties to confer about the matters for examination before or promptly after the notice or subpoena is served. The amendment would also require that a subpoena notify a nonparty organization of its duty to confer and to designate each person who will testify.	
EV 404	Proposed amendment to subdivision (b) would expand the prosecutor's notice obligations by: (1) requiring the prosecutor to "articulate in the notice the permitted purpose for which the prosecutor intends to offer the evidence and the reasoning that supports the purpose"; (2) deleting the requirement that the prosecutor must disclose only the "general nature" of the bad act; and (3) deleting the requirement that the defendant must request notice. The proposed amendments also replace the phrase "crimes, wrongs, or other acts" with the original "other crimes, wrongs, or acts."	

Effective (no earlier than) December 1, 2021

Current Step in REA Process:

- Approved by Judicial Conference (Sept 2020)

REA History:

- Approved by Standing Committee (June 2020)
- Approved by relevant advisory committee (Apr/May 2020)
- Published for public comment (Aug 2019-Feb 2020)
- Unless otherwise noted, approved for publication (June 2019)

Rule	Summary of Proposal	Related or Coordinated Amendments
AP 3	The proposed amendment to Rule 3 addresses the relationship between the contents of the notice of appeal and the scope of the appeal. The proposed amendment changes the structure of the rule and provides greater clarity, expressly rejecting the *expressio unius* approach, and adds a reference to the merger rule.	AP 6, Forms 1 and 2
AP 6	Conforming amendment to the proposed amendment to Rule 3.	AP 3, Forms 1 and 2
AP Forms 1 and 2	Conforming amendments to the proposed amendment to Rule 3, creating Form 1A and Form 1B to provide separate forms for appeals from final judgments and appeals from other orders.	AP 3, 6
BK 2005	The proposed amendment to subsection (c) of the replaces the reference to 18 U.S.C. § 3146(a) and (b) (which was repealed in 1984) with a reference to 18 U.S.C. § 3142.	
BK 3007	The proposed amendment clarifies that credit unions may be served with an objection claim under the general process set forth in Rule 3007(a)(2)(A) - by first-class mail sent to the person designated on the proof of claim.	
BK 7007.1	The proposed amendment would conform the rule to recent amendments to Rule 8012 and Appellate Rule 26.1.	
BK 9036	The proposed amendment would require high-volume paper notice recipients (initially designated as recipients of more than 100 court papers notices in calendar month) to sign up for electronic service and noticing, unless the recipient designates a physical mailing address if so authorized by statute.	

Effective (no earlier than) December 1, 2022

Current Step in REA Process:

- Published for public comment (Aug 2020-Feb 2021)

Rule	Summary of Proposal	Related or Coordinated Amendments
AP 25	The proposed amendment to Rule 25 extends the privacy protections afforded in Social Security benefit cases to Railroad Retirement Act benefit cases.	
BK 3002	The proposed amendment would allow an extension of time to file proofs of claim for both domestic and foreign creditors if "the notice was insufficient under the circumstances to give the creditor a reasonable time to file a proof of claim."	
BK 5005	The proposed changes would allow papers to be transmitted to the U.S. trustee by electronic means rather than by mail, and would eliminate the requirement that the filed statement evidencing transmittal be verified.	
BK 7004	The proposed amendments add a new Rule 7004(*i*) clarifying that service can be made under Rule 7004(b)(3) or Rule 7004(h) by position or title rather than specific name and, if the recipient is named, that the name need not be correct if service is made to the proper address and position or title.	
BK 8023	The proposed amendments conform the rule to pending amendments to Appellate Rule 42(b) that would make dismissal of an appeal mandatory upon agreement by the parties.	AP 42(b)
BK Restyled Rules (Parts I & II)	The proposed rules, approximately 1/3 of current bankruptcy rules, are restyled to provide greater clarity, consistency, and conciseness without changing practice and procedure. The remaining bankruptcy rules will be similarly restyled and published for comment in 2021 and 2022, with the full set of restyled rules expected to go into effect no earlier than December 1, 2024.	
SBRA Rules (BK 1007, 1020, 2009, 2012, 2015, 3010, 3011, 3014, 3016, 3017.1, 3017.2 (new), 3018, 3019)	The SBRA Rules would make necessary rule changes in response to the Small Business Reorganization Act of 2019. The SBRA Rules are based on Interim Bankruptcy Rules adopted by the courts as local rules in February 2020 in order to implement the SBRA which when into effect February 19, 2020.	
SBRA Forms (Official Forms 101, 122B, 201, 309E-1, 309E-2, 309F-1, 309F-2, 314, 315, 425A)	The SBRA Forms make necessary changes in response to the Small Business Reorganization Act of 2019. All but the proposed change to Form 122B were approved on an expedited basis with limited public review in 2019 and became effective February 19, 2020, the effective date of the SBRA. They are being published along with the SBRA Rules in order to give the public a full opportunity to comment.	

Effective (no earlier than) December 1, 2022

Current Step in REA Process:

- Published for public comment (Aug 2020-Feb 2021)

Rule	Summary of Proposal	Related or Coordinated Amendments
CV 12	The proposed amendment to paragraph (a)(4) would extend the time to respond (after denial of a Rule 12 motion) from 14 to 60 days when a United States officer or employee is sued in an individual capacity for an act or omission occurring in connection with duties performed on the United States' behalf.	
CV Supplemental Rules for Social Security Review Actions Under 42 U.S.C. § 405(g)	Proposed set of uniform procedural rules for cases under the Social Security Act in which an individual seeks district court review of a final administrative decision of the Commissioner of Social Security pursuant to 42 U.S.C. § 405(g).	
CR 16	Proposed amendment addresses the lack of timing and the lack of specificity in the current rule with regard to expert witness disclosures, while maintaining reciprocal structure of the current rule.	

TAB 1C

THIS PAGE INTENTIONALLY BLANK

Advisory Committee on Evidence Rules
Minutes of the Meeting of October 25, 2019
Vanderbilt University Law School
Nashville, TN.

The Judicial Conference Advisory Committee on the Federal Rules of Evidence (the "Committee") met on October 25, 2019 at the Vanderbilt University Law School in Nashville, Tennessee.

The following members of the Committee were present:
Hon. Debra A. Livingston, Chair
Hon. James P. Bassett
Hon. J. Thomas Marten
Hon. Thomas D. Schroeder
Traci L. Lovitt, Esq.
Kathryn N. Nester, Esq., Federal Public Defender
Elizabeth J. Shapiro, Esq., Department of Justice

Also present were:
Hon. David G. Campbell, Chair of the Committee on Rules of Practice and Procedure
Hon. James C. Dever III, Liaison from the Criminal Rules Committee
Hon. Carolyn B. Kuhl, Liaison from the Standing Committee
Professor Catherine T. Struve, Associate Reporter to the Standing Committee (by phone)
Professor Daniel J. Capra, Reporter to the Committee
Professor Liesa L. Richter, Academic Consultant to the Committee
Timothy Lau, Esq., Federal Judicial Center
Ted Hunt, Esq., Department of Justice
Rebecca A. Womeldorf, Esq., Secretary, Standing Committee; Rules Committee Chief Counsel
Shelly Cox, Administrative Analyst, Committee on Rules of Practice and Procedure

I. Miniconference on Best Practices for Managing *Daubert* Questions; Rule 702

On the morning of the Committee's Fall 2019 meeting, the Committee held a miniconference on "Best Practices" for managing *Daubert* issues. The miniconference was designed to further the Committee's objective to provide education to the bench and bar on proper management of expert testimony as an addition to (or an alternative to) an amendment to Fed. R. Evid. 702. The Committee invited five experienced federal judges and a distinguished professor to share ideas about "Best Practices" in managing *Daubert* questions and in conducting *Daubert* hearings. The judges all have extensive experience in managing *Daubert* issues, and each has written extensive and influential *Daubert* opinions. The miniconference was moderated by the Reporter. A transcript

of the miniconference will be published in the Fordham law Review and copies will be distributed to federal judges.

The Chair opened the afternoon Committee meeting by applauding the great discussion that was generated at the miniconference and she invited comments for Committee discussion. Judge Campbell commented that the discussion was extremely helpful in focusing judges on the need to evaluate the admissibility requirements of Rule 702 and *Daubert* through Rule 104(a), using a preponderance of the evidence standard. He suggested that caselaw describing *Daubert* questions as primarily for the jury blurs the inquiry and noted that lawyers do not focus on the judge's obligation to make a preponderance finding when they brief *Daubert* issues. Judge Campbell stated that there may be no clear answer as to how to improve Rule 702, but that an amendment or Committee note emphasizing the trial judge's obligation to find all Rule 702 requirements by a preponderance of the evidence before admitting expert opinion testimony could be very beneficial. The Chair noted that the Committee had previously considered adding the Rule 104(a) preponderance standard to the text of Rule 702, but had ultimately rejected that option. The Reporter highlighted the problems caused by adding the Rule 104(a) standard to the text of Rule 702 – namely that the Rule 104(a) standard applies to many admissibility inquiries where it is not stated expressly in rule text – but reminded the Committee that it could emphasize the application of Rule 104(a) to Rule 702 in a Committee note if it moved forward on any other amendments to the Rule.

Judge Campbell also noted that the miniconference revealed that there can be many different problems with expert opinion testimony that might be characterized as expert "overstatement" – many of which are not the focus of the Committee's recent consideration of an amendment to Rule 702 to prevent "overstatement." In particular, he noted that an expert might attempt to testify to an opinion beyond his or her qualifications, or that an expert might be qualified and have a reliable foundation for one opinion and then attempt to add an additional opinion not supported by that same foundation. Judge Campbell suggested that these would be examples of expert "overstatement" that the Committee was not trying to address with an amendment. He explained that the Committee's concerns were centered more around an expert's "degree of confidence" for an opinion and suggested that much of expert opinion testimony (such as experience-based testimony) does not raise issues of an expert's "degree of confidence."

A Committee member responded that any factor that can affect whether a person goes to jail is significant --- for example, that risk arises when a forensic expert overstates the results that can fairly be reported from a feature-comparison. Judge Campbell agreed and the Reporter noted that even narrow rules amendments can be very effective and helpful. Still, Judge Campbell queried whether a "degree of confidence" amendment would be adding complexity to the cases not affected by that factor. The DOJ representative argued that adding a new "degree of confidence" factor to Rule 702 could create a battleground for litigants that could undermine the Rule. Judge Campbell reiterated his concern that a limitation on "overstatement" or a requirement regarding "degree of confidence" could lead to trial judges being asked to wordsmith expert opinions.

The Chair noted the ambiguity in the meaning of the term "overstatement." If a particular methodology has an error rate and the expert testifies to 100% certainty regarding an opinion, it is easy to recognize that as an "overstatement." But the Chair noted that it wasn't so clear how to

apply an "overstatement" prohibition to experience-based experts, for example. She suggested that the existing *Daubert* factors all represent standards with plenty of room for a trial judge to exercise judgment within a reasonable range. In contrast, "overstatement" seems to be a more binary factor – testimony either is or is not an "overstatement." Judge Campbell responded that "degree of confidence" may indeed reflect a standard about which judges may exercise judgment (rather than a binary inquiry). He suggested that a "degree of confidence" factor would have to be limited to types of expertise in which there is some concrete result that the expert attempts to surpass in testifying. One example might be a cell tower expert who overpromises on the precision of cell towers in locating a person's phone. He opined that it might be optimal to limit an amendment to Rule 702 to opinions with an identifiable data point from which to measure "degree of confidence" --- such as a forensic test, which provides a quantifiable result.

The Chair turned the discussion to judicial education regarding forensic evidence and science generally, querying whether the miniconference had revealed any effective methods for enhanced education. She noted that the Reporter was working with the FJC and Duke and Fordham Law Schools to put together a day-long conference on forensic evidence for federal judges to attend. One Committee member also noted that programs have been presented for judges at conferences of district and circuit courts. Another suggested that trial judges read the DOJ's uniform language regarding forensic testimony, emphasizing that opposing counsel may not object to expert overstatements and that trial judges would be better equipped to deal with the issue if they have examined the appropriate language. He suggested that trial judges should also learn to tell criminal defense counsel to review the DOJ uniform language so they are prepared to object to offending overstatements in forensic testimony. In sum, these Committee members noted that education for lawyers might be just as important as additional education for judges. Another Committee member suggested that DOJ training of non-DOJ expert witnesses on the appropriate uniform language to be used in testifying about forensic evidence could be very helpful. He noted the many cases in which the testifying experts are not DOJ analysts familiar with and bound by the DOJ policy on uniform language, and suggested that more training of the non-DOJ experts could improve the forensic expert testimony being offered in federal court.

DOJ representative Ted Hunt highlighted numerous training initiatives being undertaken by DOJ with respect to the uniform language. He described upcoming formal training for prosecutors at the National Advocacy Center, as well as engagement with state and local examiners who may be using Standard Operating Procedures not compliant with DOJ standards. He also discussed the efforts to interface with a working group of state and local leaders to educate them about feature comparison methods and to recast some of the outdated verbiage embedded in the state and local standards. Finally, he noted that efforts were underway at DOJ to strengthen some of the existing uniform language to ensure that it remains up to date. He expressed surprise that some of the federal judges participating in the miniconference had observed non-compliant overstatements in recent cases. Mr. Hunt also noted that DOJ was engaged in a working group with federal public defenders to raise awareness of the uniform language and of testimonial requirements for feature comparison experts.

Dr. Lau of the Federal Judicial Center noted that one of the participants in the miniconference had suggested that it would be helpful for judges to have a list of "red flags" that might indicate a reliability problem with expert opinion testimony. He suggested that it might be fruitful for the

FJC to explore a "red flags" list for certain areas of expertise for judges. Beyond that, Dr. Lau suggested that much of the needed education appeared to be directed to the bar rather than the bench and he suggested that much of this lawyer education was beyond the purview of the FJC. .

The Chair noted that judges can certainly help remind lawyers about the DOJ uniform language and the problem of forensic overstatement outside the trial context. Another Committee member offered that it is much easier to give reminders and admonitions in the civil context where there is significant briefing on expert issues and time to discuss and consider them, but that it is much more challenging in criminal cases where the testimony comes in "on the fly." Judge Campbell emphasized that it is very important to educate defense lawyers, particularly CJA lawyers, about appropriate forensic testimony and the risks of overstatement.

The Chair then asked Judge Dever, the Liaison from the Criminal Rules Committee, to update the Committee regarding a draft proposal to amend Federal Rule of Criminal Procedure 16 to improve advance disclosure of expert opinion evidence in criminal cases. Judge Dever noted that the goal was to have a draft proposal to the Standing Committee for its January meeting and to prepare a final draft at the April meeting of the Criminal Rules Committee. Judge Dever explained that the gist of the proposed amendment was to require a more complete statement of an expert's opinion in pre-trial disclosures in criminal cases, and to require trial judges in every criminal case to set a time for expert disclosure. Judge Dever noted that the DOJ was instrumental in helping the Committee come up with appropriate language to capture these concepts. He explained that the Criminal Rules Committee considered setting a specific number of days before trial for expert disclosures in the text of Rule 16, but determined that a set number of days would provide inadequate flexibility across districts and types of cases. But he noted that too many trial judges permit expert disclosures to be made in criminal cases right before trial. To correct the unfairness inherent in that practice without setting a rigid number of days, the Criminal Rules Committee compromised with language requiring trial judges to set a specific time for expert disclosures that will provide a "fair opportunity for the defendant to meet the government's evidence." (This language was taken from the Federal Rules of Evidence.) He noted that the proposal would require more detailed disclosures about expert opinions as well, such as a complete statement of all opinions that will be offered at trial, expert publications, and past testimony. Finally, the report will have to be signed by the expert, so it can be used to impeach the expert's trial testimony to the extent it is inconsistent with the report.

The Reporter suggested that the proposed amendment to Criminal Rule 16 might not have much impact in the forensics area, where the Committee has been focused, because the "Yates Memo" regarding disclosure of forensic evidence already required timely disclosure of the information covered by the proposed amendment to Rule 16. Judge Dever suggested that the amendment would be helpful in all cases because it would prevent a prosecutor from making disclosures three days prior to trial, would require a meet & confer between counsel, and would prevent an expert from disclosing two opinions and then testifying to five opinions at trial. The Reporter agreed that transforming a DOJ policy into a binding rule would be beneficial. A Committee member inquired whether the substantive disclosures under an amended Rule 16 would be broader or narrower than the disclosures currently required under the "Yates Memo." It was suggested that Rule 16 would add protections, in part, because it would require an expert witness to sign expert disclosures, making it difficult for the expert on cross-examination to avoid or reject

portions of the case file that are turned over under the "Yates Memo." Also, by requiring an expert to state all trial opinions in the disclosure, it will prevent an expert from giving one opinion before trial and tacking on additional opinions during testimony. Another Committee member also pointed out that advance disclosure of an expert opinion will help defense counsel identify and object to any "overstatement" with time for study and reflection.

The Reporter noted that the benefit of an amendment to Rule 16 might be tempered by the fact that some witnesses who might be experts are actually called by the government as lay witnesses, thus avoiding disclosure. He noted the confusion in the case law regarding the distinction between lay opinion testimony offered under Rule 701 of the Evidence Rules and expert opinion testimony offered under Rule 702. He explained that a witness offering an opinion on gang-related behavior, for example, might be offered as an expert under Rule 702 in some jurisdictions, but admitted as a lay witness under Rule 701 in others. The Reporter noted that the Advisory Committee attempted to resolve this issue with the 2000 amendment to Rule 701 that prohibited lay opinion testimony "based on scientific, technical, or other specialized knowledge." Still the line between expert and lay opinion testimony gets blurred in the courts. The Reporter suggested that the Evidence Rules Committee should explore mechanisms for distinguishing between lay and expert testimony to prevent prosecutors from avoiding obligations under an amended Rule 16.

II. Rule 615

The Reporter opened the discussion of Rule 615 by reminding the Committee of the conflict that exists in the courts about the meaning of a sequestration order. When a court invokes Rule 615, it is unclear whether that means only that testifying witnesses must leave the courtroom or whether such an order includes protections against obtaining information about trial testimony outside the courtroom (such as in the media or by virtue of daily transcripts or conversations). In most circuits, protections beyond the courtroom are *automatically* included in a Rule 615 order. In some circuits, however, courts have held that such an order only demands exclusion from the courtroom and does not include any protections against disclosures outside of it. These latter courts read Rule 615 by its express terms; the rule text provides only for "excluding" witnesses from the courtroom. The Reporter noted that both interpretations of Rule 615 can create notice problems for litigants and witnesses. In the former jurisdictions, a witness might not appreciate that an order excluding him from the courtroom automatically prohibits other access to trial testimony. In the latter jurisdictions, a lawyer might think that "invoking the Rule" is sufficient to extend protection beyond the courtroom and might not appreciate the need to specifically request additional protections.

The Reporter noted that the Committee had considered and rejected the possibility of amending Rule 615 to extend sequestration automatically beyond the courtroom in every case. Instead the Committee opted for a draft that would highlight a trial judge's authority to expand protections beyond the courtroom and would alert lawyers that they need to request and receive an explicit order including such expanded protection. He noted that while the Committee supported a discretionary amendment to Rule 615 that would allow for protection outside the courtroom, it had expressed concern about the issue of counsel communicating trial testimony during witness preparation. In particular, the Committee wanted to follow up on the opinion in *United States v.*

Rhynes, 218 F.3d 310 (4th Cir. 2000) (*en banc*), which held that a sequestered witness's testimony could *not* be excluded after defense counsel disclosed trial testimony in the course of preparing the witness to testify.

The Reporter explained that the case law reflected in the agenda materials did not establish that counsel are exempt from prohibitions on disclosures of trial testimony to witnesses. Indeed, he explained that there are many cases that prevent attorneys from disclosing trial testimony to sequestered witnesses, because lawyers can effectively prepare witnesses without disclosing trial testimony and because a lawyer exemption from such protections would create a gap in protection that could swallow the rule entirely.

The Reporter explained that the three drafting alternatives for an amendment to Rule 615 included in the agenda materials varied only with respect to the treatment of counsel. One amendment option would prohibit counsel from conveying trial testimony to sequestered witnesses. Another would exempt counsel from any prohibition on conveying trial testimony to sequestered witnesses outside the courtroom. The third amendment alternative is silent as to the treatment of counsel, leaving courts to determine how to supervise counsel on a case-by-case basis.

The Reporter explained that counsel's preparation of sequestered witnesses presents issues of professional responsibility as well as the Sixth Amendment right to effective counsel --- topics that are typically beyond the ken of the Evidence Rules. An amendment that is silent with respect to counsel was included as an alternative because it would be most hands-off as to the complicated policy issues. The Reporter explained that bracketed material was included in the draft Advisory Committee note to this third option to alert the parties and the court to the issues regarding counsel, but to take no position in the rule on counsel's use of trial testimony to prepare witnesses. He informed the Committee that the plan was to discuss the variations at the fall meeting and to create a draft amendment that could be voted on by the Committee at the Spring 2020 meeting.

The Federal Public Defender suggested that the Sixth Amendment right to confront witnesses should be added to the bracketed language in the draft Advisory Committee note discussing the issues raised by counsel's communication of trial testimony to sequestered witnesses --- and the Reporter agreed to add such language. The Public Defender noted that criminal defense lawyers win and lose cases based on cross-examination and that if one testifying officer has access to the testimony of another officer, the all-important right to cross-examine effectively is seriously hampered. Judge Campbell inquired whether defense counsel would be happy to be bound by a prohibition on revealing trial testimony themselves. The Federal Defender responded that it would not pose any issue with respect to preparation of the defendant because the parties are allowed to remain in the courtroom and so defense lawyers wouldn't likely have any objection. Most importantly, she opined that trial judges deciding how to manage counsel should consider the right to confront witnesses in the forefront of their analysis.

One Committee member noted that attorney preparation with witness testimony is a proper ground for cross-examination and that such cross-examination about conversations with counsel is common. He suggested that the impeaching effect of these conversations provide a limit on counsel's discussions with witnesses and that he favors the alternative for amending Rule 615 that is silent as to treatment of counsel. Another Committee member expressed reservations about an

amendment that would prevent lawyers from talking to witnesses and stated a preference for allowing the issue of counsel conferring with witnesses to be handled on cross-examination.

The Chair agreed that the question of counsel's witness preparation is a can of worms, but queried whether the other problems with Rule 615 are sufficiently significant to justify an amendment. She also noted the increasing difficulty that lawyers will have in controlling witness conduct outside the courtroom, particularly given ubiquitous internet access. She suggested that adding discretionary language to the Rule would encourage judges to enter more orders that extend beyond the courtroom. The Reporter responded that the draft proposals would not encourage or incentivize orders controlling conduct outside the courtroom. Instead, the draft proposals would encourage the trial judge to *consider* the issue and to provide clear and fair notice of the limits of any sequestration order that is entered. More importantly, in most circuits, a basic Rule 615 order *already* extends beyond the courtroom automatically. So in those circuits the amendment would not encourage more orders; and in the other circuits it will result in more orders only if the court in its discretion decides to extend the order outside the courtroom --- something it can already do today.

Judge Campbell suggested that the amendment alternative that is silent as to counsel would address the current concerns about sequestration without getting embroiled in the counsel question. The Chair agreed, as did another Committee member. Another Committee member also suggested that added clarification is advantageous for lawyers – how can lawyers be expected to appreciate the operation of sequestration if the Rule is vague?

The Reporter suggested adding language to the bracketed language contained in the draft Committee note to emphasize that the amendment is neutral with respect to protections beyond the courtroom and is not encouraging extension of sequestration orders. The Chair agreed with this proposal.

The Reporter agreed to prepare a draft amendment for the Spring 2020 meeting in keeping with the Committee's recommendations.

III. Rule 106 Rule of Completeness

The Reporter opened the discussion of Rule 106 by explaining that the Committee's review of the rule of completeness has revealed that it is one of the most complicated rules in the Federal Rules of Evidence. Because of the complexity of the Rule, the Chair suggested that the Committee try to focus on only a couple of the issues raised by the completeness doctrine at this meeting and have a longer discussion of all issues at the Spring 2020 meeting in the hope of coming up with a proposed amendment.

The Reporter reminded the Committee that the hearsay issue raised by completeness requests is the most significant problem with the existing Rule. While many circuits permit completion with otherwise inadmissible hearsay, some courts, like the Sixth Circuit, have held that a criminal defendant may not introduce a completing remainder necessary to correct a misleading impression created by the government's initial partial presentation of his statement. In essence, these cases

acknowledge the unfairness in the presentation that has been made, but find that the hearsay doctrine forecloses any remedy otherwise provided by Rule 106. The most significant question for the Committee is how to fix that serious defect in the interpretation of Rule 106.

The Chair emphasized that Rule 106 was intended to be only a partial codification of the doctrine of completeness, as recognized by the Supreme Court in *Beech Aircraft*, and was adopted to affect the timing of completion by allowing interruption of an opponent's case to complete misleading written and recorded statements. She noted that the common law doctrine of completion was much broader than Rule 106 and expressed concerns about retaining the standard adopted for a partial codification and extending it to a full codification of the doctrine of completeness. In particular, the Chair expressed concerns about an amended rule that would entirely displace the common law of completion. The Reporter queried whether the current draft heading for a proposed amendment to Rule 106 that characterizes the rule as the "Rule of Completeness" was creating that concern about displacing the common law in its entirety. The Chair stated that the heading purporting to capture all of the rule of completeness was a problem and that it would be important not to rewrite the common law of completeness. The Reporter responded that the heading was altered in the restyling process and that it would be very easy to modify to avoid the suggestion that Rule 106 displaces all common law completion rights.

The DOJ representative noted that the right to interrupt one's adversary with a completing statement was the entire purpose of Rule 106 as originally adopted. She questioned whether it made sense to retain Rule 106 if that right to contemporaneous completion were eliminated in favor of flexible timing in an amended Rule. The Reporter explained that the federal courts have interpreted the timing requirement flexibly, notwithstanding the strict language of Rule 106, and that an amendment that made the timing flexible would merely reflect the practice in the federal courts. That said, the Reporter acknowledged that the Committee could leave the timing requirement unchanged in an amended provision and reminded the Committee that the timing issue was the least important of the concerns with the existing Rule.

Judge Campbell inquired whether it would be accurate to say that existing Rule 106 does only one thing, but that an amended provision that added all of these changes would be doing three additional things (flexible timing, oral statements, otherwise inadmissible hearsay permitted). The Reporter agreed with that characterization. The Chair remarked that the Committee would not need to address the timing issue in an amended rule so long as it was careful to leave the common law untouched. Even if a party did not complete immediately under Rule 106, that party could still attempt to do so later under the common law of completion.

The Reporter again raised the significant hearsay question. The Chair opined that completing hearsay could be admitted for its truth if it independently satisfied a hearsay exception and could be admitted for its non-hearsay value of showing context if it did not fall within an exception. She noted that Wigmore was against reading Rule 106 as a hearsay exception and suggested that completing remainders might be insufficiently reliable to be admitted for their truth. She opined that Judge Grimm, who brought his concerns about Rule 106 to the Committee, would be satisfied with this approach, allowing the completing statement to be used for context only. The Reporter disagreed, noting that Judge Grimm expressed a preference for having the completing remainder admitted for its truth. That said, the Reporter suggested that an amendment that elided the issue of

the purpose for which the otherwise inadmissible remainder was offered might be satisfactory to all – as in, the completing statement may be admitted "over a hearsay objection." This amendment would prevent situations like those seen in the Sixth Circuit where the completing remainder is excluded, but would not necessarily make the completing remainder admissible for its truth.

Another participating judge reminded the Committee of the completeness scenarios trial judges face in court on a routine basis. Because of the increased use of video-recording during interrogations, prosecutors have video recordings of a defendant's admissions to present at trial, with the government offering one portion and the defendant seeking to complete with another. This judge noted that the increasing availability of video-recorded statements would make these completeness issues more common. The Reporter noted that the right to complete in these scenarios has to be addressed under the fairness standard in existing Rule 106 and that this narrow triggering standard would not be changed in an amended provision.

Another Committee member asked how the judge had handled these scenarios and he explained that the prosecution had abandoned its efforts to use the partial statements due to the defense objection and had, instead, relied on other evidence to prove the points demonstrated in the video interrogations. The Committee member queried whether the judge would have permitted the remainders in for their truth or for context if he had admitted them. He said probably for context only. The Committee member then expressed skepticism that a jury can understand an instruction limiting the use of a completing statement to context only. He suggested that juries are good at following many limiting instructions, but that a limiting instruction in this circumstance would be very difficult for jurors to comprehend and follow.

Another Committee member suggested that the hearsay issue might be addressed only in an Advisory Committee note to minimal amendments to Rule 106. Judge Campbell responded that these completion issues arise in the heat of trial and that trial judges only have time to review rule text before making an instant decision. He suggested that Rule106 – more than many others – needs to provide clear rule text to aid trial judges. Another Committee member echoed this observation, explaining that Rule 106 issues arise in "real-time" and that there are rarely motions *in limine* with respect to these issues. The Chair suggested that a minimalist amendment would simply add a second sentence to the existing rule that reads: "The court may admit the completing statement for its truth if it would otherwise be admissible or for context." Such an amended rule would resolve the hearsay question and leave remaining issues to a common law solution.

One Committee member expressed concern that completion would allow the admission of unreliable hearsay of criminal defendants. The Reporter in response noted that the parts of a defendant's statement offered by the government are themselves hearsay, and are not admissible because they are reliable --- but rather as party-opponent statements admissible under the adversary theory of litigation. The Chair again expressed reservations about creating a hearsay exception based on a fairness standard. The Reporter reminded the Committee that the fairness standard has been interpreted very narrowly and permits completion in very few circumstances. He stated that an amendment allowing substantive use of completing statements would not open the floodgates to hearsay so long as that narrow fairness trigger was retained.

Based upon the discussion of the hearsay and timing issues, the Reporter promised to present revised drafting alternatives for an amendment to Rule 106 at the Spring 2020 meeting that would:

- Rewrite the heading for the Rule to reflect the narrow scope of the provision and avoid displacing all common law completion;

- Eliminate flexibility with respect to the timing of completion and require completion contemporaneously (consistent with existing Rule 106);

- Provide two alternatives for addressing the hearsay issue: 1) allowing completion "over a hearsay objection" and 2) adding a second sentence to Rule 106 stating that "The court may admit the completing statement for its truth if it would otherwise be admissible or for context."

The Chair suggested that a completing remainder of a criminal defendant's statement would have to be presented simultaneously *by the prosecution* if the Rule remained a rule of interruption and that the completing remainder would be "otherwise admissible" as a statement of a party opponent when admitted by the prosecution --- even though it was likely to be unreliable.

The Reporter closed the discussion by noting that the Committee needed to continue its consideration of whether to include oral statements in an amended Rule 106 at the spring meeting. One question was whether to simply add oral statements to Rule 106's existing paragraph or to create a separate subsection for oral statements. Committee members unanimously disapproved of a separate subsection as unnecessarily complicated.

A Committee member noted that one draft amendment in the agenda materials simply dropped the modifiers "written or recorded" from the existing rule text and questioned whether that change would suffice to cover all written, video-recorded, and oral statements. The Reporter promised to consider that question for the next meeting. The DOJ representative repeated the Department's opposition to including oral, unrecorded statements in Rule 106. In response the Reporter referred the Committee to his memo, which indicated that almost all courts are *already* allowing admission of oral statements to complete, usually by citing Rule 611(a). He argued that all that adding oral statements to Rule 106 would do would be to treat all completeness issues under a single rule.

IV. Closing Matters

The Chair thanked Vanderbilt University for hosting the Committee and again praised the high quality of the miniconference on *Daubert* Best Practices. She thanked everyone for their contributions to a productive meeting. The meeting was adjourned.

Respectfully Submitted,

Daniel J. Capra
Liesa L. Richter

TAB 1D

MINUTES
COMMITTEE ON RULES OF PRACTICE AND PROCEDURE
June 23, 2020

The Judicial Conference Committee on Rules of Practice and Procedure (Standing Committee or Committee) convened on June 23, 2020 by videoconference. The following members participated in the meeting:

Judge David G. Campbell, Chair
Judge Jesse M. Furman
Daniel C. Girard, Esq.
Robert J. Giuffra Jr., Esq.
Judge Frank Mays Hull
Judge William J. Kayatta Jr.
Peter D. Keisler, Esq.
Professor William K. Kelley
Judge Carolyn B. Kuhl
Judge Patricia Millett
Judge Gene E.K. Pratter
Elizabeth J. Shapiro, Esq.*
Kosta Stojilkovic, Esq.
Judge Jennifer G. Zipps

The following attended on behalf of the Advisory Committees:

Advisory Committee on Appellate Rules
Judge Michael A. Chagares, Chair
Professor Edward Hartnett, Reporter

Advisory Committee on Bankruptcy Rules
Judge Dennis R. Dow, Chair
Professor S. Elizabeth Gibson, Reporter
Professor Laura Bartell, Associate Reporter

Advisory Committee on Criminal Rules
Judge Raymond M. Kethledge, Chair
Professor Sara Sun Beale, Reporter
Professor Nancy J. King, Associate Reporter

Advisory Committee on Civil Rules
Judge John D. Bates, Chair
Professor Edward H. Cooper, Reporter
Professor Richard L. Marcus, Associate Reporter

Advisory Committee on Evidence Rules
Judge Debra Ann Livingston, Chair
Professor Daniel J. Capra, Reporter

Others providing support to the Committee included: Professor Catherine T. Struve, the Standing Committee's Reporter; Professor Daniel R. Coquillette, Professor Bryan A. Garner, and Professor Joseph Kimble, consultants to the Standing Committee; Rebecca A. Womeldorf, the Standing Committee's Secretary; Bridget Healy, Scott Myers, and Julie Wilson, Rules Committee Staff Counsel; Brittany Bunting and Shelly Cox, Rules Committee Staff Analysts; Allison A. Bruff, Law Clerk to the Standing Committee; and John S. Cooke, Director, and Dr. Tim Reagan, Senior Research Associate, of the Federal Judicial Center (FJC).

* Elizabeth J. Shapiro (Deputy Director, Federal Programs Branch, Civil Division) and Andrew D. Goldsmith (National Coordinator of Criminal Discovery Initiatives) represented the Department of Justice on behalf of the Honorable Jeffrey A. Rosen, Deputy Attorney General.

OPENING BUSINESS

Professor Catherine Struve, Reporter to the Standing Committee, and Professor Daniel Coquillette, Consultant, honored Judge David Campbell for his 15 years of service with the Rules Committees and presented mementos to Judge Campbell on behalf of the Standing Committee's members, staff, and consultants and the advisory committee Chairs and Reporters. Three former Standing Committee Chairs (Judges Lee Rosenthal, Anthony Scirica, and Jeffrey Sutton) joined to congratulate Judge Campbell for a remarkable tenure with the Rules Committees. Department of Justice (DOJ) representative Elizabeth Shapiro presented a letter from Attorney General William P. Barr thanking Judge Campbell for his leadership in the rulemaking process and service to the federal judiciary. Judge Campbell thanked everyone for the kind comments and gifts of recognition.

Judge Campbell opened the meeting with a roll call and welcomed those listening to the meeting by telephone. Judge Campbell noted that the Chief Justice has extended until December 31, 2020 the terms of Rules Committees members scheduled to end on October 1, 2020. Judge Campbell welcomed a new member of the Standing Committee, Judge Patricia Millett of the D.C. Circuit, who fills the unexpired term of Judge Sri Srinivasan who recently became Chief Judge of the D.C. Circuit. Before her judicial service, Judge Millett had a distinguished career as a Supreme Court practitioner in the U.S. Solicitor General's Office and in private practice. Judge Campbell recognized those who have been newly appointed to serve as committee chairs beginning in the fall: Judge John Bates as Chair of the Standing Committee, Judge Robert Dow as Chair of the Advisory Committee on Civil Rules, Judge Jay Bybee as Chair of the Advisory Committee on Appellate Rules, and Judge Patrick Schiltz as Chair of the Advisory Committee on Evidence Rules. Judge Campbell thanked Judges Michael Chagares and Debra Livingston for their service as chairs.

APPROVAL OF THE MINUTES FROM THE PREVIOUS MEETING

Upon motion by a member, seconded by another, and on voice vote: **The Committee unanimously approved the minutes of the January 28, 2020 meeting.**

STATUS OF PENDING RULES AMENDMENTS

Ms. Rebecca Womeldorf reported that proposed amendments are proceeding through the Rules Enabling Act process without incident and referred members to the detailed tracking chart in the agenda book for further details. Judge Campbell noted that, since the Committee's last meeting, the Supreme Court had adopted a package of proposed amendments to the Appellate, Bankruptcy, Civil, and Evidence Rules. Those proposed amendments are before Congress, with a presumed effective date of December 1, 2020.

CONSIDERATION OF EMERGENCY RULES UNDER THE CARES ACT

Professor Struve provided an overview of the congressional directive in the Coronavirus Aid, Relief, and Economic Security (CARES) Act to the Judicial Conference to consider potential rules amendments to ameliorate the effects on court operations of future emergencies. The

advisory committees have begun work on this effort, with each advisory committee focusing on its own rules set. Public comment on potential emergency procedures has been sought. The advisory committees are working on drafts for discussion at their fall 2020 meetings with the goal of presenting drafts to the Standing Committee with requests for publication in the summer of 2021. Professor Struve explained that Professor Daniel Capra will coordinate the advisory committees' collective efforts. Under the ordinary timeline of the Rules Enabling Act process, any such rules amendments could go into effect as early as December 1, 2023.

Professor Sara Beale reported on the Criminal Rules Advisory Committee's emergency rules work, which will proceed through a subcommittee, chaired by Judge James Dever. The reporters and subcommittee are conducting research and preparing for a miniconference to be held in July.

Judge John Bates provided a summary of the Civil Rules Advisory Committee's emergency rules work. A subcommittee, chaired by Judge Kent Jordan, was formed after Congress passed the CARES Act. The subcommittee has met by several times and will meet again in one week. The first task is gathering information from judges, clerks, practitioners, and the public. The reporters have examined much of that information. Judge Bates added that the question remains whether any amendments to the Civil Rules are needed and what shape they should take. Among the areas of review that have been identified generally are service issues, remote proceedings, time limits, and conducting trials. The subcommittee's goal is to have recommendations to present to the full Advisory Committee at its fall 2020 meeting.

Judge Dennis Dow reported that the Bankruptcy Rules Advisory Committee has formed a CARES Act subcommittee which has met several times. The subcommittee has discussed a general approach which would grant courts the authority to continue hearings and extend deadlines. An alternate approach would authorize courts to do so in individual cases by motion or sua sponte, notwithstanding other limitations and restrictions that may exist in the rules. The latter approach mirrors a similar approach being considered regarding possible changes to the bankruptcy code. The subcommittee has reviewed the Bankruptcy Rules and identified those with deadlines and provisions governing extensions. It found few, if any, impediments in the rules to a more general approach. Professor Elizabeth Gibson is preparing a draft for review at the subcommittee's next meeting. Judge Dow noted that, in the process of reviewing the rules and public submissions, several other areas have been identified. Those include electronic filing and online payment of fees by unrepresented parties, guidelines for using remote hearing technology, burdens imposed by signature verification requirements, and issues regarding service of process by mail. The subcommittee will continue study of these issues and others.

Judge Chagares reported on the work of the Appellate Rules Advisory Committee's subcommittee on emergency rules. Each subcommittee member reviewed the Appellate Rules to identify potential issues. Appellate Rule 2 provides helpful flexibility but only permits a court to suspend rules in individual cases. The subcommittee is considering an emergency provision for broader application. Rule 33 provides for appeal conferences in person or by telephone and may require revision to account for modern technology. The subcommittee expects to present any potential rules amendments at the Advisory Committee's next meeting.

Professor Capra explained that he and Judge Livingston reviewed the Evidence Rules and concluded that no amendments were necessary to address issues such as remote proceedings. Professor Capra conferred with state evidence rules committees, and they observed that evidence rules distinguish between testimony and physical presence in court. "Testimony" as used in the rules, encompasses remote testimony. Further, Rule 611 provides trial judges with authority to control the mode of testimony. Professor Capra noted that trial practice would be impacted by the use of remote testimony and the inability of juries to make credibility determinations in the same way. A remote trial renders Rule 615, which deals with sequestration of witnesses, irrelevant because witnesses will not be in the courtroom. For the past two years, the Advisory Committee has been considering whether to amend Rule 615 to clarify whether sequestration can extend beyond physical presence in the courtroom. Professor Capra added that the Advisory Committee will continue to monitor the rules for possible emergency issues. Judge Campbell repeated a question raised in a public submission regarding authentication of evidence, namely whether a faster procedure for authentication should be available to shorten remote trials. Professor Capra pointed to recent amendments to Rule 902(13) and (14), which may alleviate this problem, but stated the Advisory Committee will take another look. Finally, Professor Capra noted that remote trials may raise a face-to-face confrontation issue which will need to be considered by the rules committees generally.

A member of the Standing Committee asked whether there has been any coordination with other Judicial Conference committees on the possible implications of emergency rules. Judge Campbell explained that there has been significant coordination with the Committee on Court Administration and Case Management (CACM Committee) regarding CARES Act procedures and other accommodations. He added that this coordination should continue as the advisory committees begin formulating draft emergency rule amendments. He also suggested seeking input from the Committee on Defender Services and the Criminal Law Committee. Ms. Womeldorf noted that the Administrative Office staff supporting those Judicial Conference committees – as well as the CACM Committee and the Committee on Bankruptcy Administration – are monitoring the Rules Committees' response to the CARES Act directive to consider emergency rules.

MULTI-COMMITTEE REPORTS

Judge Chagares reported on the E-filing Deadline Joint Subcommittee which is exploring the possibility of an earlier-than-midnight deadline for electronic filing. The subcommittee continues to gather information, including data from the FJC about actual filing patterns, i.e., what time of day litigants are filing and who is filing. Judge Chagares explained that the subcommittee seeks to cast a wide net to gather as much input as possible and has reached out to law school deans, bar associations, paralegal associations, and legal assistant associations. Based on a survey conducted by the Lawyers Advisory Committee for the District of New Jersey, there are strong opinions on different sides of the electronic-filing deadline issue. The subcommittee will continue to study this issue closely.

Judge Bates reported on the Appeal Finality After Consolidation Joint Civil-Appellate Subcommittee which was formed to examine the question whether rules amendments might be proposed to address the effects of Civil Rule 42 consolidation orders on the final-judgment approach to appeal jurisdiction in the wake of the Supreme Court's decision in *Hall v. Hall*, 138

S. Ct. 1118 (2018). In *Hall*, the Court ruled that disposition of all claims among all parties to a case that began as an independent action is a final judgment, notwithstanding the consolidation of that action with one or more other actions pursuant to Rule 42(a). The subcommittee, chaired by Judge Robin Rosenberg, is comprised of members from the Appellate Rules Advisory Committee and Civil Rules Advisory Committee. The subcommittee is looking at the effects of the *Hall* decision and developing information from the FJC. Empirical research on consolidated cases will inform the subcommittee's work to determine whether any rule change is needed. This process will take time.

REPORT OF THE ADVISORY COMMITTEE ON APPELLATE RULES

Judge Chagares and Professor Edward Hartnett provided the report of the Appellate Rules Advisory Committee, which last met on April 3, 2020 by telephone conference. The Advisory Committee presented several action items and information items.

Action Items

Final Approval of Proposed Amendment to Rule 42 (Voluntary Dismissal). Judge Chagares explained that the proposed amendment to Rule 42 would assure litigants that an appeal will be dismissed if the parties settle the case at the appellate level. The current rule provides that such an appeal "may [be] dismiss[ed]" by the circuit clerk and the proposed amendment would restructure the rule to remove ambiguity. Two legal entities filed comments after publication of the draft rule. The Association of the Bar of the City of New York (ABCNY) suggested that the Advisory Committee include language giving additional examples in proposed Rule 42(b)(3). Because the proposed amendment uses non-exclusive language, the Advisory Committee decided against providing additional examples. The ABCNY also suggested adding the phrase "if provided by applicable statute" to the amendment language. Because nothing in the rule permits courts of appeals to take actions by order that are not otherwise authorized by law, the Advisory Committee found the suggested addition unnecessary. The National Association of Criminal Defense Lawyers (NACDL) submitted a comment supporting the amendment as "well taken" but suggested additional language regarding the responsibilities of individual criminal defendants and defense counsel with respect to dismissals of appeals. The Advisory Committee decided against this suggestion, as the appellate rules generally do not address defense attorneys' responsibilities to clients.

Judge Chagares explained that the Advisory Committee made minor changes to the proposed amendment based on suggestions from Standing Committee members at the last meeting. First, the word "mere" was taken out of the proposed language in Rule 42(b)(3). Second, the Advisory Committee made a change to paragraph (3) to clarify that it applies only to dismissals under Rule 42(b) itself. Minor changes were also made in response to helpful suggestions by the style consultants. Judge Chagares sought final approval of the proposed amendment to Rule 42.

Referencing a comment filed by NACDL, Judge Bates flagged a concern that some local circuit rules will be inconsistent with the proposed rule's statement that a court "must" dismiss. He noted that several circuits' local rules contain other requirements (beyond those in Rule 42) for dismissal. The Fourth Circuit's local rule, for example, requires in criminal cases that a stipulation

of dismissal or motion for voluntary dismissal must be signed or consented to by the defendant. Another circuit's local rule requires an affidavit. Judge Chagares responded that the Advisory Committee had not addressed that issue. Professor Coquillette commented that a local rule which includes additional requirements beyond a uniform national rule may be considered inconsistent. Professor Capra clarified that unless a national rule prohibits additional requirements imposed by local rules, a local rule that does so is not necessarily inconsistent. Professors Coquillette and Capra agreed that local rule variances that do not facially contradict a uniform national rule have not been considered inconsistent historically. Judge Bates observed that the amendment might create uncertainty for attorneys practicing in circuits that have local rules that mandate requirements in addition to those in Rule 42 for dismissal. He asked whether language should be added to the committee note to address this potential problem. Professor Coquillette expressed concern about committee notes that change the meaning of the actual rule text. Professor Struve suggested that Judge Bates's question may warrant further consideration by the Advisory Committee, as it raises unexplored issues. She inquired whether discussion with circuit clerks may help resolve the question. Judge Campbell added that, unlike some other rules, proposed Rule 42 requires the circuit clerk to take an action rather than the parties. He recommended that the Advisory Committee take a closer look at local rules before moving forward with the proposal. Judge Chagares agreed.

Final Approval of Proposed Amendment to Rule 3 (Appeal as of Right—How Taken) and Conforming Amendments to Rule 6 and Forms 1 and 2. Judge Chagares explained that the Advisory Committee began studying issues with notices of appeal in 2017. Research revealed inconsistency across the circuits in how designations in a notice of appeal are used to limit the scope of an appeal. In 2019, the Supreme Court stated in *Garza v. Idaho*, 139 S. Ct. 738, 746 (2019), that the filing of a notice of appeal should be a "simple, non-substantive act." Consistent with *Garza*, the proposed amendments seek to simplify an

d make more uniform the process for filing a notice of appeal.

Professor Hartnett summarized the comments received on the proposal after publication. The first critical comment, submitted by Michael Rosman, asserted that the proposal was inconsistent with Civil Rule 54(b). In Mr. Rosman's view, there is no finality for appeal purposes (under 28 U.S.C. § 1291) until the district court enters a single document that recites the disposition of every claim by every party in an action; in this view, finality does not occur if the district court merely enters an order that disposes of all remaining claims. Professor Hartnett noted that neither the Advisory Committee nor the Standing Committee at its January meeting were persuaded by this critique, which had been submitted previously. The second critical comment, submitted by Judge Steven Colloton, urged abandonment of this project on the theory that litigants should be held to the choices made in their notice of appeal. In Judge Colloton's view, it is easy for a litigant to designate everything, and the Advisory Committee should not be encouraging counsel to seek to expand the scope of appeal beyond what is specified in the notice. The Advisory Committee considered this critique but was not persuaded.

Other comments urging suggestions for expanding or simplifying the proposed rule were considered and rejected by the Advisory Committee. Professor Hartnett explained that one of the suggestions, which proposed a simplification, might make the designation of a judgment or order completely irrelevant and might not overcome the problem initially identified. NACDL suggested

expanding proposed Rule 3(c)(5) to appeals in criminal cases. The provisions in paragraph (5) concern Appellate Rule 3's connection to Civil Rule 58. Professor Hartnett noted that NACDL did not identify a specific problem in criminal cases that such expansion would address. Instead, NACDL's concern was that a rule limited to civil cases might lead courts to adopt an expressio unius conclusion that a similar approach should not be taken in criminal cases. Rather than changing the proposed rule, the Advisory Committee added language to the committee note to explain that while similar issues might arise in criminal cases – and perhaps similar treatment may be appropriate – this rule is not expressing a view one way or the other about those issues. The Advisory Committee also received a suggestion regarding Rule 4(a)(4)(B)(ii)'s treatment of appeals from orders disposing of motions listed in Rule 4(a)(4)(A). The suggestion is that Rule 4(a)(4)(B)(ii) be amended to remove the requirement that appellants file a new or amended notice of appeal in order to challenge orders disposing of such motions. The Advisory Committee chose not to make changes in response to this suggestion, which would require further study and republication. This question, however, is closely related to a new suggestion to more broadly allow the relation forward of notices of appeal to cover decisions issued after the filing of the notice. The Advisory Committee decided that the best way to address these issues would be to roll them forward for future consideration.

At the Standing Committee's January 2020 meeting, members raised some concern that the proposed rule may inadvertently change the doctrine that treats a judgment as final notwithstanding a pending motion for attorneys' fees. To address this concern, the Advisory Committee added language to the committee note explaining that the proposed amendment has no effect on Supreme Court doctrine as laid out in *Budinich v. Becton Dickinson & Co.*, 486 U.S. 196 (1988), and *Ray Haluch Gravel Co. v. Cent. Pension Fund of Int'l Union of Operating Engineers & Participating Employers*, 571 U.S. 177 (2014). Professor Hartnett explained that these holdings – which treat attorneys' fees as collateral to the merits of the case for purposes of the final judgment rule – can coexist with the proposed amendment.

In response to Judge Colloton's submission, the Advisory Committee made one change to the rule text as published. Judge Colloton expressed concern about litigants filing (after the entry of final judgment) a notice of appeal designating only a prior interlocutory order. The Advisory Committee added language to proposed Rule 3(c)(7) that states an appeal must not be dismissed for failure to properly designate the judgment if the notice of appeal was filed after the entry of the judgment and designates an order that merged into that judgment.

One matter divided the Advisory Committee: whether to continue to permit a party to limit the scope of the notice of appeal. A minority of members concluded that such limitation should no longer be permitted. In their view, courts should look to the briefs to narrow the claims and issues on appeal. In contrast, most members found value in leaving this aspect of the proposal as published – allowing parties to limit the scope if expressly stated. For example, in multi-party cases, a party who has settled as to some claims may wish to appeal the disposition of other claims without violating a settlement agreement. The Advisory Committee voted to retain the feature permitting limitation and to revisit the issue in three years if problems develop. Judge Chagares observed that a provision in current Rule 3(c)(1)(B) permits the express limiting of a notice of appeal.

The Advisory Committee also sought final approval of conforming amendments to Rule 6 and Forms 1 and 2. Judge Chagares reported that the Chief Judge of the United States Tax Court has expressed approval for the proposed amendment to Form 2 (concerning notices of appeal from decisions of the Tax Court).

Professor Struve thanked Judge Chagares, Professor Hartnett, and the Advisory Committee for their work on this thorny problem. Judge Campbell offered suggestions regarding the committee note. First, he suggested that "and limit" be removed from the portion of the committee note that discusses the role of the briefs with respect to the issues on appeal. Second, he suggested clarification of two rule references in the note. These suggestions were accepted by Judge Chagares. A judge member recommended substitute language for the multiple uses of the term "trap" in the committee note. Professor Hartnett responded that the phrasing had been studied and that it is not pejorative or indicative of intentional trap-setting. Another member suggested adding "inadvertently" to the first sentence using the word "trap" in the committee note – thus: "These decisions inadvertently create a trap . . . ." Judge Chagares and Professor Hartnett accepted the suggestion and changed the committee note accordingly.

Upon motion, seconded by a member, and on a voice vote: **The Committee decided to recommend the amendment to Rule 3 and conforming amendments to Rule 6 and Forms 1 and 2 for final approval by the Judicial Conference.**

Publication of Proposed Amendment to Rule 25 (Filing and Service). The Advisory Committee sought publication of an amendment to Rule 25 to extend existing privacy protections to Railroad Retirement Act benefit cases. Judge Chagares explained that counsel for the Railroad Retirement Board requested protections for their litigants like those provided in Social Security benefit cases. Because Railroad Retirement Act benefit cases are appealed directly to the court of appeals, amending Civil Rule 5.2 would not work to extend privacy protections to those cases. The Advisory Committee made no changes to the draft amendment since the January 2020 Standing Committee meeting.

A judge member commented that, in other areas of the law such as ERISA, the Hague Convention, and medical malpractice, courts address privacy concerns on an ad hoc basis rather than with a categorical rule. This member expressed hesitation about picking out one area for categorical treatment without stepping back and looking comprehensively at balancing the public's right to access court records against individual privacy concerns. He also inquired whether such endeavor fell within the scope of the Committee's mandate. In response, Judge Chagares noted that Civil Rule 5.2(c) restricts only remote electronic access. He also explained that the Advisory Committee has focused on Railroad Retirement Act benefit cases because they are a close analog to Social Security benefit cases. In other cases that involve medical information, courts are still empowered to enter orders to protect that information. Judge Chagares further noted that the Supreme Court recently emphasized the close relation between the Social Security Act and the Railroad Retirement Act. Professor Hartnett explained that the Railroad Retirement Act benefit cases in the court of appeals mirror Social Security benefit cases in the district court, as they are essentially appellate in nature. Both types of cases involve administrative records full of sensitive information. Professor Edward Cooper recalled that when the Civil Rules Advisory Committee was working on Civil Rule 5.2, the Social Security Administration made powerful representations

regarding the filing of an administrative record. Under statute, it is required in every case to file a complete administrative record, which involves large amounts of sensitive information beyond the capacity of the court to redact. The Civil Rules Advisory Committee was persuaded that a categorical rule was appropriate for Social Security benefit cases. The judge member suggested that there are hundreds of ERISA disability cases every year that are almost identical to Social Security disability cases. Those cases also require the filing of an administrative record. The judge member asked whether the Rules Enabling Act publication process would reach stakeholders in other types of cases like ERISA proceedings. Judge Campbell suggested that the committees deliberately invite input from those stakeholders, as has been done with other rules in the past. The judge member agreed that such feedback would be beneficial, particularly from stakeholders not covered by the proposed amendment. Judge Chagares concurred in this approach.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved the proposed amendment to Rule 25 for publication with added request for comment from identified groups.**

Information Items

Rules 35 (En Banc Determination) and 40 (Petition for Panel Rehearing). Judge Chagares stated that the Advisory Committee is conducting a comprehensive study of Rules 35 and 40 with a view to reducing duplication and confusion.

Suggestion Regarding Decision on Grounds Not Argued. Judge Chagares described a suggestion submitted by the American Academy of Appellate Lawyers (AAAL) that would require the court to give notice and opportunity for additional briefing before deciding a case on unbriefed grounds. After studying this issue, the Advisory Committee concluded that it was not well-suited for rulemaking. Upon the Advisory Committee's recommendation, Judge Chagares wrote to each circuit chief judge with a copy of the AAAL's suggestion. He received feedback that unanimously concluded such a rule change was unnecessary. The Advisory Committee will reconsider this issue in three years.

Suggestion Regarding In Forma Pauperis Standards. Professor Hartnett noted that the Appellate Rules Advisory Committee continues to look into this issue. There remains a question whether rulemaking can resolve the issue. Professor Hartnett explained that, at the very least, the Advisory Committee could consider possible changes to Form 4 (the form for affidavits accompanying motions to appeal *in forma pauperis*).

Suggestion Regarding Rule 4(a)(2). Current Rule 4(a)(2) allows a notice of appeal filed after the announcement of a decision but before its entry to be treated as filed after the entry of decision. This provision allows modestly premature notices of appeal to remain viable. Professor Bryan Lammon's suggestion proposes broader relation forward. The Advisory Committee considered this question a decade ago and decided against taking action. In his suggestion, Professor Lammon argues that the issue has not resolved itself in the intervening decade. The Advisory Committee is looking to see if any rule change can be made to protect those who file their notice of appeal too early.

Suggestion Regarding Rule 43 (Substitution of Parties). Judge Chagares described a suggestion regarding amending Rule 43 to require use of titles instead of names of government officers sued in their official capacities. The Advisory Committee decided to table this suggestion while its clerk representative gathers information from clerks of court.

Review of Recent Amendments. Judge Chagares reviewed the impact of two recent amendments to the Appellate Rules. In 2019, Rule 25(d)(1) was amended to eliminate the requirement for proof of service when service is made solely through the court's electronic-filing system. At least two circuits continue to require certificates of service, despite the rule change. The Advisory Committee's clerk representative agreed to reach out to the clerks of court to resolve the issue. In 2018, Rule 29(a)(2) was amended to permit the rejection or striking of an amicus brief that would result in a judge's disqualification. The Advisory Committee polled the clerks to find out if any amicus briefs had been stricken under the new rule. At least three circuits have stricken such amicus briefs since the amendment became effective.

Judge Chagares thanked everyone involved during his tenure with the Rules Committees and wished everyone and their families well.

REPORT OF THE ADVISORY COMMITTEE ON BANKRUPTCY RULES

Judge Dow and Professors Gibson and Laura Bartell delivered the report of the Bankruptcy Rules Advisory Committee, which last met on April 2, 2020 by videoconference. The Advisory Committee presented several action items and two information items.

Action Items

Final Approval of Proposed Amendment to Rule 2005 (Apprehension and Removal of Debtor to Compel Attendance for Examination). Judge Dow explained that Rule 2005 deals generally with the apprehension of debtors for examination under oath. The last subpart deals with release of debtors. Current Rule 2005(c) refers to provisions of the criminal code that have since been repealed. The proposed change substitutes a reference to the relevant section in the current criminal code. The proposed amendment was published in August 2019. The Advisory Committee received no comments of substance. The National Conference of Bankruptcy Judges expressed a general indication of support for the proposed amendment. Judge Dow stated that the Advisory Committee recommends that the Standing Committee approve the proposed amendment to Rule 2005 as published. There were no comments from members of the Standing Committee.

Upon motion, seconded by a member, and on a voice vote: **The Committee decided to recommend the amendment to Rule 2005 for approval by the Judicial Conference.**

Final Approval of Proposed Amendment to Rule 3007 (Objections to Claims). Judge Dow next introduced the proposed amendment to Rule 3007, which deals generally with objections to claims filed by creditors. The subpart at issue – Rule 3007(a)(2)(A) – deals with service of those objections on creditors. It generally provides for service by first-class mail. Rule 3007(a)(2)(A)(ii) imposes a heightened service requirement for "insured depository institution[s]." "Insured

depository institution" has two different definitions in the bankruptcy rules and bankruptcy code. Rule 7004(h) imports a definition for "insured depository institution" from the Federal Deposit Insurance Act (FDIA). The FDIA definition (which is incorporated into Rule 7004(h)) does not encompass credit unions because credit unions are insured by the National Credit Union Administration rather than by the Federal Deposit Insurance Corporation. The bankruptcy code also defines "insured depository institution," in 11 U.S.C. § 101(35), and the Code's definition expressly does include credit unions. The Code definition applies to the Bankruptcy Rules pursuant to Rule 9001.

Several years ago, Rule 3007 was revised to make clear that generally standard service was adequate for purposes of the rule. But the Rule, as amended, provides that if the claimant is an insured depository institution, service must also be made according to the method prescribed by Rule 7004(h). The Advisory Committee recognized the exception to conform to the congressional desire for enhanced service on entities included under the FDIA definition. The Advisory Committee, however, did not think there was any congressional intent to afford enhanced service to entities that fall outside the FDIA definition. For purposes of consistency with other bankruptcy rules, and to conform to what the Advisory Committee understands as the congressionally-intended scope for enhanced service, the proposed amendment to Rule 3007(a)(2)(A)(ii) inserts a reference to the FDIA definition. The Advisory Committee received one comment, and it expressed support for the proposed amendment. There were no comments or questions from the Standing Committee.

Upon motion, seconded by a member, and on a voice vote: **The Committee decided to recommend the amendment to Rule 3007 for approval by the Judicial Conference.**

Final Approval of Proposed Amendment to Rule 7007.1 (Corporate Ownership Statement). Rule 7007.1 deals with disclosure of corporate ownership information in adversary proceedings. Judge Dow explained that the proposed amendment to Rule 7007.1 seeks to conform to the language in related rules: Appellate Rule 26.1, Bankruptcy Rule 8012, and Civil Rule 7.1. As published, the proposed amendment would amend Rule 7007.1(a) to encompass nongovernmental corporations that seek to intervene, would make stylistic changes to the rule, and would change the title of Rule 7007.1 from "Corporate Ownership Statement" to "Disclosure Statement." The Advisory Committee received two comments in response to publication. One comment suggested that the word "shall" in Rule 7007.1 be changed to "must." While the Advisory Committee agreed with the suggestion, it concluded that such word change will be considered when Part VII is restyled. The other comment, from the National Conference of Bankruptcy Judges, suggested that Rule 7007.1 retain the title and language referring to "corporate ownership statement." The comment offered two reasons: (1) "disclosure statement" is a term of art in bankruptcy law; and (2) five other bankruptcy rules refer to the same document as a corporate ownership statement. The Advisory Committee was persuaded by this and voted to approve Rule 7007.1 with the current title ("Corporate Ownership Statement") retained and the word "disclosure" in subparagraph (b) changed to "corporate ownership," with the other features of the proposed amendments remaining unchanged since publication.

Upon motion, seconded by a member, and on a voice vote: **The Committee decided to recommend the amendment to Rule 7007.1 for approval by the Judicial Conference.**

Final Approval of Proposed Amendment to Rule 9036 (Notice and Service Generally). Professor Gibson introduced the proposed amendment to Rule 9036. She explained that the Advisory Committee has been considering possible amendments to the Bankruptcy Rules to increase the use of electronic service and noticing in the bankruptcy courts. One amendment to Rule 9036 became effective on December 1, 2019. When the 2019 amendment to Rule 9036 was published for public comment in 2017, related proposed amendments to Rule 2002(g) and Official Form 410 were also published. The proposed amendments to Rule 2002(g) and Official Form 410 would have authorized creditors to designate an email address on their proof of claim for receipt of notices and service. Based on comments received during the 2017 publication period, the Advisory Committee decided to hold the proposed amendments to Rule 2002(g) and Official Form 410 in abeyance.

The current proposed amendment to Rule 9036 was published in August 2019 and would encourage the use of electronic noticing and service in several ways. First, the rule would recognize the court's authority to provide notice or make service through the Bankruptcy Noticing Center to entities that currently receive a high volume of paper notices from the bankruptcy courts. This program, set up through the Administrative Office, would inform high-volume paper-notice recipients to register for electronic noticing. The proposed amendment would acknowledge this process and authorize notice in that manner. Anticipating that the Advisory Committee would move forward with the earlier-mentioned amendments to Rule 2002(g) and Official Form 410, Professor Gibson explained that the rule as published would have allowed courts and parties to provide notice to a creditor at an email address indicated on the proof of claim.

The Advisory Committee received seven sets of comments on the published proposal to amend Rule 9036. Commenters expressed concern about the proposed amendments to Rule 9036 as well as about the earlier-published proposals to amend Rule 2002(g) and Official Form 410. There was, however, enthusiastic support for the program to encourage high-volume paper-notice recipients to register for electronic bankruptcy noticing. The commenters included the Bankruptcy Noticing Working Group, the Bankruptcy Clerks Advisory Group, an ad hoc group of 34 clerks of court, and individual court staff members. Their concerns fell into three categories: clerk monitoring of email bounce-backs; the administrative burden of the proof-of-claim opt-in form for email noticing, and the interplay of the proposed amendments to Rules 2002(g) and 9036. Because the same provision regarding bounce-backs is in the version of Rule 9036 that went into effect last December and in Rule 8011(c)(3), the Advisory Committee decided not to change the language in the published version of Rule 9036(d); but it did add a new sentence to that subdivision stating that the recipient has a duty to keep the court informed of the recipient's current email address.

The greatest concern was the administrative burden of allowing creditors to opt-in to email noticing and service on their proof-of-claim form (Official Form 410). Some commenters asserted that without an automated process for extracting email addresses from proofs of claim, the burden of checking each proof of claim would be too great. Others suggested that, even with automation, the process would be time consuming and burdensome (given that paper proofs of claim would continue to be filed). Persuaded by this reasoning, at its spring 2020 meeting, the Advisory Committee voted not to pursue the opt-in check-box option on the proof of claim form. Accordingly, it revised the proposed amendment to Rule 9036 so as to omit the reference to

Rule 2002(g)(1). Professor Gibson further explained that the Advisory Committee's ultimate approach here does not give any benefit to parties because parties do not have access to the Bankruptcy Noticing Center. Future improvements to CM/ECF may allow entry of email addresses in a way that will be accessible to parties. The language in proposed Rule 9036(b)(2) would allow for parties to take advantage of that future development.

Judge Campbell observed that the Advisory Committee's revisions to the Rule 9036 proposal provide a good illustration of the value of the Rules Enabling Act's public-comment process.

Upon motion, seconded by a member, and on a voice vote: **The Committee decided to recommend the amendment to Rule 9036 for approval by the Judicial Conference.**

Retroactive Approval of Amendments to Official Forms 101, 201, 122A-1, 122B, and 122C-1. Enacted in March 2020, the CARES Act made certain changes to the bankruptcy code, which required changes to five Official Forms. Because the law took effect immediately, the Advisory Committee acted under its delegated authority to make conforming changes to Official Forms, subject to later approval by the Standing Committee and notice to the Judicial Conference. Professor Gibson explained the two main changes the CARES Act made to the bankruptcy code, both of which will sunset in one year from the effective date of the Act. First, the Act provided a new definition of "debtor" for purposes of subchapter V of Chapter 11. The new one-year definition raised the debt limit for a debtor under subchapter V from $2,725,625 to $7,500,000. As a result of that legislative change, there are at least three categories of Chapter 11 debtors: (1) A debtor that satisfies the definition of small business debtor, with debts of at most $2,725,625; (2) a debtor with debts over $2,725,625 but not more than $7,500,000; and (3) a debtor that doesn't meet either definition, and proceeds as a typical Chapter 11 debtor. The court will separately need to know which category a debtor falls within to know whether special provisions apply. The Advisory Committee thus amended two bankruptcy petition forms – Official Forms 101 and 201 – to accommodate these changes.

Second, the CARES Act changed the definition of "current monthly income" in the Bankruptcy Code to add a new exclusion from computation of currently monthly income for federal payments related to the Coronavirus Disease 2019 (COVID-19) pandemic. An identical exclusion was also inserted in § 1325(b)(2) for computing disposable income. Both changes are effective for one year, unless extended by Congress. These changes effect eligibility for Chapter 7 and the required payments under Chapter 13. As a result, the Advisory Committee added a new exclusion in Official Forms 122A-1, 122B, and 122C-1.

Judge Campbell asked whether the Advisory Committee would seek to reverse these amendments if Congress did not extend the sunset date of the relevant CARES Act provisions. Professor Gibson replied in the affirmative.

Upon motion, seconded by a member, and on a voice vote: **The Committee decided to retroactively approve the technical and conforming amendments to Official Forms 101, 201, 122A-1, 122B, and 122C-1, and to provide notice to the Judicial Conference.**

Publication of Restyled Parts I and II of the Bankruptcy Rules. Professor Bartell introduced the first two parts of the restyled Bankruptcy Rules. She observed that the restyling process should get easier over time, as the first two parts required the Advisory Committee to resolve issues that will recur in subsequent parts. She noted that the style consultants have been wonderful to work with, and their work has made the restyled Bankruptcy Rules much easier to understand. For the restyling process, the Advisory Committee endorsed five basic principles. First, the Advisory Committee will avoid any substantive changes, even where some may be needed. Second, the restyled rules will not modify any term defined in the bankruptcy code. This does not include terms used, but not defined, in the code. Third, the restyled rules will preserve terms of art. There was some disagreement between the Advisory Committee and the style consultants on what constitutes a term of art. Fourth, all Advisory Committee members would remain open to new ideas suggested by the style consultants. Finally, the Advisory Committee will defer to the style consultants on matters of pure style.

Professor Bartell addressed one substantive issue that arose. In the past, Congress has directly amended certain bankruptcy rules. Rule 2002(o) (Notice for Order of Relief in Consumer Case) is a result of legislative amendment and was originally designated as Rule 2002(n) as set forth in the legislation. A subsequent amendment adding a provision earlier in the list of subdivisions in the rule resulted in changing the designation of Rule 2002(n) to 2002(o), and minor stylistic changes have been made since the provision was legislatively enacted. The question arose whether the Advisory Committee had authority to make stylistic changes to or revise the designation of the rule. The Advisory Committee concluded that any congressionally enacted rules should be left as Congress enacted them.

Judge Campbell thanked Judge Marcia Krieger for her work and leadership as Chair of the Restyling Subcommittee, as well as Professor Bartell and the style consultants, Professors Bryan Garner, Joe Kimble, and Joe Spaniol. Judge Dow echoed this sentiment and opined that the bankruptcy rules will be much improved by this process. Judge Dow also noted that progress has been made on Parts III and IV of the rules. Professors Garner and Kimble expressed their appreciation for being involved in the restyling process and the work done so far. A judge member of the Standing Committee said that the restyled rules are much more readable.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved for publication the Restyled Parts I and II of the Bankruptcy Rules.**

Publication of SBRA Rules and Official Forms. The Advisory Committee is seeking publication of the rules and forms amendments previously published and issued on an expedited basis as interim rules, in response to the Small Business Reorganization Act (SBRA). The interim rules include amendments to the following Bankruptcy Rules: 1007, 1020, 2009, 2012, 2015, 3010, 3011, 3014, 3016, 3017.1, 3017.2 (new), 3018, and 3019. Professor Gibson noted that the only change made to the interim rules was stylistic. In response to suggestions by the style consultants, the Advisory Committee made stylistic changes to Rule 3017.2. The Advisory Committee did not make the suggested style changes to Rule 3019(c) because they would have created an inconsistency among the subheadings in the rule. Professor Gibson explained that the headings would be reconsidered as part of the restyling process.

Professor Gibson also introduced the changes made to Official Forms 101, 122B, 201, 309E-1, 309E-2, 309F-1, 309F-2, 314, 315, and 425A. Under its delegated authority, the Advisory Committee previously made technical and conforming amendments to all but one of these forms in response to the SBRA. Despite these already having taken effect, the Advisory Committee seeks to republish them for a longer period and in conjunction with the proposed amendments to the SBRA rules. The package of forms prepared for summer 2020 publication includes one addition beyond the forms initially amended in response to the SBRA: Form 122B needed to be amended to update instructions related to individual debtors proceeding under subchapter V.

Judge Campbell commended the Advisory Committee for this impressive work. Congress passed the SBRA with a short window before its effective date. Despite this, the Advisory Committee managed to produce revised rules and forms, get them approved by the Standing Committee and by the Executive Committee of the Judicial Conference, and distribute them to all the bankruptcy courts before the SBRA took effect so they could be adopted as local rules.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved for publication the amendments to Rules 1007, 1020, 2009, 2012, 2015, 3010, 3011, 3014, 3016, 3017.1, 3017.2, 3018, and 3019 and Official Forms 101, 122B, 201, 309E-1, 309E-2, 309F-1, 309F-2, 314, 315, and 425A.**

Publication of Proposed Amendment to Rule 3002(c)(6) (Time for Filing Proof of Claim). Judge Dow next addressed the proposed amendment to Rule 3002(c)(6), which provides that the court may extend the deadline to file a proof of claim if the notice of the need to file a claim was insufficient to give the creditor a reasonable time to file because the debtor failed to file the required list of creditors. The Advisory Committee identified several problems with this provision. First, the rule would almost never come into play because a failure to file the list of creditors required by Rule 1007 is also cause for dismissal. Because such a case would likely be dismissed, there would be no claims allowance process. Second, under the language of paragraph (c)(6), the authorization to grant an extension is extremely narrow. For example, there is no provision for notices that omit a creditor's name or include an incorrect address. Further, Professor Bartell's research revealed a split in the caselaw. The proposed amendment seeks to resolve these problems by stating a general standard for the court's authority to grant an extension if the notice was insufficient to give a creditor reasonable time to file a claim. This same standard currently applies to creditors with foreign addresses. The proposed amendment would bring consistency to domestic creditors and provide more flexibility for the courts to offer relief as warranted.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved for publication the amendments to Rule 3002.**

Publication of Proposed Amendment to Rule 5005 (Filing and Transmittal of Papers). Professor Bartell explained that Rule 9036 allows clerks and parties to provide notices or serve documents (other than those governed by Rule 7004) by electronic filing. She then introduced proposed amendment to Rule 5005. Rule 5005(b) governs transmittal of papers to the U.S. trustee and requires that such papers be mailed or delivered to an office of, or another place designated by, the U.S. trustee. It also requires the entity transmitting the paper file as proof of transmittal a verified statement. The Advisory Committee consulted with the Executive Office for U.S. Trustees

about whether Rule 5005 accurately reflects current practice and whether it could be conformed more closely to the practice under Rule 9036. The proposed amendment, which is supported by the Executive Office for U.S. Trustees, would allow papers to be transmitted to the U.S. trustee by electronic means and eliminate the requirement to file a verified statement.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved for publication the amendment to Rule 5005.**

Publication of Proposed Amendment to Rule 7004 (Process; Service of Summons, Complaint). A committee note to Rule 7004's predecessor, Rule 704, specified that in serving a corporation or partnership or other unincorporated association by mail, it is not necessary for the officer or agent of the defendant to be named in the address so long as the mail is addressed to the defendant's proper address and directed to the attention of the officer or agent by reference to his position or title. When Rule 704 became Rule 7004, that committee note was dropped and no longer included in the published version of Rule 7004. Professor Bartell explained that, as a result, courts have divided over whether a notice addressed to a position or title is effective under Rule 7004. The Advisory Committee's proposal would insert a new subdivision (i), which inserts the substance of the previous committee note for Rule 704 into Rule 7004.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved for publication the amendment to Rule 7004.**

Publication of Proposed Amendment to Rule 8023 (Voluntary Dismissal). Professor Bartell introduced the proposed amendment to Rule 8023, which is based on Appellate Rule 42(b), regarding voluntary dismissal of appeals. She indicated that the Standing Committee's deferred consideration of the proposed amendments to Appellate Rule 42(b) should not affect the Standing Committee's decision to approve the proposed amendment to Bankruptcy Rule 8023 for publication. She noted that the version of the proposed amendment to Rule 8023 in the agenda book needed two minor additional changes to conform to Appellate Rule 42(b). First, the phrase "under Rule 8023(a) or (b)" should be added to subdivision (c). Second, the word "mere" should be eliminated from subdivision (c). The resulting rule text for Rule 8023(c) would read ". . . for any relief under Rule 8023(a) or (b) beyond the dismissal of an appeal . . . ." Professor Bartell also suggested that publication of the proposed amendment to Rule 8023 should not preclude the Advisory Committee from making further changes if Appellate Rule 42(b) is changed.

Judge Campbell asked whether a decision by the Appellate Rules Advisory Committee not to move forward with the proposed amendments to Appellate Rule 42(b) would affect the Bankruptcy Rules Advisory Committee's desire to move forward with the proposed amendment to Bankruptcy Rule 8023. Professor Bartell responded affirmatively and clarified that the proposed amendment to Rule 8023 is purely conforming. Because Appellate Rule 42(b) has already been published and is being held at the final approval stage, the Bankruptcy Rules Advisory Committee can publish the conforming amendment to Bankruptcy Rule 8023 and be ready for final approval if Appellate Rule 42(b) is later approved.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved for publication the amendment to Rule 8023.**

Information Items

Amendment to Interim Rule 1020. As previously noted, the CARES Act altered the definition of "debtor" under subchapter V of Chapter 11. This change required an amendment of interim Rule 1020, which was previously issued in response to the SBRA. The Advisory Committee drafted the amendment to the interim rule to reflect the definition of debtor in § 1182(1) of the Bankruptcy Code. The Standing Committee approved the amendment, and the Executive Committee of the Judicial Conference authorized its distribution to the courts. Professor Gibson noted that Rule 1020 is one of the rules that the Advisory Committee is publishing as part of the SBRA rules package. The version being published with the SBRA rules is the original interim Rule 1020. Because the version amended in response to the CARES Act will sunset in one year, it will no longer be applicable by the time the published version of Rule 1020 goes into effect.

Director's Forms for Subchapter V Discharge. The Advisory Committee approved three Director's Forms for subchapter V discharges. One is for a case of an individual filing for under subchapter V and in which the plan is consensually confirmed. The other two apply when confirmation is nonconsensual. These forms appear on the Administrative Office website.

REPORT OF THE ADVISORY COMMITTEE ON CIVIL RULES

Judge Bates and Professors Cooper and Richard Marcus provided the report of the Civil Rules Advisory Committee, which last met on April 1, 2020 by videoconference. The Advisory Committee presented three action items and several information items.

Actions Items

Judge Bates introduced the proposed amendment to Civil Rule 7.1 (Disclosure Statement) for final approval. The proposed amendment to Rule 7.1(a)(1) parallels recent amendments to Appellate Rule 26.1 and Bankruptcy Rule 8012(a) adding nongovernmental corporate intervenors to the requirement for filing disclosure statements. The technical change to Rule 7.1(b) conforms to the change to subdivision (a). Judges Bates stated that the amendment to subdivision (b) was not published but is appropriate for final approval as a technical and conforming amendment. The new provision in Rule 7.1(a)(2) seeks to require timely disclosure of information that is necessary to ensure diversity of citizenship for jurisdictional purposes. Problems have arisen with certain noncorporate entities – particularly limited liability companies (LLCs) – because of the attribution rules for citizenship. Many courts and individual judges require disclosure of this citizenship information.

Most public comments received supported the proposed amendment. In response to the comments, the Advisory Committee revised the language concerning the point in time that is relevant for purposes of the citizenship disclosure. Judge Bates explained that the time relevant to determining citizenship is usually when the action is either filed in or removed to federal court. The proposed language also accommodates other times that may apply for determining jurisdiction. The comments opposing the amendment expressed hope that the Supreme Court or Congress would address the issue of LLC citizenship. The Advisory Committee believes that

action through a rule amendment is warranted. Judge Bates noted that in response to a concern previously raised by a member of the Standing Committee, a sentence was added to the committee note to clarify that the disclosure does not relieve a party asserting diversity jurisdiction from the Rule 8(a)(1) obligation of pleading grounds for jurisdiction.

A member of the Standing Committee asked whether the language regarding other relevant times can be made more precise. Professor Cooper responded that the language is deliberately imprecise to avoid trying to define the relatively rare circumstances when a different time becomes controlling for jurisdiction. He provided examples of such circumstances. He also noted that a defendant in state court who is a co-citizen of the plaintiff cannot create diversity jurisdiction by changing his or her domicile and then removing the case to federal court. The law prohibits this, even though at the time of removal there would be complete diversity. Professor Cooper explained that the Advisory Committee sought to avoid more definite language based on the twists and turns of diversity jurisdiction and removal.

A judge member asked how the provision in question interplays with Rule 7.1(b) (Time to File). What triggers the obligation to file under subdivision (b) if there is another time that is relevant to determining the court's jurisdiction? This member observed that it was unclear whether a party or intervenor is obliged to refile or supplement under subdivision (b). Professor Cooper explained that two distinct concepts are at play: the time at which the disclosure is made and the time of the existent fact that must be disclosed. He provided an example. A party discloses the citizenship of everyone that is attributed to it, as an LLC. Later on, the party discovers additional information that was in existence (but not known to the party) at the time for determining diversity. Paragraph (b)(2) would trigger the obligation to supplement.

Another member suggested it would be better to require a party at the outset to disclose known information and impose an obligation to update that disclosure within a certain time if there is a change in circumstances that affects the previous disclosure. He also expressed concern about the language in Rule 7.1(a)(2) that places "at another time that may be relevant" with the conjunction "or" between subparagraphs (A) and (B). Professor Cooper explained that Rule 7.1(b)(1) sets the time for disclosure up front and Rule 7.1(a)(2)(B) refers to the citizenship that is attributed to that party at some time other than the time for disclosure. Judge Campbell commented that he understood Rule 7.1(a) as the "what" of what must be disclosed and Rule 7.1(b) as the "when." Professor Cooper confirmed that Judge Campbell's understanding aligned with the intent of the proposed amendment. Judge Campbell suggested revising Rule 7.1(a)(2)(B) to state "at any other time relevant to determining the court's jurisdiction." Discussion followed on the possibility of collapsing subparagraphs (A) and (B) into one provision.

A judge member echoed similar concerns regarding subparagraph (B)'s vagueness. This member suggested using as an alternative "at some other time as directed by the court." On the rare occasions when this arises, he explained, presumably the issue of the relevant time will be litigated, and the court can issue an order specifying it. This member also observed that, although subparagraph (B) would require a lawyer to make a legal determination as to what another relevant time may be, the rule does not require the lawyer to specify what that moment in time was.

Another judge member asked whether subparagraphs (A) and (B) are intended to qualify "file" or "attributed." Professor Cooper responded that the provisions are intended to qualify "attributed." A different member shared concerns about the "or" structure of Rule 7.1(a)(2)(A) and (B). This structure leaves it to the discretion and understanding of the filers whether they fall into the category that applies most often or some other category. This member favored a version that would reflect that most cases will be governed by subparagraph (A) and include a carve-out provision such as "if ordered by the court or if an alternative situation applies." He also suggested some of this uncertainty may be best resolved through commentary rather than rule language. Another judge member asked about the purpose of "unless the court orders otherwise" earlier in Rule 7.1(a)(2). This member suggested that this language might play into the resolution of subparagraph (B).

Professor Cooper then proposed a simplification of paragraph (2): "is attributed to that party or intervenor at the time that controls the determination of jurisdiction." Judge Bates noted that this proposal would still require the lawyer to make a legal determination. Judge Campbell offered an alternative, namely to instruct the parties that if the action is filed in federal court, they must disclose citizenship on the date of filing. If the action is removed to federal court, they must disclose citizenship on the date of removal. This alternative makes it clear what the parties' obligations are when they are making the disclosure and leaves it to judges to ask for more. Judge Bates agreed that this suggestion provides a clearer approach than trying to address a very rare circumstance in the rule. He also responded to a question raised earlier regarding "unless the court orders otherwise." The committee note addresses situations in which a judge orders a party not to file a disclosure statement or not to file publicly for privacy and confidentiality reasons.

A different member suggested that ambiguity remained whether subparagraphs (A) and (B) qualify "file" or "attributed." This member suggested breaking up paragraph (2) into two sentences to make clear that the latter provisions qualify "attributed." A judge member asked whether the committee note could resolve the ambiguity, but Judge Campbell noted that the committee note is not always read.

Judge Campbell recapped what the proposal would look like based on suggestions so far. Rule 7.1(a)(2) would state "In an action in which jurisdiction is based on diversity under 28 U.S.C. § 1332(a), a party or intervenor must, unless the court orders otherwise, file a disclosure statement at the time provided in subdivision (b) of this rule." A second sentence would then state that the disclosure statement must name and identify the "citizenship of every individual or entity whose citizenship is attributed to that party or intervenor at the time the action is filed in or removed to federal court." Another judge member pointed out that this proposal raises issues regarding an intervenor, whose attributed citizenship may not be relevant at the time of filing or removal.

In response to an earlier suggestion about using the committee note to resolve the issue, Professor Garner noted that many textualist judges will not look to committee notes. Such judges will consider a committee note on par with legislative history. Professor Coquillette agreed and observed that it is not good rulemaking practice to include something in a note that could change the meaning of the rule text. A judge member agreed and encouraged simpler rule language.

Judge Campbell recommended that the Advisory Committee continue working on the draft amendment to Rule 7.1 to consider the comments and issues raised. Judge Bates agreed and stated that the Advisory Committee would resubmit a redrafted rule in the future.

Publication of Proposed Supplemental Rules for Social Security Review Actions Under 42 U.S.C. § 405(g). Judge Bates then introduced the proposed Supplemental Rules for Social Security Review Actions. He noted that this project raises the issue of transsubstantivity. The subcommittee, chaired by Judge Sara Lioi, has been working on this for three years. The initial proposal came from the Administrative Conference of the United States. The Social Security Administration has strongly supported adoption of rules specific to Social Security review cases. Both the DOJ and the claimants' bar groups have expressed modest opposition. The Advisory Committee received substantial input – generally supportive – from district court judges and magistrate judges. The proposed rules recognize the essentially appellate nature of Social Security review proceedings. The cases are reviewed on a closed administrative record. These cases take up a substantial part of the federal docket. Judge Bates explained that the proposed rules are modest and simple. The Advisory Committee rejected the idea of considering supplemental rules for all administrative review cases given the diversity of that case category and the complicated nature of some types of cases.

The Supplemental Rules provide for a simplified complaint and answer. The proposed rules also address service of process and presentation of the case through a briefing process. Judge Bates noted several examples of civil or other rules that address specific areas separately from the normal rules. Some are narrow, while others are broad. The Rules Enabling Act authorizes general rules of practice and procedure. Here, the Advisory Committee is dealing with a unique yet voluminous area in which special rules can increase efficiency. When applied in Social Security review cases, the Civil Rules do not fit perfectly, a conclusion supported by magistrate judges and the Social Security Administration. The Advisory Committee submits that the benefits of these Supplemental Rules outweigh the risks and that the Rules Enabling Act will be able to protect against future arguments for more substance-specific rules of this kind.

The DOJ's opposition to the proposal stems from the possibility of these Supplemental Rules opening the door to more requests for subject-specific rules in other areas. After close study by the subcommittee and input from stakeholders, the Advisory Committee believed that publication and resulting comment process will shed light on whether the transsubstantivity concerns should foreclose adoption of this set of supplemental rules. Remaining issues are not focused on the specific language of the proposed rules, but rather on whether special rules for this area are warranted at all.

Judge Bates further clarified that the proposed Supplemental Rules would apply only to Social Security review actions under 42 U.S.C. § 405(g). They would not cover more complicated Social Security review matters that do not fit this framework (e.g., class actions). Professor Cooper added that the subcommittee worked very hard on this proposal, holding numerous conference calls and hosting two general conferences attended by representatives of interested stakeholders. The subcommittee has significantly refined the proposal. Professor Coquillette commended the work of the subcommittee and Advisory Committee. He also expressed his support for the decision

to draft Supplemental Rules, rather than to build a special rule into the Civil Rules themselves. The risk of transsubstantivity problems is much less under this approach.

A member of the Standing Committee commented that the decision here involves weighing the benefit that these rules would bring against the erosion of the transsubstantivity principle. He asked what kind of input the Advisory Committee received regarding the upside of this proposal. Judge Bates responded that one intended benefit is consistency among districts in handling these cases. Professor Cooper added that many judges already use procedures like the proposed Supplemental Rules with satisfactory results. He noted that the claimants' bar representatives have expressed concern that the proposed Supplemental Rules will frustrate local preferences of judges that employ different procedures.

A member noted that no one is criticizing the content of the proposed Supplemental Rules – a reflection of the care and time put in by the subcommittee. And no one is saying that the proposed rules favor a particular side. The debate largely surrounds transsubstantivity and form. A judge member generally agreed, but raised the concern expressed by some magistrate judges that the content of Supplemental Rules will limit their flexibility in case management. For example, in counseled cases some magistrate judges require a joint statement of facts. Who files first might be determined by whether the claimant has counsel: if so, then the claimant files first, but if not, then the government files first. In this judge's district the deadlines are a lot longer than those in the proposed rules. This member suggested a carve-out provision – "unless the court orders otherwise" – in the Supplemental Rules to give individual courts more leeway. He clarified that he did not oppose publication of the proposal but anticipated additional criticism and pushback.

Professor Coquillette commended the work of the subcommittee. He recognized that the Rules Committees are sensitive to the issue of transsubstantivity. One possible issue is Congress taking Supplemental Rules like this as precedent to carve out other parts of the rules. He inquired whether this issue was the basis of the DOJ's modest opposition to the proposal. Judge Bates confirmed that it was.

Judge Campbell expressed his support for publication. This situation is unique in that a government agency, the Administrative Conference of the United States, approached the Rules Committees and asked for this change. Another government agency, the Social Security Administration, has said this rule change would produce a significant benefit. The Supplemental Rules are drafted in a way that reduces the transsubstantivity concern. He cautioned against adding a carve-out provision that would allow courts to deviate, as that would not produce the desired benefit.

A DOJ representative clarified that, despite the Department's mild opposition to the proposed rules, the Department does not oppose publication. The Department may formally comment again after publication. An academic member commended the Advisory Committee and subcommittee for their elegant approach to a very difficult problem. A judge member asked whether the Supplemental Rules should be designated alphabetically rather than numerically. Professor Cooper explained that some sets of supplemental rules use letters to designate individual rules, while other sets use numbers. Professor Cooper added that his preference is to use numbers for these proposed Supplemental Rules. The judge member suggested that using letters might help

to avoid confusion, as lawyers might be citing to both the Civil Rules and the Supplemental Rules in the same submission. Judge Bates stated that the Advisory Committee will consider this issue during the publication and comment period.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved for publication the proposed Supplemental Rules for Social Security Review Actions Under 42 U.S.C. § 405(g).**

Publication of Proposed Amendment to Rule 12(a)(4). Judge Bates introduced the proposed amendment to Rule 12(a)(4), which was initiated by a suggestion submitted by the DOJ. The proposed amendment would expand the time from 14 days to 60 days for U.S. officers or employees sued in an individual capacity to file an answer after the denial of a Rule 12 motion. This change is consistent with and parallels Rule 12(a)(3), as amended in 2000, and Appellate Rule 4(a)(1)(B)(iv), added in 2011. The extension of time is warranted for the DOJ to determine if representation should be provided or if an appeal should be taken. Judge Bates noted that the proposed language differs from the language proposed by the DOJ but captures the substance.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved for publication the proposed amendment to Rule 12(a)(4).**

Information Items

Report of the Subcommittee on Multidistrict Litigation (MDL). Judge Bates stated that the subcommittee, chaired by Judge Robert Dow, has been at work for over three years. The subcommittee is actively discussing and examining three primary subjects. The subcommittee's work is informed by members of the bar, academics, and judges.

The first area of focus is early vetting of claims. This began with plaintiff fact sheets and defense fact sheets, secondarily. It has evolved to looking at initial census of claims. The FJC has researched this subject and indicated that plaintiff fact sheets are widely used in MDL proceedings, particularly in mass tort MDLs. Plaintiff fact sheets are useful for early screening and jumpstarting discovery. Initial census forms have evolved as a preliminary step to plaintiff fact sheets and require less information. Four current MDLs are utilizing initial census forms as a kind of pilot program to see how effective they are. Whether this results in a rule amendment or a subject for best practices, there is strong desire to preserve flexibility for transferee judges.

The second area is increased interlocutory review. The subcommittee is actively assessing this issue. The defense bar has strongly favored an increased opportunity for interlocutory appellate review, particularly for mass tort MDLs. The plaintiffs' bar has strongly opposed it, arguing that 28 U.S.C. § 1292(b) and other routes to review exist now, and it is not clear that these are inadequate. Judge Bates explained that delay is a major concern, as with any interlocutory review for these MDL proceedings. Another question concerns the scope of any increased interlocutory review. Should it be available in a subset of MDLs, all MDLs, or even beyond MDLs to capture other complex cases? The role of the district court is another issue that the subcommittee is considering. The subcommittee recently held a miniconference, hosted by Emory Law School and Professor Jaime Dodge, on the topic of increased interlocutory review. The miniconference

involved MDL practitioners, transferee judges, appellate judges, and members of the Judicial Panel on Multidistrict Litigation. Judge Bates stated that the miniconference was a success and will be useful for the subcommittee. A clear divide remains between the defense bar and plaintiffs' bar regarding increased interlocutory review, with the mass tort MDL practitioners being the most vocal. The judges at the miniconference were generally cautious about expanded interlocutory appeal and concerned about delay.

The third and newest area of concentration by the subcommittee is settlement review. The question is whether there should be some judicial supervision for MDL settlements, as there is under Rule 23 for class action settlements. Leadership counsel is one area of examination. As with the interlocutory review subject, one issue here is the scope of any potential rule. Judge Bates further noted that defense counsel, plaintiffs' counsel, and transferee judges have expressed opposition to any rule requiring greater judicial involvement in MDL settlements. Academic commenters are most interested in enhancing the judicial role in monitoring settlements in MDLs. The subcommittee continues to explore these questions and has not reached any decision as to whether a rule amendment is appropriate.

A member asked what research was available on interlocutory review in MDL cases. This member observed while Rule 23(f) was likely controversial when it was adopted, it has had a positive effect. He also stated that interlocutory review in big cases would be beneficial because most big cases settle, and the settlement value is affected by the district court rulings on issues that are not subject to appellate review. Judge Bates responded that the subcommittee is looking at Rule 23(f), but that rule's approach may not be a good fit. Professor Marcus noted that information on interlocutory review in MDL cases is difficult to identify, but research has been done and practitioners on both the plaintiffs' side and defense side have submitted research to the subcommittee. A California state-court case-gathering mechanism may be worth study. He noted that initial proposals sought an absolute right to interlocutory review but proposals under consideration now are more nuanced. One member affirmed the difficulty of identifying the information sought. Concerning § 1292(b), this member suggested that generally district judges want to keep these MDLs moving and promote settlement. A district judge may effectively veto a § 1292 appeal; however, under Rule 23(f), parties can make their application to the court of appeals. Professor Marcus noted that materials in the agenda book reflected these varying models regarding the district judge's role. The member suggested that the subcommittee survey appellate judges on whether Rule 23(f) has been an effective or burdensome rule.

A judge member expressed wariness about rulemaking in the MDL context. She asked whether most of the input from judges has been from appellate judges or transferee judges, and who would be most helped by a rule providing for increased interlocutory review. Regarding settlement review, she questioned whether this is a rule issue or one more appropriately addressed by best practices. Another member opined that, of the issues discussed, the settlement review issue least warrants further study for rulemaking. Professor Marcus responded that even if the subcommittee's examination of these issues does not produce rules amendments, there is much to be gained. For example, current efforts may support best practices recommendations included in a future edition of the *Manual for Complex Litigation*. Judges Bates noted that the only area of focus that may not be addressed by a best practices approach is the issue of increased interlocutory review. A member agreed with Judge Bates. This member also raised a different issue – "opt outs"

– for the subcommittee to consider. In his MDL experience, both the defense lawyers and district judges often spend more time dealing with the opt-outs than the settlement.

A judge member emphasized that, in the interlocutory review area, the big question is whether existing avenues – mandamus, Rule 54(b), and § 1292(b) – are adequate. He suggested that § 1292(b) is a poor fit for interlocutory review in MDL cases. This member also shared that several defense lawyers have indicated hesitation to filing a § 1292(b) motion because the issue is not a controlling issue of law. Another judge member stated that the interlocutory review issue does not seem like a problem specific to MDLs. There are some non-MDL mass tort cases that raise similar key legal questions that could also benefit from some expedited interlocutory review. It is very clear that appellate judges do not want to be put in a position where they are expected to give expedited review. At the same time, district judges feel that they should have a voice in how issues fit into their complicated proceedings and whether appellate review would enhance the ultimate resolution of the case.

Another member suggested that the subcommittee look at what state courts are doing in this area. Some states have what are essentially MDLs by a different name. For example, in California, certification by the trial judge is not dispositive either way with respect to appellate review.

A judge member recalled the experience with Rule 23(f). The rule is beneficial, and its costs may not be as great as they seem. For instance, in many cases, the district court proceeding will carry on while the Rule 23(f) issue is under consideration. He also suggested that a court of appeals decision whether to grant interlocutory review can itself provide helpful feedback to the parties and district court. In his view, § 1292(b) is more a tool for the district court judge than it is for a party who believes the judge may have erred on a major issue in the case. He suggested a district court, even without a veto, could have input on the effect of delay on the case or the effect of a different ruling. Regarding the Rule 23(f) model, he pointed out that not all MDL proceedings have the same characteristics. If the subcommittee focused on a specific subset of issues likely to be pivotal but often not reviewed, perhaps the Rule 23(f) model would work in this context.

Another member stated that class certification decisions are always the subject of a Rule 23(f) petition in his experience. Only one petition has been granted, and none has changed the direction of the litigation. If this avenue for interlocutory appeal is opened, it will likely be used frequently. Absent a screening mechanism, the provision will not be invoked selectively.

Judge Campbell shared several comments. He stated his support for the subcommittee's consideration of a proposal submitted by Appellate Rules Advisory Committee member, Professor Steven Sachs, as reflected in the agenda book materials. Delay is one of the biggest issues in MDL cases in his experience. The issues that are most likely to go up on appeal are those that come up shortly before trial (e.g., *Daubert* or preemption motions). If there is a two-year delay, the case must be put on hold because, otherwise, the district court is ready to move forward with bellwether trials. He acknowledged that appellate judges do not relish the notion of expediting, but the importance of the issue could factor into their decision. If the issue is very important, they may find it justified to expedite an appeal. Professor Marcus observed that appellate decision times vary considerably among the circuits.

Judge Bates thanked the Standing Committee members for their feedback which reflects many of the discussions the subcommittee has had with judges and members of the bar. The subcommittee will continue to consider whether any of these issues merit rules amendments.

Suggestion Regarding Rule 4(c)(3) and Service by the U.S. Marshals Service in In Forma Pauperis Cases. The suggestion regarding Rule 4(c)(3) is still under review. There is a potential ambiguity with respect to service by the U.S. Marshals Service in *in forma pauperis* cases. The Advisory Committee is considering a possible amendment that would resolve the ambiguity.

Suggestion Regarding Rule 12(a) (Time to Serve a Responsive Pleading). The suggestion regarding Rules 12(a)(1), (2), and (3) is under assessment. Rules 12(a)(2) and (3) govern the time for the United States, or its agencies, officers, or employees, to respond. Rules 12(a)(2) and (3) set the time at 60 days, but some statutes set the time at 30 days. There is some concern among Advisory Committee members as to whether a rule amendment is warranted.

Suggestion Regarding Rule 17(d) (Public Officer's Title and Name). The Advisory Committee continues to consider a suggestion regarding Rule 17(d). Judge Bates explained that potential advantages exist to amending Rule 17(d) to require designation by official title rather than by name.

Judge Bates noted in closing that the agenda book reflects items removed from the Advisory Committee's agenda relating to Rules 7(b)(2), 10, and 16.

REPORT OF THE ADVISORY COMMITTEE ON CRIMINAL RULES

Judge Raymond Kethledge and Professors Beale and Nancy King presented the report of the Criminal Rules Advisory Committee, which met on May 5, 2020 by videoconference. The Advisory Committee presented one action item and one information item.

Action Items

Publication of Proposed Amendment to Rule 16 (Discovery Concerning Expert Reports and Testimony). Judge Kethledge introduced the proposed amendment to Rule 16. The core of the proposal does two things. First, it requires the district court to set a deadline for disclosure of expert testimony and includes a functional standard for when that deadline must be. Second, it requires more specific disclosures, including a complete statement of all opinions. This proposal is a result of a two-year process which included, at Judge Campbell's suggestion, a miniconference. The miniconference was a watershed in the Advisory Committee's process and largely responsible for the consensus reached. Judge Kethledge explained that the DOJ has been exemplary in the process, recognizing the problems and vagueness in disclosures under the current rule. He thanked the DOJ representatives who have been involved: Jonathan Wroblewski, Andrew Goldsmith, and Elizabeth Shapiro.

There have been changes to the proposal since the last Standing Committee meeting. The draft that the Advisory Committee presented in January required both the government and the

Page 63 of 889

defense to disclose expert testimony it would present in its "case-in-chief." Following Judge Campbell's suggestion at the last meeting, the Advisory Committee considered whether the rule should refer to evidence "at trial" or in a party's "case-in-chief." The Advisory Committee concluded that "case-in-chief" was best because that phrase is used throughout Rule 16. But the Advisory Committee added language requiring the government to disclose testimony it intends to use "during its rebuttal to counter testimony that the defendant has timely disclosed under (b)(1)(C)." Additionally, the Advisory Committee made several changes to the committee note. One, suggested by Judge Campbell, clarifies that Rule 16 does not require a verbatim recitation of expert opinion. The Advisory Committee does not seek to import Civil Rule 26's much more detailed disclosure requirements into criminal practice. In response to a point previously raised by a Standing Committee member, the Advisory Committee revised the committee note to reflect that there may be instances in which the government or a party does not know the identity (but does know the opinions) of the expert whose testimony will be presented. In those situations, the note encourages that party to seek a modification of the discovery requirement under Rule 16(d) to allow a partial disclosure. Judge Kethledge explained that the Advisory Committee did not want to establish an exception in the rule language to account for these situations.

Professor Beale described other revisions to the committee note. New language was added to make clear that the government has an obligation to disclose rebuttal expert evidence that is intended to respond to expert evidence that the defense timely disclosed. The note language emphasizes that the government and defense obligations generally mirror one another. The Advisory Committee also added a parenthetical in the note clarifying that where a party has already disclosed information in an examination or test report (and accompanying documents), the party need not repeat that information in its expert disclosure so long as it identifies the information and the prior report. Finally, the committee note was restructured to follow the order of the proposed amendment.

A judge member commended the Advisory Committee on the proposal. She also raised a question regarding committee note language referring to "prompt notice" of any "modification, expansion, or contraction" of the party's expert testimony. She suggested that "contraction" might be beyond what is required by Rule 16(c), which the note language refers to. Professor King responded that the committee note includes that language because Rule 16(c) does not speak to correction or contraction but only to addition. The Advisory Committee believed it was important to address all three circumstances. Subdivision (c) is cross-referenced in the note because it provides the procedure for such modifications. Professor Beale emphasized that the key language in the note is "correction." The rule is intended to cover fundamental modifications. Professor King added that the issue of contraction came up at the miniconference. Some defense attorneys shared experiences where expert disclosures led them to prepare for multiple experts, but the government only presented one. The judge member observed that the "contraction" language could lead to a party being penalized for disclosing too much. This member recommended removing "contraction" from the note, unless something in the rule text explicitly instructs parties of their duty to take things out of their expert disclosures. Judge Kethledge suggested the word "modification," which encapsulates contraction and expansion, be substituted in the committee note language. He added that some concern was expressed regarding the supplementation requirement and the potential for parties to intentionally delay supplementation to gain an advantage. The Advisory Committee will be alert to any public comments raising this issue.

Upon motion, seconded by a member, and on a voice vote: **The Committee approved for publication the proposed amendment to Rule 16.**

Information Items

Proposals to Amend Rule 6 (The Grand Jury). The Advisory Committee received two suggestions to modify the secrecy provisions in Rule 6(e) to allow greater disclosure for grand jury materials, particularly for cases of historical interest. The two suggestions – one from Public Citizen Litigation Group and one from Reporters Committee for Freedom of the Press – are very different. Public Citizen proposes a limited rule with concrete requirements. The Reporters Committee identifies nine factors that should inform the disclosure decision.

Judge Kethledge explained that Justice Breyer previously suggested that the Rules Committees examine the issue, and a circuit split exists. A subcommittee, chaired by Judge Michael Garcia, has been formed to consider the issue. Judge Kethledge noted that the DOJ will submit its formal position on the issue to the subcommittee. One question that came up in 2012 may be relevant now: whether the district court has inherent authority to order disclosure. Judge Kethledge advised against the Advisory Committee opining on the issue, which he described as an Article III question rather than a procedural issue.

Judge Campbell agreed that it is not the Advisory Committee's role to provide advisory opinions on what a court's power is. He stated that it may be relevant, however, for a court to know whether Rule 6 was intended to set forth an exclusive list of exceptions. Judge Kethledge observed that if the Advisory Committee states its intention for the Rule to "occupy the field" or not, that in itself could constitute taking a position on the inherent-power question. In response, Judge Campbell noted that under the Rules Enabling Act, the rules have the effect of a statute and supersede existing statutes on procedural matters. It may be relevant to a court in addressing its inherent power, in an area where Congress has legislated, to ask whether Congress intended to leave room for courts to develop common law or intended to occupy the field. When Civil Rule 37(e) was adopted in 2015 to deal with spoliation, the intent was to resolve a circuit split in the case law. The committee note stated that the rule amendment intended to foreclose a court from relying on inherent power in that area. Judge Campbell emphasized that the Advisory Committee's intent will likely be a relevant consideration in the future. Professor Coquillette added that if the Advisory Committee addresses exclusivity of the grand jury secrecy exceptions, that should be stated in the rule text rather than in a committee note. A DOJ representative explained that the core of the circuit split is whether courts have inherent authority to deviate from the list of exceptions in Rule 6(e), so avoiding the inherent authority issue in addressing the rule might be impossible.

Judge Kethledge suggested that the Advisory Committee can decide whether the disclosure of historical material is lawful without opining on the existence of inherent authority. He interpreted Justice Breyer's previous statement as encouraging the Advisory Committee to state whether the rule provides for disclosure of historical material, not necessarily whether the courts have inherent authority to do so. Judge Kethledge added that this discussion provides good food for thought as the Advisory Committee considers the Rule 6 proposals.

REPORT OF THE ADVISORY COMMITTEE ON EVIDENCE RULES

Judge Livingston and Professor Capra provided the report of the Evidence Rules Advisory Committee, which last met on October 25, 2019, in Nashville, Tennessee. The Advisory Committee did not hold a spring 2020 meeting. Judge Livingston thanked everyone for the opportunity to be a part of the rulemaking process. Professor Capra thanked both Judge Livingston and Judge Campbell for their leadership and counsel over the years.

Judge Livingston noted that the proposed amendment to Rule 404(b) is now before Congress and scheduled to take effect on December 1, 2020, absent congressional action. The Advisory Committee will decide soon whether to bring to the Standing Committee for publication any proposed amendments to Rules 106, 615 or 702.

Judge Livingston indicated that the Advisory Committee continues to seek consensus on a possible amendment to Rule 106, the rule of completeness. The question is whether to propose a narrow or broad revision to Rule 106. Professor Capra added that the Advisory Committee has discussed for years how far an amendment to Rule 106 should go.

Consideration of possible amendments to Rule 615 on excluding witnesses remains ongoing. Professor Capra explained the uncertainty reflected in caselaw concerning whether Rule 615 empowers judges to go beyond simply excluding witnesses from the courtroom. Clarity would benefit all litigants. Professor Capra noted the potential application of the rule to remote trials. Extending a sequestration order beyond the confines of the courtroom raises issues concerning lawyer conduct and professional responsibility. The committee note to any proposed rule amendment would acknowledge that the rule does not address that question.

The Advisory Committee continues its consideration of possible amendments to Rule 702 concerning expert testimony. Judge Livingston noted that the DOJ asked the Advisory Committee to delay any proposed rule amendments to Rule 702 to allow the Department to demonstrate the effectiveness of its recent reforms concerning forensic feature evidence.

The Advisory Committee frequently hears the complaints that many courts treat Rule 702's requirements of sufficient basis and reliable application as questions of weight rather than admissibility, and that courts do not look for these requirements to be proved by a preponderance of the evidence under Rule 104(a). The Advisory Committee has received numerous submissions from the defense bar with citations to cases in which some courts do not apply Rule 702 admissibility standards. Judge Livingston noted that at the symposium held by the Advisory Committee in October 2019, several judges expressed concern regarding potential amendments to Rule 702.

Judge Campbell commented that the Advisory Committee's discussion of *Daubert* motions requiring consideration of the Rule 702 requisites under the Rule 104(a) preponderance-of-the-evidence standard made *Daubert* determinations easier for him. He suggested that clarification of that process – whether in rule text, committee note, or practice guide – will result in clearer *Daubert* briefing and decisions. It was suggested that Rule 702 could be amended to add a cross-reference to Rule 104(a). Judge Livingston responded that the Advisory Committee worries

whether such an amendment would carry a negative inference vis-à-vis other evidence rules (given that there are many rules with requirements that should be analyzed under Rule 104(a)). But perhaps the committee note could explain why a cross-reference to Rule 104(a) would be added in Rule 702 and not in other rules.

OTHER COMMITTEE BUSINESS

Judge Campbell reported on the five-year update to the *Strategic Plan for the Federal Judiciary*, which is presented in the agenda book as a redlined version of the *Strategic Plan* and is being revised under the leadership of Judge Carl Stewart. Suggestions for improvement are encouraged and will be passed on to Judge Stewart.

Ms. Wilson reported on several legislative developments (in addition to the CARES Act issues that had been discussed at length earlier in the meeting). Ms. Wilson directed the Committee to the legislative tracking chart in the agenda book. Ms. Wilson highlighted that the Due Process Protections Act (S. 1380) would directly amend Criminal Rule 5. Since the last meeting of the Standing Committee, the Senate passed the bill, but the House has taken no action. In anticipation of the House taking up the bill, Judges Campbell and Kethledge submitted a letter to House leadership on May 28 expressing the Rules Committees' preference that any rule amendment occur through the Rules Enabling Act process. The letter also detailed the Criminal Rules Advisory Committee's prior consideration of this issue. In 2012, when legislation on this topic was being considered, the then-Chair of the Criminal Rules Advisory Committee, Judge Reena Raggi, submitted 900 pages of materials reflecting the Criminal Rules Advisory Committee's consideration of the question of prosecutors' discovery obligations.

Ms. Wilson also reported on the Copyright Alternative in Small-Claims Enforcement (CASE) Act of 2019 (H.R. 2426), which would create an Article I tribunal for copyright claims valued at $30,000 or less. Proceedings would be streamlined, and judicial review would be strictly limited. This is similar to the Federal Arbitration Act. The legislation has been passed by the House and a companion bill (S. 1273) has been reported out of the Senate Judiciary Committee. The Office of Legislative Affairs at the Administrative Office expects some movement in the future. The Committee on Federal-State Jurisdiction (Fed-State Committee) has been tracking the CASE Act and has asked the Rules Committees to stay involved. The Fed-State Committee may ultimately recommend that the Judicial Conference adopt a formal position opposing the legislation and, with input from the Rules Committees, suggest alternatives to the creation of a separate tribunal for copyright claims.

Ms. Wilson noted that on June 25, the House Judiciary Committee's Subcommittee on Courts, Intellectual Property, and the Internet will hold a hearing titled "Federal Courts During the COVID-19 Pandemic: Best Practices, Opportunities for Innovation, and Lessons for the Future." Judge Campbell will be the federal judiciary's witness at the hearing. His testimony will include a rules portion that details the Rules Committees' work on emergency rules.

Judge Campbell pointed to the agenda book materials summarizing efforts of federal courts and the Administrative Office to deal with the pandemic. Professor Marcus noted that the report mentions an emergency management staff at the Administrative Office and asked what other types

of emergency situations that staff has focused on in the past. Ms. Womeldorf explained that past efforts have focused on weather-related events, and she will continue to monitor the work of the Administrative Office's COVID-19 Task Force to inform the future work of this Committee.

CONCLUDING REMARKS

Before adjourning the meeting, Judge Campbell thanked the Committee's members and other attendees for their preparation and contributions to the discussion. The Committee will next meet on January 5, 2021.

Respectfully submitted,

Rebecca A. Womeldorf
Secretary, Standing Committee

TAB 1E

THIS PAGE INTENTIONALLY BLANK

SUMMARY OF THE

REPORT OF THE JUDICIAL CONFERENCE

COMMITTEE ON RULES OF PRACTICE AND PROCEDURE

The Committee on Rules of Practice and Procedure recommends that the Judicial Conference:

1. Approve the proposed amendments to Appellate Rules 3 and 6, and Forms 1 and 2 as set forth in Appendix A, and transmit them to the Supreme Court for consideration with a recommendation that they be adopted by the Court and transmitted to Congress in accordance with the law..... pp. 2-4

2. Approve the proposed amendments to Bankruptcy Rules 2005, 3007, 7007.1, and 9036 as set forth in Appendix B, and transmit them to the Supreme Court for consideration with a recommendation that they be adopted by the Court and transmitted to Congress in accordance with the law..... pp. 5-8

The remainder of the report is submitted for the record and includes the following for the information of the Judicial Conference:

REPORT OF THE JUDICIAL CONFERENCE

COMMITTEE ON RULES OF PRACTICE AND PROCEDURE

TO THE CHIEF JUSTICE OF THE UNITED STATES AND MEMBERS OF THE JUDICIAL CONFERENCE OF THE UNITED STATES:

The Committee on Rules of Practice and Procedure (Standing Committee or Committee) met by videoconference on June 23, 2020, due to the Coronavirus Disease 2019 (COVID-19) pandemic. All members participated.

Representing the advisory committees were Judge Michael A. Chagares, Chair, and Professor Edward Hartnett, Reporter, Advisory Committee on Appellate Rules; Judge Dennis Dow, Chair, Professor S. Elizabeth Gibson, Reporter, and Professor Laura B. Bartell, Associate Reporter, Advisory Committee on Bankruptcy Rules; Judge John D. Bates, Chair, Professor Edward H. Cooper, Reporter, and Professor Richard Marcus, Associate Reporter, Advisory Committee on Civil Rules; Judge Raymond M. Kethledge, Chair, Professor Sara Sun Beale, Reporter, and Professor Nancy J. King, Associate Reporter, Advisory Committee on Criminal Rules; Judge Debra Ann Livingston, Chair, and Professor Daniel J. Capra, Reporter, Advisory Committee on Evidence Rules.

Also participating in the meeting were Professor Catherine T. Struve, the Standing Committee's Reporter; Professor Daniel R. Coquillette, Professor Bryan A. Garner, and Professor Joseph Kimble, consultants to the Standing Committee; Rebecca A. Womeldorf, the Standing Committee's Secretary; Bridget Healy, Scott Myers, and Julie Wilson, Rules Committee Staff Counsel; Allison Bruff, Law Clerk to the Standing Committee; and John S.

Cooke, Director, and Dr. Tim Reagan, Senior Research Associate, of the Federal Judicial Center (FJC).

Elizabeth J. Shapiro, Deputy Director, Federal Programs Branch, Civil Division, and Andrew Goldsmith, National Coordinator of Criminal Discovery Initiatives, represented the Department of Justice (DOJ) on behalf of Deputy Attorney General Jeffrey A. Rosen.

In addition to its general business, including a review of the status of pending rules amendments in different stages of the Rules Enabling Act process and pending legislation affecting the rules, the Committee received and responded to reports from the five rules advisory committees and two joint subcommittees. The Committee also discussed the Rules Committees' work on developing rules for emergencies as directed by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L. No. 116-136, 134 Stat. 281. Additionally, the Committee discussed an action item regarding judiciary strategic planning and was briefed on pending legislation that would affect the rules and the judiciary's response to the COVID-19 pandemic.

FEDERAL RULES OF APPELLATE PROCEDURE

Rules and Forms Recommended for Approval and Transmission

The Advisory Committee on Appellate Rules submitted proposed amendments to Rules 3 and 6, and Forms 1 and 2, with a recommendation that they be approved and transmitted to the Judicial Conference. The amendments were published for public comment in August 2019.

Rule 3 (Appeal as of Right—How Taken), Rule 6 (Appeal in a Bankruptcy Case), Form 1 (Notice of Appeal to a Court of Appeals From a Judgment or Order of a District Court), and Form 2 (Notice of Appeal to a Court of Appeals From a Decision of the United States Tax Court)

The proposed amendment to Rule 3 revises the requirements for a notice of appeal. Some courts of appeals, using an *expressio unius* rationale, have treated a notice of appeal from a final judgment that mentions one interlocutory order but not others as limiting the appeal to that

order, rather than reaching all of the interlocutory orders that merge into the judgment. In order to reduce the loss of appellate rights that can result from such a holding, and to provide other clarifying changes, the proposed amendment changes the language in Rule 3(c)(1)(B) to require the notice of appeal to "designate the judgment—or the appealable order—from which the appeal is taken." The proposed amendment further provides that "[t]he notice of appeal encompasses all orders that, for purposes of appeal, merge into the designated judgment or appealable order. It is not necessary to designate those orders in the notice of appeal." The proposal also accounts for situations in which a case is decided by a series of orders over time and for situations in which the notice is filed after entry of judgment but designates only an order that merged into the judgment. Finally, the proposed amendment explains how an appellant may limit the scope of a notice of appeal if it chooses to do so. The proposed amendments to Forms 1 and 2 reflect the proposed changes to Rule 3. The proposed amendment to Rule 6 is a conforming amendment.

The comments received regarding Rule 3 were split, with five comments supporting the proposal (with some suggestions for change) and two comments criticizing the proposal. No comments were filed regarding the proposed amendments to Rule 6, and the only comments regarding Forms 1 and 2 were style suggestions. Most issues raised in the comments had been considered by the Advisory Committee during its previous deliberations. The Advisory Committee added language in proposed Rule 3(c)(7) to address instances where a notice of appeal filed after entry of judgment designates only a prior order merged into the judgment and added a corresponding explanation to the committee note. The Advisory Committee also expanded the committee note to clarify two issues and made minor stylistic changes to Rule 3 and Forms 1 and 2.

The Standing Committee unanimously approved the Advisory Committee's recommendation that the proposed amendments to Rules 3 and 6, and Forms 1 and 2, be approved and transmitted to the Judicial Conference.

> **Recommendation:** That the Judicial Conference approve the proposed amendments to Appellate Rules 3 and 6, and Forms 1 and 2 as set forth in Appendix A, and transmit them to the Supreme Court for consideration with a recommendation that they be adopted by the Court and transmitted to Congress in accordance with the law.

Rule Approved for Publication and Comment

The Advisory Committee submitted a proposed amendment to Rule 25 (Filing and Service), with a request that it be published for public comment in August 2020. The Standing Committee unanimously approved the Advisory Committee's request.

The proposed amendment to Rule 25(a)(5) responds to a suggestion regarding privacy concerns for cases under the Railroad Retirement Act. The proposed amendment would extend the privacy protections afforded in Social Security benefit cases to Railroad Retirement Act benefit cases. The Advisory Committee will identify specific stakeholder groups and seek their comments on the proposed rule amendment.

Information Items

The Advisory Committee met by videoconference on April 3, 2020. Agenda items included continued consideration of potential amendments to Rules 35 (En Banc Determination) and 40 (Petition for Panel Rehearing) in an effort to harmonize the rules. The Advisory Committee decided not to pursue rulemaking to address appellate decisions based on unbriefed grounds. It tabled a suggestion to amend Rule 43 (Substitution of Parties) to require the use of titles rather than names in cases seeking relief against officers in their official capacities, pending inquiry into the practice of circuit clerks. The Advisory Committee also decided to establish two new subcommittees to consider suggestions to regularize the standards and procedures governing

Page 63 of 889

in forma pauperis status and to amend Rule 4(a)(2), the rule that addresses the filing of a notice of appeal before entry of judgment, to more broadly allow the relation forward of notices of appeal.

The Advisory Committee will reconsider a potential amendment to Rule 42 (Voluntary Dismissal) following discussion and comments at the June 23, 2020 Standing Committee meeting. The proposed amendment to Rule 42 was published in August 2019. As published, the proposed amendment would have required the circuit clerk to dismiss an appeal if the parties file a signed dismissal agreement specifying how costs are to be paid and pay any court fees that are due. (The amendment would accomplish this by replacing the word "may" in the current rule with "must.") The proposed amendment would have also added a new paragraph (a)(3) providing that a court order is required for any relief beyond the dismissal of an appeal, and a new subdivision (c) providing that Rule 42 does not alter the legal requirements governing court approval of a settlement, payment, or other consideration. At the Standing Committee meeting, a question was raised concerning the proposed amendment's effect on local circuit rules that impose additional requirements before an appeal can be dismissed. The Advisory Committee will continue to study Rule 42, with a particular focus on the question concerning local rules.

FEDERAL RULES OF BANKRUPTCY PROCEDURE

Rules Recommended for Approval and Transmission

The Advisory Committee on Bankruptcy Rules submitted proposed amendments to Rules 2005, 3007, 7007.1, and 9036. The amendments were published for public comment in August 2019.

Rule 2005 (Apprehension and Removal of Debtor to Compel Attendance for Examination)

The proposed amendment to Rule 2005(c) replaces the current reference to "the provisions and policies of title 18, U.S.C., § 3146(a) and (b)" – sections that have been repealed

– with a reference to "the relevant provisions and policies of title 18 U.S.C. § 3142" – the section that now deals with the topic of conditions of release. The only comment addressing the proposal supported it. Accordingly, the Advisory Committee unanimously approved the amendment as published.

Rule 3007 (Objections to Claims)

The proposed amendment to Rule 3007(a)(2)(A)(ii) clarifies that the special service method required by Rule 7004(h) must be used for service of objections to claims only on insured depository institutions as defined in section 3 of the Federal Deposit Insurance Act, 12 U.S.C. § 1813. The clarification addresses a possible reading of the rule that would extend such special service not just to banks, but to credit unions as well. The only relevant comment supported the proposed amendment and the Advisory Committee recommended final approval of the rule as published.

Rule 7007.1 (Corporate Ownership Statement)

The proposed amendment extends Rule 7007.1(a)'s corporate-disclosure requirement to would-be intervenors. The proposed amendment also makes conforming and stylistic changes to Rule 7007.1(b). The changes parallel the recent amendment to Appellate Rule 26.1 (effective December 1, 2019), and the proposed amendments to Bankruptcy Rule 8012 (adopted by the Supreme Court and transmitted to Congress on April 27, 2020) and Civil Rule 7.1 (published for public comment in August 2019).

The Advisory Committee made one change in response to the comments. It agreed to retain the terminology "corporate ownership statement" because "disclosure statement" is a bankruptcy term of art with a different meaning. With that change, it recommended final approval of the rule.

Rule 9036 (Notice and Service Generally)

The proposed amendment to Rule 9036 would encourage the use of electronic noticing and service in several ways. The proposed amendment recognizes a court's authority to provide notice or make service through the Bankruptcy Noticing Center ("BNC") to entities that currently receive a high volume of paper notices from the bankruptcy courts. The proposed amendment also reorganizes Rule 9036 to separate methods of electronic noticing and service available to courts from those available to parties. Under the amended rule, both courts and parties may serve or provide notice to registered users of the court's electronic-filing system by filing documents with that system. Both courts and parties also may serve and provide notice to any entity by electronic means consented to in writing by the recipient. But only courts may serve or give notice to an entity at an electronic address registered with the BNC as part of the Electronic Bankruptcy Noticing program.

The proposed amendment differs from the version previously published for comment. The published version was premised in part on proposed amendments to Rule 2002(g) and Official Form 410. As discussed below, the Advisory Committee decided not to proceed with the proposed amendments to Rule 2002(g) and Official Form 410.

The Advisory Committee received seven comments regarding the proposed amendments, mostly from court clerks or their staff. In general, the comments expressed great support for the program to encourage high-volume paper-notice recipients to register for electronic bankruptcy noticing. But commenters opposed several other aspects of the proposed amendment. The concerns fell into three categories: clerk monitoring of email bounce-backs; administrative burden of a proof-of-claim opt-in for email noticing and service; and the interplay of the proposed amendments to Rules 2002(g) and 9036.

The Advisory Committee addressed concerns about clerk monitoring of email bounce-backs by adding a sentence to Rule 9036(d): "It is the recipient's responsibility to keep its electronic address current with the clerk."

The Advisory Committee was persuaded by clerk office concerns that the administrative burden of a proof-of-claim opt-in outweighed any benefits, and therefore decided not to go forward with the earlier proposed amendments to Rule 2002(g) and Official Form 410 and removed references to that option that were in the published version of Rule 9036. This decision also eliminated the concerns raised in the comments about the interplay between the proposed amendments to Rules 2002(g) and 9036. With those changes, the Advisory Committee recommended final approval of Rule 9036.

The Standing Committee unanimously approved the Advisory Committee's recommendation that the proposed amendments to Rules 2005, 3007, 7007.1, and 9036 be approved and transmitted to the Judicial Conference

> **Recommendation:** That the Judicial Conference approve the proposed amendments to Bankruptcy Rules 2005, 3007, 7007.1, and 9036 as set forth in Appendix B, and transmit them to the Supreme Court for consideration with a recommendation that they be adopted by the Court and transmitted to Congress in accordance with the law.

Rules and Official Forms Approved for Publication and Comment

The Advisory Committee submitted proposed amendments to three categories of rules and forms with a request that they be published for public comment in August 2020. The Standing Committee unanimously approved the Advisory Committee's request.

The three categories are: (1) proposed restyled versions of Parts I and II of the Bankruptcy Rules; (2) republication of the Interim Rule and Official Form amendments previously approved to implement the Small Business Reorganization Act of 2019 (SBRA); and (3) proposed amendments to Rules 3002(c)(6), 5005, 7004, and 8023.

Restyled Rules, Parts I and II

At its fall 2018 meeting, after an extensive outreach to bankruptcy judges, clerks, lawyers and organizations, the Advisory Committee began the process of restyling the bankruptcy rules. This endeavor follows similar projects that produced comprehensive restyling of the Federal Rules of Appellate Procedure in 1998, the Federal Rules of Criminal Procedure in 2002, the Federal Rules of Civil Procedure in 2005, and the Federal Rules of Evidence in 2011. The Advisory Committee now proposes publication of restyled drafts of approximately one third of the full bankruptcy rules set consisting of the 1000 series and 2000 series of rules. The proposed restyled rules are the product of intensive and collaborative work between the style consultants who produced the initial drafts, and the reporters and the Restyling Subcommittee who provided comments to the style consultants on those drafts. In considering the subcommittee's recommendations, the Advisory Committee endorsed the following basic principles to guide the restyling project:

1. *Make No Substantive Changes*. Most of the comments the reporters and the subcommittee made on the drafts were aimed at preventing an inadvertent substantive change in meaning by the use of a different word or phrase than in the existing rule. The rules are being restyled from the version in effect at the time of publication. Future rule changes unrelated to restyling will be incorporated before the restyled rules are finalized.

2. *Respect Defined Terms*. Any word or phrase that is defined in the Code should appear in the restyled rules exactly as it appears in the Code definition without restyling, despite any possible flaws from a stylistic standpoint. Examples include the unhyphenated terms "equity security holder," "small business case," "small business debtor," "health care business," and "bankruptcy petition preparer." On the other hand, when terms are used in the Code but are not defined, they may be restyled in the rules, such as "personal financial-management course," "credit-counseling statement," and "patient-care ombudsman."

3. *Preserve Terms of Art*. When a phrase is used commonly in bankruptcy practice, the Advisory Committee recommended that it not be restyled. Such a phrase that was often used in Part I of the rules was "meeting of creditors."

4. *Remain Open to New Ideas*. The style consultants suggested some different approaches in the rules, which the Advisory Committee has embraced, including making references to specific forms by form number, and listing recipients of notices by bullet points.

5. *Defer on Matters of Pure Style*. Although the subcommittee made many suggestions to improve the drafting of the restyled rules, on matters of pure style the Advisory Committee committed to deferring to the style consultants when they have different views.

The Advisory Committee also decided not to attempt to restyle rules that were enacted by Congress. As a result, the restyled rules will designate current Rule 2002(o) (Notice of Order for Relief in Consumer Case) as 2002(n) as set forth in Section 321 of the Bankruptcy Amendments and Federal Judgeship Act of 1984, Pub. L. 98-353, 98 Stat. 357, and the Advisory Committee will not recommend restyling the wording as it was set forth in the Act. Other bankruptcy rules that were enacted by Congress in whole or in part are Rule 2002(f), 3001(g), and 7004(h).

Although the Advisory Committee requested that the Part I and II restyled rules be published for public comment in August 2020, those proposed amendments will not be sent forward for final approval until the remaining portions of the Bankruptcy Rules have been restyled. Work has already begun on a group of rules expected to be published in 2021, and the Advisory Committee anticipates that the final batch of rules will be published for comment in 2022. After all the rules have been restyled, published, and given final approval by the Standing Committee, the Rules Committees hope to present the full set of restyled Bankruptcy Rules to the Judicial Conference for approval at its fall 2023 meeting.

SBRA Rules and Forms

On August 23, 2019, the President signed into law the Small Business Reorganization Act of 2019, Pub. L. No. 116-54, which creates a new subchapter V of chapter 11 for the reorganization of small business debtors, an alternative procedure that small business debtors can elect to use. Upon recommendation of the Standing Committee, on December 16, 2019, the

Executive Committee, acting on an expedited basis on behalf of the Judicial Conference, authorized the distribution of Interim Rules of Bankruptcy Procedure 1007, 1020, 2009, 2012, 2015, 3010, 3011, 3014, 3016, 3017.1, 3017.2, 3018, and 3019 to the courts so they could be adopted locally, prior to the February 19, 2020 effective date of the SBRA, to facilitate uniformity of practice until the Bankruptcy Rules can be revised in accordance with the Rules Enabling Act. The Advisory Committee has now begun the process of promulgating national rules governing cases under subchapter V of chapter 11 by seeking publication of the amended and new rules for comment in August 2020, along with the SBRA form amendments.

The SBRA rules consist of the following:

- Rule 1007 (Lists, Schedules, Statements, and Other Documents; Time Limits),
- Rule 1020 (Small Business Chapter 11 Reorganization Case),
- Rule 2009 (Trustees for Estates When Joint Administration Ordered),
- Rule 2012 (Substitution of Trustee or Successor Trustee; Accounting),
- Rule 2015 (Duty to Keep Records, Make Reports, and Give Notice of Case or Change of Status),
- Rule 3010 (Small Dividends and Payments in Cases Under Chapter 7, Subchapter V of Chapter 11, Chapter 12, and Chapter 13),
- Rule 3011 (Unclaimed Funds in Cases Under Chapter 7, Subchapter V of Chapter 11, Chapter 12, and Chapter 13),
- Rule 3014 (Election Under § 1111(b) by Secured Creditor in Chapter 9 Municipality or Chapter 11 Reorganization Case),
- Rule 3016 (Filing of Plan and Disclosure Statement in a Chapter 9 Municipality or Chapter 11 Reorganization Case),
- Rule 3017.1 (Court Consideration of Disclosure Statement in a Small Business Case),
- new Rule 3017.2 (Fixing of Dates by the Court in Subchapter V Cases in Which There Is No Disclosure Statement),
- Rule 3018 (Acceptance or Rejection of Plan in a Chapter 9 Municipality or a Chapter 11 Reorganization Case), and
- Rule 3019 (Modification of Accepted Plan in a Chapter 9 Municipality or a Chapter 11 Reorganization Case).

The Advisory Committee recommended publishing the SBRA rules as they were recommended to the courts for use as interim rules with some minor stylistic changes to Rule 3017.2.

Unlike the SBRA interim rules, the SBRA Official Forms were issued on an expedited basis under the Advisory Committee's delegated authority to make conforming and technical amendments to official forms (subject to subsequent approval by the Standing Committee and notice to the Judicial Conference, (JCUS-MAR 16, p. 24)). Nevertheless, the Advisory Committee committed to publishing the forms for comment in August 2020, along with the SBRA rule amendments, in order to ensure that the public has an opportunity to review the rules and forms together.

The SBRA Official Forms consist of the following:

- Official Form 101 (Voluntary Petition for Individuals Filing for Bankruptcy),
- Official Form 201 (Voluntary Petition for Non-Individuals Filing for Bankruptcy),
- Official Form 309E-1 (Notice of Chapter 11 Bankruptcy Case (For Individuals or Joint Debtors)),
- Official Form 309E-2 (Notice of Chapter 11 Bankruptcy Case (For Individuals or Joint Debtors under Subchapter V)),
- Official Form 309F-1 (Notice of Chapter 11 Bankruptcy Case (For Corporations or Partnerships)),
- Official Form 309F-2 (Notice of Chapter 11 Bankruptcy Case (For Corporations or Partnerships under Subchapter V)),
- Official Form 314 (Ballot for Accepting or Rejecting Plan),
- Official Form 315 (Order Confirming Plan), and
- Official Form 425A (Plan of Reorganization for Small Business Under Chapter 11).

In addition, the Advisory Committee recommends one additional SBRA-related form amendment to Official Form 122B (Chapter 11 Statement of Your Current Monthly Income). The instructions to that form currently require that it be filed "if you are an individual and are filing for bankruptcy under Chapter 11." This statement is not accurate if the debtor is an individual filing under subchapter V of Chapter 11. The proposed amendment to the form clarifies that it is not applicable to subchapter V cases.

Rules 3002(c)(6), 5005, 7004, and 8023

Rule 3002 (Filing Proof of Claim or Interest). Under Rule 3002(c)(6)(B), an extension of time to file proofs of claim may be granted to foreign creditors if "the notice was insufficient

under the circumstances to give the creditor a reasonable time to file a proof of claim." The Advisory Committee recommended an amendment that would allow a domestic creditor to obtain an extension under the same circumstances.

Rule 5005 (Filing and Transmittal of Papers). The Advisory Committee recommended publication of an amendment to Rule 5005(b) that would allow papers to be transmitted to the U.S. trustee by electronic means and would eliminate the requirement that the filed statement evidencing transmittal be verified.

Rule 7004 (Process; Service of Summons, Complaint). The Advisory Committee recommended publication of a new subsection (i) to clarify that Rule 7004(b)(3) and Rule 7004(h) permit use of a title rather than a specific name in serving a corporation or partnership, unincorporated association or insured depository institution. Service on a corporation or partnership, unincorporated association or insured depository institution at its proper address directed to the attention of the "Chief Executive Officer," "President," "Officer for Receiving Service of Process," or "Officer" (or other similar titles) or, in the case of Rule 7004(b)(3), directed to the attention of the "Managing Agent," "General Agent," or "Agent" (or other similar titles) suffices, whether or not a name is also used or such name is correct.

Rule 8023 (Voluntary Dismissal). The proposed amendment to Rule 8023 would conform the rule to changes currently under consideration for Appellate Rule 42(b). As noted earlier in this report, the proposed amendment to Appellate Rule 42 was published for comment in August 2019, but the amendment is not yet moving forward for final approval because the Advisory Committee will study further the amendments' implications for local circuit provisions that impose additional requirements for dismissal of an appeal. The proposed amendment to Rule 8023 will be published for comment in the meantime.

Information Items

The Advisory Committee met by videoconference on April 2, 2020. In addition to its recommendations for final approval and for public comment discussed above, it recommended five official form amendments and one interim rule amendment in response to the CARES Act.

Notice of Conforming Changes to Official Forms 101, 201, 122A-1, 122B, and 122C-1

The CARES Act made several changes to the Bankruptcy Code, most of them temporary, to provide financial assistance during the COVID-19 pandemic. For the one-year period after enactment, the definition of "debtor" for subchapter V cases is changed, requiring conforming changes to Official Forms 101 and 201. For the same one-year time period, the definitions of "current monthly income" and "disposable" income are amended to exclude certain payments made under the CARES Act. These changes required conforming amendments to Official Forms 122A-1, 122B, and 122C-1. The Advisory Committee approved the necessary changes at its April 2, 2020 meeting pursuant to its authority to make conforming and technical changes to Official Forms subject to retroactive approval by the Standing Committee and notice to the Judicial Conference. The Standing Committee approved the amendments at its June 23, 2020 meeting, and notice is hereby provided to the Judicial Conference. The amended forms are included in Appendix B. These amendments have a duration of one year after the effective date of the CARES Act, at which time the former version of these forms will go back into effect.

Interim Rule 1020 (Chapter 11 Reorganization Case for Small Business Debtors or Debtors Under Subchapter V)

One of the interim rules that was adopted by courts to implement the SBRA, Interim Rule 1020, required a temporary amendment due to the new definition of a Chapter 11, subchapter V debtor that was introduced by the CARES Act.

The Advisory Committee voted unanimously at its spring meeting to approve the proposed amendment to Interim Rule 1020 for issuance as an interim rule for adoption by each

judicial district. By email vote concluding on April 11, the Standing Committee unanimously approved the Advisory Committee's recommendation, and, on April 14, the Executive Committee, acting on an expedited basis on behalf of the Judicial Conference, approved the request. Because the CARES Act definition of a subchapter V debtor will expire in 2021, the temporary amendment to Interim Rule 1020 is not incorporated into the proposed amendments to Rule 1020 that are recommended for public comment (under the Rules Enabling Act, permanent amendments to Rule 1020 to address the SBRA would not take effect before December 1, 2022).

FEDERAL RULES OF CIVIL PROCEDURE

Rules Approved for Publication and Comment

The Advisory Committee submitted a proposed amendment to Rule 12, as well as new Supplemental Rules for Social Security Actions Under 42 U.S.C. § 405(g), with a request that they be published for public comment in August 2020. The Standing Committee unanimously approved the Advisory Committee's request.

Rule 12 (Defenses and Objections: When and How Presented; Motion for Judgment on the Pleadings; Consolidating Motions; Waiving Defenses; Pretrial Hearing)

The proposed amendment to Rule 12(a)(4) extends the time to respond (after denial of a Rule 12 motion) when a United States officer or employee is sued in an individual capacity for an act or omission occurring in connection with duties performed on the United States' behalf. Under the current rule, the time to serve a responsive pleading after notice that the court has denied a Rule 12 motion or has postponed its disposition until trial is 14 days. The DOJ, which often represents federal employees or officers sued in an individual capacity, submitted a suggestion urging that the rule be amended to extend the time to respond in these types of actions to 60 days.

The Advisory Committee agreed that the current 14-day time period is too short. First, personal liability suits against federal officials are subject to immunity defenses, and a denial of a

qualified or absolute immunity defense at the Rule 12 motion-to-dismiss stage can be appealed immediately. The appeal time in such circumstances is 60 days, the same as in suits against the federal government itself. In its suggestion, the DOJ points out that, under the current rule, when a district court rejects an immunity defense, a responsive pleading must be filed before the government has determined whether to appeal the immunity decision.

The suggestion is a logical extension of the concerns that led to the adoption several years ago of Rule 12(a)(3), which sets the time to serve a responsive pleading in such individual-capacity actions at 60 days, and Appellate Rule 4(a)(1)(B)(iv), which sets the time to file an appeal in such actions at 60 days.

Supplemental Rules for Social Security Review Actions Under 42 U.S.C. § 405(g)

The proposal to append to the Civil Rules a set of supplemental rules for Social Security disability review actions under 42 U.S.C. § 405(g) is the result of three years of extensive study by the Advisory Committee.

This project was prompted by a suggestion by the Administrative Conference of the United States that the Judicial Conference "develop for the Supreme Court's consideration a uniform set of procedural rules for cases under the Social Security Act in which an individual seeks district court review of a final administrative decision of the Commissioner of Social Security pursuant to 42 U.S.C. § 405(g)." Section 405(g) provides that an individual may obtain review of a final decision of the Commissioner of Social Security "by a civil action." A nationwide study commissioned by the Administrative Conference revealed widely differing district court procedures for these actions.

A subcommittee was formed to consider the suggestion. The subcommittee's first tasks were to gather additional data and information from the various stakeholders and to determine whether the issues revealed by the Administrative Conference's study could – or should – be

corrected by rulemaking. With input from both claimant and government representatives, as well as the Advisory Committee and Standing Committee, the subcommittee developed draft rules for discussion.

Over time, the draft rules were revised and simplified. During this process, the subcommittee continued to discuss whether a better approach might be to develop model local rules or best practices. Ultimately, with feedback from the Advisory Committee, the Standing Committee, and district and magistrate judges, the subcommittee determined to press forward with developing proposed rules for publication. A continuing question that has been the focus of discussion in both the Advisory Committee and the Standing Committee is whether the benefits of the proposed supplemental rules would outweigh the costs of departing from the usual presumption against substance-specific rulemaking. The federal rules are generally trans-substantive and the Rules Committees have, with limited exceptions, avoided promulgating rules applicable to only a particular type of action.

The proposed supplemental rules – eight in total – are modest and drafted to reflect the unique character of § 405(g) actions. The proposed rules set out simplified pleadings and service, make clear that cases are presented for decision on the briefs, and establish the practice of presenting the actions as appeals to be decided on the briefs and the administrative record. While trans-substantivity concerns remain, the Advisory Committee believes the draft rules are an improvement over the current lack of uniform procedures and looks forward to receiving comments in what will likely be a robust public comment period.

Information Items

The Advisory Committee met by videoconference on April 1, 2020. In addition to the action items discussed above, the agenda included a report by the Multidistrict Litigation (MDL) Subcommittee and consideration of suggestions that specific rules be developed for MDL

proceedings. As previously reported, the subcommittee has engaged in a substantial amount of fact gathering, with valuable assistance from the Judicial Panel on Multidistrict Litigation and the FJC. Subcommittee members have also participated in numerous conferences hosted by different constituencies, most recently a virtual conference focused on interlocutory appeal issues in MDLs hosted by the Institute for Complex Litigation and Mass Claims at Emory University School of Law. It is still to be determined whether this work will result in any recommendation for amendments to the Civil Rules.

The Advisory Committee will continue to consider a potential amendment to Rule 7.1, the disclosure rule, following discussion and comments at the June 23, 2020 Standing Committee meeting. The proposed amendment to Rule 7.1(a) was published for public comment in August 2019. The proposed amendment to Rule 7.1(b) is a technical and conforming amendment and was not published for public comment. The proposed amendment to Rule 7.1(a)(1) would require the filing of a disclosure statement by a nongovernmental corporation that seeks to intervene, a change that would conform the rule to the recent amendment to Appellate Rule 26.1 (effective December 1, 2019) and the proposed amendment to Bankruptcy Rule 8012 (adopted by the Supreme Court and transmitted to Congress on April 27, 2020). The proposed amendment to Rule 7.1(a)(2) would create a new disclosure aimed at facilitating the early determination of whether diversity jurisdiction exists under 28 U.S.C. § 1332(a), or whether complete diversity is defeated by the citizenship of a nonparty individual or entity that is attributed to a party.

FEDERAL RULES OF CRIMINAL PROCEDURE

Rule Approved for Publication and Comment

The Advisory Committee on Criminal Rules submitted a proposed amendment to Criminal Rule 16 (Discovery and Inspection), with a request that it be published for public

comment in August 2020. The Standing Committee unanimously approved the Advisory Committee's request.

The proposed amendment to Rule 16, the principal rule that governs discovery in criminal cases, would expand the scope of expert discovery. The Advisory Committee developed its proposal in response to three suggestions (two from district judges) that pretrial disclosure of expert testimony in criminal cases under Rule 16 should more closely parallel Civil Rule 26.

In considering the suggestions and developing a proposed amendment, the Advisory Committee drew upon two informational sessions. First, at the Advisory Committee's fall 2018 meeting, representatives from the DOJ updated the Advisory Committee on the DOJ's development and implementation of policies governing disclosure of forensic and non-forensic evidence. Second, in May 2019, the Rule 16 Subcommittee convened a miniconference to explore the issue with stakeholders. Participants included defense attorneys, prosecutors, and DOJ representatives who have extensive personal experience with pretrial disclosures and the use of experts in criminal cases. At the miniconference, defense attorneys identified two problems with the current rule: (1) the lack of a timing requirement; and (2) the lack of detail in the disclosures provided by prosecutors.

Over the next year, the subcommittee worked on drafting a proposed amendment. Drafts were discussed at Advisory Committee meetings and at the Standing Committee's January 2020 meeting. The proposed amendment approved for publication addresses the two shortcomings in the current rule identified at the miniconference – the lack of timing and the lack of specificity – while maintaining the reciprocal structure of the current rule. It is intended to facilitate trial preparation by allowing the parties a fair opportunity to prepare to cross-examine expert witnesses who testify at trial and to secure opposing expert testimony if needed.

Information Item

The Advisory Committee met by videoconference on May 5, 2020. In addition to finalizing for publication the proposed amendment to Rule 16, the Advisory Committee formed a subcommittee to consider suggestions to amend the grand jury secrecy provisions in Rule 6 (The Grand Jury), an issue last on the Advisory Committee's agenda in 2012.

The Advisory Committee has received two suggestions that the secrecy provisions in Rule 6(e) be amended to allow for disclosure of grand jury materials under limited circumstances. A group of historians and archivists seeks, in part, an amendment adding records of "historical importance" to the list of exceptions to the secrecy provisions. Another group comprised of media organizations urges that Rule 6 be amended "to make clear that district courts may exercise their inherent supervisory authority, in appropriate circumstances, to permit the disclosure of grand jury materials to the public." In addition to these two suggestions, in a statement respecting the denial of certiorari in *McKeever v. Barr*, 140 S. Ct. 597 (2020), Justice Breyer pointed out a conflict among the circuit courts regarding whether the district court retains inherent authority to release grand jury materials in "appropriate cases" outside of the exceptions enumerated in Rule 6(e). *Id.* at 598 (statement of Breyer, J.). He stated that "[w]hether district courts retain authority to release grand jury material outside those situations specifically enumerated in the Rules, or in situations like this, is an important question. It is one I think the Rules Committee both can and should revisit." *Id.*

FEDERAL RULES OF EVIDENCE

Information Items

The Advisory Committee did not hold a spring 2020 meeting, but is continuing its consideration of several issues, including: various alternatives for an amendment to Rule 106 (the rule of completeness); Rule 615 and the problems raised in case law and in practice

regarding the scope of a Rule 615 order; and forensic expert evidence, *Daubert*, and possible amendments to Rule 702. The DOJ has asked that the Rules Committees hold off on amending Rule 702 in order to allow time for the DOJ's new policies regarding forensic expert evidence to take effect. The Advisory Committee will discuss this request along with other issues related to Rule 702 at its upcoming meetings.

OTHER ITEMS

An additional action item before the Committee was a request by the Judiciary Planning Coordinator that the Committee review a draft update to the *Strategic Plan for the Federal Judiciary* for the years 2020-2025. The Committee did so and had no changes to suggest.

The Committee was also updated on the work of two joint subcommittees: the E-filing Deadline Joint Subcommittee, formed to consider a suggestion that the electronic filing deadlines in the federal rules be changed from midnight to an earlier time of day, such as when the clerk's office closes in the court's respective time zone; and the Appeal Finality After Consolidation Joint Civil-Appellate Subcommittee, which is considering whether the Appellate and Civil Rules should be amended to address the effect (on the final-judgment rule) of consolidating separate cases. Both subcommittees have asked the FJC to gather empirical data to assist in determining the need for rules amendments.

Finally, the Committee discussed the CARES Act, including its impact on criminal proceedings and its directive to consider the need for court rules to address future emergencies. On March 29, 2020, on the joint recommendation of the chairs of this Committee and the Committee on Court Administration and Case Management, the Judicial Conference found that emergency conditions due to the national emergency declared by the President under the National Emergencies Act, 50 U.S.C. §§ 1601-1651, with respect to the COVID-19 pandemic will materially affect the functioning of the federal courts. Under § 15002(b) of the CARES Act,

this finding allows courts, under certain circumstances, to temporarily authorize the use of video or telephone conferencing for certain criminal proceedings.

Section 15002(b)(6) of the CARES Act directs the Judicial Conference to develop measures for the courts to address future emergencies. In response to that directive, the Committee heard reports on the subcommittees formed by each advisory committee to consider possible rules amendments that would provide for procedures during future emergencies. As a starting point, the advisory committees solicited public comments on challenges encountered during the COVID-19 pandemic in state and federal courts from lawyers, judges, parties, or the public, and on solutions developed to deal with those challenges. The committees were particularly interested in hearing about situations that could not be addressed through the existing rules or in which the rules themselves interfered with practical solutions. Over 60 substantive comments were received. The Standing Committee asked each advisory committee to identify rules that should be amended to account for emergency situations and to develop discussion drafts of proposed amendments at the committees' fall meetings for consideration by the Standing Committee at its January 2021 meeting.

Respectfully submitted,

(b)(6) per EOUSA

David G. Campbell, Chair

Jesse M. Furman	Carolyn B. Kuhl
Daniel C. Girard	Patricia A. Millett
Robert J. Giuffra Jr.	Gene E.K. Pratter
Frank M. Hull	Jeffrey A. Rosen
William J. Kayatta Jr.	Kosta Stojilkovic
Peter D. Keisler	Jennifer G. Zipps

TAB 1F

THIS PAGE INTENTIONALLY BLANK

Name	Sponsor/ Co-Sponsor(s)	Affected Rule	Text, Summary, and Committee Report	Actions
Protect the Gig Economy Act of 2019	**H.R. 76** *Sponsor:* Biggs (R-AZ)	CV 23	**Bill Text:** https://www.congress.gov/116/bills/hr76/BILLS-116hr76ih.pdf **Summary (authored by CRS):** This bill amends Rule 23 of the Federal Rules of Civil Procedure to expand the preliminary requirements for class certification in a class action lawsuit to include a new requirement that the claim does not allege misclassification of employees as independent contractors. **Report:** None.	• 1/3/19: introduced in the House; referred to Judiciary Committee; Judiciary Committee referred to its Subcommittee on the Constitution, Civil Rights, and Civil Justice
Injunctive Authority Clarification Act of 2019	**H.R. 77** *Sponsor:* Biggs (R-AZ) *Co-Sponsors:* Meadows (R-NC) Rose (R-TN) Roy (R-TX) Wright (R-TX)	CV	**Bill Text:** https://www.congress.gov/116/bills/hr77/BILLS-116hr77ih.pdf **Summary (authored by CRS):** This bill prohibits federal courts from issuing injunctive orders that bar enforcement of a federal law or policy against a nonparty, unless the nonparty is represented by a party in a class action lawsuit. **Report:** None.	• 1/3/19: introduced in the House; referred to Judiciary Committee; Judiciary Committee referred to its Subcommittee on Crime, Terrorism, and Homeland Security • 2/25/20: hearing held by Senate Judiciary Committee on same issue ("Rule by District Judge: The Challenges of Universal Injunctions")
Litigation Funding Transparency Act of 2019	**S. 471** *Sponsor:* Grassley (R-IA) *Co-Sponsors:* Cornyn (R-TX) Sasse (R-NE) Tillis (R-NC)	CV 23	**Bill Text:** https://www.congress.gov/116/bills/s471/BILLS-116s471is.pdf **Summary:** Requires disclosure and oversight of TPLF agreements in MDL's and in "any class action." **Report:** None.	• 2/13/19: introduced in the Senate; referred to Judiciary Committee

Due Process Protections Act	**S. 1380** *Sponsor:* Sullivan (R-AK) *Co-Sponsors:* Booker (D-NJ) Cornyn (R-TX) Durbin (D-IL) Lee (R-UT) Paul (R-KY) Whitehouse (D-RI)	CR 5	**Bill Text:** https://www.congress.gov/116/bills/s1380/BILLS-116s1380es.pdf **Summary:** This bill would amend Criminal Rule 5 (Initial Appearance) by: 1. redesignating subsection (f) as subsection (g); and 2. inserting after subsection (e) the following: "(f) Reminder Of Prosecutorial Obligation. -- (1) IN GENERAL. -- In all criminal proceedings, on the first scheduled court date when both prosecutor and defense counsel are present, the judge shall issue an oral and written order to prosecution and defense counsel that confirms the disclosure obligation of the prosecutor under Brady v. Maryland, 373 U.S. 83 (1963) and its progeny, and the possible consequences of violating such order under applicable law. (2) FORMATION OF ORDER. -- Each judicial council in which a district court is located shall promulgate a model order for the purpose of paragraph (1) that the court may use as it determines is appropriate." **Report:** None.	• 5/8/19: introduced in the Senate; referred to Judiciary Committee • 5/20/20: reported out of Judiciary Committee and passed Senate without amendment by unanimous consent • 5/22/20: received in the House • 5/28/20: letter from Rules Committee Chairs sent to Judiciary Committee Chairman and Ranking Member • 9/21/20: passed House without amendment by voice vote
Assessing Monetary Influence in the Courts of the United States Act (AMICUS Act)	**S. 1411** *Sponsor:* Whitehouse (D-RI) *Co-Sponsors:* Blumenthal (D-CT) Hirono (D-HI)	AP 29	**Bill Text:** https://www.congress.gov/116/bills/s1411/BILLS-116s1411is.pdf **Summary:** In part, the legislation would require certain amicus curiae to disclose whether counsel for a party authored the brief in whole or in part and whether a party or a party's counsel made a monetary contribution intended to fund the preparation or submission of the brief. **Report:** None.	• 5/9/19: introduced in the Senate; referred to Judiciary Committee

	H.R. 3993 *Sponsor:* Johnson (D-GA) *Co-Sponsors:* Cohen (D-TN) Lieu (D-CA)	AP 29	Identical to Senate bill (see above)	• 7/25/19: introduced in the House; referred to Judiciary Committee • 8/28/19: Judiciary Committee referred to its Subcommittee on Courts, Intellectual Property, and the Internet
Back the Blue Act of 2019	**S. 1480** *Sponsor:* Cornyn (R-TX) *Co-Sponsors:* Barrasso (R-WY) Blackburn (R-TN) Blunt (R-MO) Boozman (R-AR) Capito (R-WV) Cassidy (R-LA) Cruz (R-TX) Daines (R-MT) Fischer (R-NE) Hyde-Smith (R-MS) Isakson (R-GA) Perdue (R-GA) Portman (R-OH) Roberts (R-KS) Rubio (R-FL) Tillis (R-NC)	§ 2254 Rule 11	**Bill Text:** https://www.congress.gov/116/bills/s1480/BILLS-116s1480is.pdf **Summary:** Section 4 of the bill is titled "Limitation on Federal Habeas Relief for Murders of Law Enforcement Officers." It adds to § 2254 a new subdivision (j) that would apply to habeas petitions filed by a person in custody for a crime that involved the killing of a public safety officer or judge. Section 4 also amends Rule 11 of the Rules Governing Section 2254 Cases in the United States District Courts -- the rule governing certificates of appealability and time to appeal -- by adding the following language to the end of that Rule: "Rule 60(b)(6) of the Federal Rules of Civil Procedure shall not apply to a proceeding under these rules in a case that is described in section 2254(j) of title 28, United States Code." **Report:** None.	• 5/15/19: introduced in the Senate; referred to Judiciary Committee
	H.R. 5395 *Sponsor:* Bacon (R-NE) *Co-Sponsors:* Cook (R-CA) Graves (R-LA) Johnson (R-OH) Stivers (R-OH)		Identical to Senate bill (see above).	• 12/11/19: introduced in House; referred to Judiciary Committee • 1/30/20: Judiciary Committee referred to its Subcommittee on Crime, Terrorism, and Homeland Security

Justice in Forensic Algorithms Act of 2019	**H.R. 4368** *Sponsor:* Takano (D-CA) *Co-Sponsors:* Evans (D-PA) Johnson (D-GA)		**Bill Text:** https://www.congress.gov/116/bills/hr4368/BILLS-116hr4368ih.pdf **Summary:** The stated purpose of the bill is, in part, "[t]o prohibit the use of trade secrets privileges to prevent defense access to evidence in criminal proceedings . . . ." The bill amends the Evidence Rules by adding two new rules and amends Criminal Rule 16(a)(1) by adding a new paragraph (H): • Evidence Rule 107. Inadmissibility of Certain Evidence that is the Result of Analysis by Computational Forensic Software. In any criminal case, evidence that is the result of analysis by computational forensic software is admissible only if— (1) the computational forensic software used has been submitted to the Computational Forensic Algorithm Testing Program of the Director of the National Institute of Standards and Technology and there have been no material changes to that software since it was last tested; and (2) the developers and users of the computational forensic software agree to waive any and all legal claims against the defense or any member of its team for the purposes of the defense analyzing or testing the computational forensic software. • Evidence Rule 503. Protection of Trade Secrets in a Criminal Proceeding. In any criminal case, trade secrets protections do not apply when defendants would otherwise be entitled to obtain evidence. • Criminal Rule 16(a)(1)(H). Use of Computational Forensic Software. Any results or reports resulting from analysis by computational forensic software shall be provided to the defendant, and the defendant shall be accorded access to an executable copy of the version of the computational forensic software, as well as earlier versions of the software,	• 9/17/19: introduced in the House; referred to Judiciary Committee and the Committee on Science, Space, and Technology • 10/2/19: Judiciary Committee referred to its Subcommittee on Courts, Intellectual Property, and the Internet

			necessary instructions for use and interpretation of the results, and relevant files and data, used for analysis in the case and suitable for testing purposes. Such a report on the results shall include— (i) the name of the company that developed the software; (ii) the name of the lab where test was run; (iii) the version of the software that was used; (iv) the dates of the most recent changes to the software and record of changes made, including any bugs found in the software and what was done to address those bugs; (v) documentation of procedures followed based on procedures outlined in internal validation; (vi) documentation of conditions under which software was used relative to the conditions under which software was tested; and (vii) any other information specified by the Director of the National Institute of Standards and Technology in the Computational Forensic Algorithm Standards. **Report:** None.	

CARES Act	**H.R. 748**	CR (multiple)	**Bill Text (as enrolled):** https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf **Summary:** Section 15002 applies to the federal judiciary. Subsection (b)(1)(5) authorizes videoconferencing for criminal proceedings if determined that emergency conditions due to COVID-19 will materially affect court. Proceedings include detention hearings, initial appearances, preliminary hearings, waivers of indictments, arraignments, revocation proceedings, felony pleas and sentencings. Subsection (b)(6) directs the Judicial Conference and the Supreme Court to consider rules amendments that address emergency measures courts can take when an emergency is declared under the National Emergencies Act. **Report:** None.	• 3/27/20: became Public Law No. 116-136 • Spring 2020: Advisory Committees form subcommittees to study rules amendments to address emergency situations
Abuse of the Pardon Prevention Act	**H.R. 7694** *Sponsor:* Schiff (D-CA) *Co-Sponsor:* Nadler (D-NY)	CR 6	**Bill text:** https://www.congress.gov/116/bills/hr7694/BILLS-116hr7694ih.pdf **Summary:** Under Section 2, subsection (a), when the President grants an individual a pardon for a covered offense, within 30 days the Attorney General must provide Congress with "all materials obtained or prepared by the prosecution team, including the Attorney General and any United States Attorney, and all materials obtained or prepared by any investigative agency of the United States government, relating to the offense for which the individual was so pardoned." Subsection (b) states that "Rule 6(e) [which addresses recording and disclosing of grand jury proceedings] of the Federal Rules of Criminal Procedure may not be construed to prohibit the disclosure of information required by subsection (a) of this section." **Report:** None. **Related Bills:** H.R. 1627 (introduced 4/12/19) and S. 2090 (introduced 7/11/19)	• 7/21/20: introduced in House; referred to Judiciary Committee • 7/23/20: mark-up session held; reported out of Judiciary Committee

TAB 2

TAB 2A

FORDHAM

University School of Law

Lincoln Center, 150 West 62nd Street, New York, NY 10023-7485

Daniel J. Capra
Philip Reed Professor of Law

Phone: (b)(6) per EOUSA
e-mail: (b)(6) per EOUSA

Memorandum To: Advisory Committee on Evidence Rules
From: Daniel J. Capra and Liesa A. Richter
Re: Possible Amendment to Rule 702
Date: October 1, 2020

The Advisory Committee has been considering possible amendments to Rule 702 for the last six meetings. A subcommittee, chaired by Judge Schroeder, assisted the Committee in narrowing the issues. By the time of the last meeting, the Committee's focus had narrowed to two possible changes:

1. An amendment that would prevent an expert from overstating the results that could be reliably obtained from the method used by the expert --- or to put it another way, possibly, the limitation would be that the expert would not be allowed to express an opinion with a "degree of confidence" that is not supported by the foundation for the expert's testimony.

2. An amendment clarifying that the questions of sufficiency of facts or data and reliable application of method are questions for the court, and must be proved to the court by a preponderance of the evidence under Rule 104(a).

This memorandum further develops the matters that the Committee wished to continue discussing, and addresses some of the questions raised at the last few meetings. It is divided into three parts. Part One is a discussion of the overstatement problem and whether an amendment might be useful. Part Two is a discussion of the admissibility/weight problem. Part Three sets forth drafting alternatives, and a draft Committee Note.

In addition, an extensive digest on recent case law on forensic evidence is set forth in the agenda book immediately after this memo. (It was previously part of the memo but it got so lengthy that I thought it would be better now as a freestanding document).

Finally, the agenda book under this tab reproduces: 1) Judge Schroeder's recent article in the Notre Dame Law Review on the Rule 104(a)/104(b) questions; and 2) a number of reports from the defense bar advocating the adoption of an amendment that would specify that the reliability requirements of Rule 702 be established by a preponderance of the evidence.

Is should be emphasized that none of the proposals discussed in this memo are to be voted on at this meeting. The vote on the Rule 702 proposal will take place at the Spring 2021 meeting.

I. The Problem of Overstatement

A. Overstatement of Results in Forensics

Many speakers at the Boston College Symposium in 2017 argued that one of the major problems with forensic experts is that they overstate their conclusions --- examples include testimony of a "zero error rate" or a "practical impossibility" that a bullet could have been fired from a different gun; or that the witness is a "scientist" when the forensic method is not scientific. Expert overstatement was a significant focus of the PCAST report. And a report from the National Commission on Forensic Sciences addresses overstatement, with its proposal that courts should forbid scientific experts from stating their conclusion to a "reasonable degree of [field of expertise] certainty," because that term is an overstatement, has no scientific meaning and serves only to confuse the jury.

Notably, the DOJ has issued a prohibition on use of the "reasonable degree of certainty" language by forensic experts, as well as important limitations on testimony regarding rates of error (as discussed below).

Both the National Academy of Science and PCAST reports emphasize that forensic experts have overstated results and that the courts have done little to prevent this practice --- the courts are often relying on precedent rather than undertaking an inquiry into whether an expert's opinion overstates the results of the forensic test.

The forensic case law digest sets forth many cases in which experts sought to testify to a conclusion that was not supported by the results that could be reliably reached by the forensic method. As the digest notes, there are a few cases in which courts have limited overstatement --- particularly with respect to ballistics testimony. But by and large the courts have allowed forensic experts to testify, essentially, to a match --- such as that the bullet fragment came from the defendant's gun, or that the latent fingerprint is that of the defendant. Some "protective" courts prohibit such a definitive conclusion, but nonetheless allow the expert to testify to a reasonable degree of certainty, or to a "practical impossibility" that it is anyone other than the defendant that is the source of the evidence.

Judge Rakoff, at the Boston Symposium, suggested that a provision prohibiting an expert from overstating results should be added to Rule 702 --- and that this would be a meaningful change because the courts generally have not relied on any language in the existing rule to control the problem of overstatement. The participants at the Vanderbilt symposium were not of one mind

as to the need for a specific limitation on overstatement. But the discussion essentially concluded that: 1) a limit on overstatement can already be teased out of the existing language of the rule (i.e., reliable method reliably applied); and 2) it could nonetheless be helpful to the courts to add a specific limitation on overstatement, as it could be directly relied upon.

It goes without saying that most of the problems of forensic overstatement occur at the state level --- and especially this may be so going forward, given the DOJ's attempts at quality control at the federal level. But the case law digest on federal cases, set forth in the agenda book after this memo, supports the notion that overstatement of forensic results is a *federal* problem as well, and remains a problem even in the recent cases.

And, as discussed below, there is an argument that problems remain with forensic "identification" testimony even under the DOJ protocols. Thus, it would seem that there is some reason to seek to control overstatement, especially in forensic evidence cases. The question for the Committee is whether this "control" should come from a rule amendment or rather should be left to DOJ protocols, cross-examination, and judicial education.

B. Can Overstatement by Forensic Experts be Controlled Without an Amendment?

Assuming that overstatement by forensic experts is a problem --- a pretty good assumption looking at the case law digest --- are there other sources of regulation that might make an amendment unnecessary?

Five possible sources might exist: 1) Court regulation under existing law; 2) Education efforts; 3) DOJ efforts to regulate forensic experts; 4) Cross-examination; and 5) Providing for more robust discovery of expert opinions. These are discussed in turn.

1. Court Regulation: The case digest demonstrates that some courts are making efforts to control overstatement. But it is only a handful that are really doing so. Many courts *think* they are doing so by prohibiting experts from testifying to a zero error rate. But those courts as an alternative are allowing experts to testify to a reasonable degree of scientific or professional certainty, which is a meaningless and yet misleading standard. Given that most courts rely on precedent in this area, and that the *best* precedent is to allow testimony to a reasonable degree of scientific or professional certainty, there seems to be little hope for meaningful regulation by the courts any time soon.

2. Education: It might be thought that the NAS report, the PCAST report, and other sources would lead to more regulation of overstatement of forensic experts. But the case digest indicates that these reports have made very little practical impact on the courts. The National Commission

on Forensic Science report attacking the "reasonable degree of certainty" standard was issued several years ago[1] and has been widely distributed, but courts are still happily using that "reasonable degree" standard as if it has solved the problem of overstatement. Judicial training through FJC may well be useful, but will it be as impactful as a rule amendment? Given the fact that courts rely heavily on precedent in evaluating forensic testimony, it would seem that for a *court* to act, a change of law is, at the least, an important means of effectuating change in accompaniment with judicial education.

Another possibility is to educate *defense counsel* about the reliability and overstatement concerns addressed in the NSF and PCAST report. It appears to be the case that defense counsel often do not even cross-examine forensic experts, and the ones that do are not often using the PCAST and NSF reports to do so. (There are exceptions to this statement, as shown in a few cases included in the forensic case digest.) Perhaps a report on what the Advisory Committee has found concerning forensic evidence, sent to defense counsel organizations, might be helpful.

But the thing is, even if defense counsel do raise issues, there are plenty of indications that they are not being credited by the courts. So, while education along these lines might be helpful, it seems to remain the case that it should probably serve as supplement to, as opposed to a substitution for, a rule amendment.[2]

3. DOJ: The Department has been making extensive efforts to control some of the problems that have been evident in the testimony of forensic experts. Apropos of overstatement, a DOJ directive instructs Department analysts working in federal laboratories --- and United States attorneys --- to refrain from using the phrase "reasonable degree of scientific certainty" when testifying, and to disclose other limitations on their results. There are a number of directives, each targeted toward a specific forensic discipline, but they all provide regulation on overstatement of results. An example is the directive regarding toolmark testimony, in pertinent part as follows:

> ● An examiner shall not assert that two or more fractured items were once part of the same object unless they physically fit together or when a microscopic comparison of the surfaces of the fractured items reveals a fit.
>
> ● When offering a fracture match conclusion, an examiner shall not assert that two or more fractured items originated from the same source to the exclusion of all other sources. This may wrongly imply that a fracture match conclusion is based upon

[1] See https://www.justice.gov/ncfs/file/795146/download (concluding that "the term 'reasonable degree of scientific [or discipline] certainty' has no place in the judicial process").

[2] Beyond education on forensic issues: At the Vanderbilt Conference, participants discussed the possibility of the Committee encouraging or taking part in efforts to educate courts and litigants more broadly on *Daubert* questions. Suggestions included developing a list of "red flags" for courts to consider in evaluating expert testimony. The Committee may wish to discuss such possibilities at the meeting. There was no indication in the Vanderbilt discussion that any of these broader educational efforts would be tied to rulemaking.

statistically-derived or verified measurement or an actual comparison to all other fractured items in the world, rather than an examiner's expert opinion.

● An examiner shall not assert that examinations conducted in the forensic firearms/toolmarks discipline are infallible or have a zero error rate.

● An examiner shall not provide a conclusion that includes a statistic or numerical degree of probability except when based on relevant and appropriate data.

● An examiner shall not cite the number of examinations conducted in the forensic firearms/toolmarks discipline performed in his or her career as a direct measure for the accuracy of a proffered conclusion. An examiner may cite the number of examinations conducted in the forensic firearms/toolmarks discipline performed in his or her career for the purpose of establishing, defending, or describing his or her qualifications or experience.

● An examiner shall not use the expressions "reasonable degree of scientific certainty," "reasonable scientific certainty," or similar assertions of reasonable certainty in either reports or testimony, unless required to do so by a judge or applicable law.

These standards addressed directly to overstatement obviously represent an important advance and they are an excellent development. ***But despite these efforts there remains an argument that an amendment limiting overstatement will be useful and even necessary.*** This is so for a number of reasons:

● There are questions of implementation of the DOJ protocols, as the edict has been in effect since 2016 and experts are still overstating their conclusions, according to the case digest. For example, a case from 2018, discussed in the case digest, indicates that a ballistics expert was prepared to testify that it was a "practical impossibility" for the bullet to be fired from a different gun. And ProPublica has done a study which raises questions about whether the DOJ standards are working. The ProPublica report concludes as follows:

> The bureau's lab technicians and scientists had long testified in court that they could determine what fingertip left a print and which scalp grew a hair "to the exclusion of all others." Research and exonerations by DNA analysis have repeatedly disproved those claims, and the U.S. Department of Justice no longer permits its forensic scientists to make such unequivocal statements.
>
> ProPublica found that examiners on the Forensic Audio, Video and Image Analysis Unit, based at the FBI Lab in Quantico, Virginia, continue to use similarly flawed methods and to testify to the precision of these methods, according to a review of court records and examiners' written reports and published articles. At ProPublica's request, several statisticians and forensic science experts reviewed the unit's methods. The experts

identified numerous instances of examiners overstating their techniques' precision and said some of their assertions defied logic.[3]

● There are significant questions about the impact of the DOJ standards on witnesses from state labs, or from state law enforcement agencies. In one case in the digest, *United States v. Shipp,* it was an NYPD detective who was prepared to testify to a ballistics match. And at the Vanderbilt symposium, Judge Sargus noted a recent case of his in which the expert, from ICE, testified to a zero rate of error for fingerprint identification.

This is not at all to understate the DOJ efforts. It is just to say that there may be room for court regulation to supplement these efforts.

● Even if the "reasonable degree" language is eradicated --- and it may not be because judges may require it --- there remains debate about what an expert *can* testify to as an alternative.[4] One can argue that courts should be controlling such an important debate, the outcome of which can literally be the difference between freedom and a prison sentence.

● Leaving protections up to the DOJ means that any failure in compliance is not actionable—even though the result might be an unjust conviction, or a guilty plea that would not otherwise have been entered.

● Adding something to Rule 702 that the Department is assertedly already doing should not be burdensome on the Department. Indeed there is precedent for such an approach --- the proposed amendments to the notice provisions of Rule 404(b), according to the Department, impose no obligations on U.S. attorneys that they are not already doing. Yet the Committee unanimously determined that there is definite value to the system in codifying obligations in the Evidence Rules, rather than leaving them to internal DOG guidelines.

[3] https://www.propublica.org/article/a-key-fbi-photo-analysis-method-has-serious-flaws-study-says

The ProPublica report also notes that it is not just those feature-comparison analyses addressed in PCAST that are problematic. The report also discusses research done by experts at UC Berkeley challenging the reliability of testimony that jeans worn by the defendant match the jeans in a photo or video. The premise of the testimony is that jeans have unique wear marks around their seams. Government experts have testified to a match in bank robbery cases. But the reviewing experts conclude that the premise of uniqueness in wear marks is without foundation. They found a significant risk of false positives.

[4] The National Commission on Forensic Science has this to say about alternatives to the "reasonable degree of certainty language:

> Additional work is needed in both the scientific and legal communities to identify appropriate language that may be used by experts to express conclusions and opinions to the trier of fact based on observations of evidence and data derived from evidence. Rather than use "reasonable…certainty" terminology, experts should make a statement about the examination itself, including an expression of the uncertainty in the measurement or in the data. The expert should state the bases for that opinion (e.g., the underlying information, studies, observations) and the limitations relating to the results of the examination.

● The Department's reforms, as salutary as they are, would not affect overstatement by experts called by any litigants other than the government in a criminal case (including experts for the criminal defense).

● There is no guarantee that the Department's protocols will remain in place --- administrations change, objectives change, and nobody has a right to enforce an existing DOJ protection. With an amendment to Rule 702, there is a pretty strong guarantee that limitations on overstatement will remain in place.

● It is possible that a court will permit testimony contravening the DOJ guidelines. This has actually happened. In *United States v. Hunt,* 2020 WL 2842844 (W.D.Okla), the defendant asked the court "to place limitations on the Government's firearm toolmark experts because the jury will be unduly swayed by the experts if not made aware of the limitations on their methodology." The Government responded that "no limitation is necessary because Department of Justice guidance sufficiently limits a firearm examiner's testimony." The court recognized and quoted those limitations --- including the prohibition of testimony to a reasonable degree of certainty. But nonetheless it concluded as follows:

> [T]he Court will permit the Government's experts to testify that their conclusions were reached to a reasonable degree of ballistic certainty, a reasonable degree of certainty in the field of firearm toolmark identification, or any other version of that standard.

Thus, the court in *Hunt* allowed the expert to testify to a reasonable degree of certainty even though it is not permitted under the DOJ guidelines. The DOJ guidelines have an exception for when the expert *is required* to so testify. But that exception should not apply here --- the court permitted the expert to testify to a reasonable degree of certainty, but certainly did not require it.

I have not been able to determine whether the expert in *Hunt* actually testified in violation of the DOJ guidelines. There is some indication that the DOJ is taking such judicial authorization as an *order* to testify in violation of the guidelines. But in any case, the fact that the court permitted such testimony in violation of the guidelines surely raises some question about their efficacy in controlling overstatement.

● Finally and most importantly, there are legitimate questions, previously discussed by the Committee, on whether the testimony that is permitted by the DOJ guidelines remains an overstatement, given the fact that the forensic inquiry is rife with subjective determinations. The guidelines allow an expert to testify that a comparison of two or more specific patterns indicate that they *originated from the same source.* As stated in previous memos, the DOJ Uniform Language for Testimony and Reports ***attempts to walk a fine line between allowing the forensic***

expert to testify to identity of the source of a crime scene sample and disavowing any certainty that this is in fact the case.[5]

The DOJ explanation is as follows: While the forensic examiner is allowed to conclude that the fingerprints or toolmarks originated from the same source, this conclusion is then subject to qualifications that such a conclusion should not be interpreted as indicating that the examiner *has in fact* identified the source of the crime scene pattern. According to the Uniform Language, a "source identification" of, say, a toolmark means only that the examiner has seen sufficient pattern agreement to "provide extremely strong support for the proposition that the two toolmarks came from the same source and extremely weak support for the proposition that the two toolmarks came from different sources." While this sounds as though the strength of the evidence is based on a statistical assessment, the Uniform Language makes clear that this is *merely the examiner's opinion*, and has no statistical foundation.

But how is a jury to make sense of this fine distinction? Why would a jury not think that when the expert is providing a source identification, she is saying that "there is a match"? Is it not completely confusing to say, "I am making a source identification, but not to the exclusion of all other sources?" As the PCAST report concluded:

> Without appropriate estimates of accuracy, an examiner's statement that two samples are similar—or even indistinguishable—is scientifically meaningless: it has no probative value, and considerable potential for prejudicial impact. Nothing—not training, personal experience nor professional practices—can substitute for adequate empirical demonstration of accuracy

The American Association for the Advancement of Science has expressed its concern about the DOJ standards on testimony about "identifying" a fingerprint:

> There is no scientific basis for estimating the number of individuals who might have a particular pattern of features; therefore, there is no scientific basis on which an examiner

[5] Reporter's Note: This fine line (or fuzzy line) was evident in the explanations provided by the DOJ at the Denver Miniconference: See 87 Fordham L.Rev. at 1370-71 (explaining that a statement of identification is permissible because "it is not an empirical claim on the external world. . . The claim is simply based on identification, and identification is different than individualization and uniqueness.").

Moreover, at previous Committee meetings, some of the Committee's discussion indicated confusion and concern about the DOJ's line between "identification" and "match". For example, the Minutes of the Spring 2019 meeting provide the following account:

> Judge Campbell queried how an examiner logically could state that a mark came from a particular defendant without saying it *didn't* come from another person.
>
> Another Committee member expressed similar confusion about the DOJ characterization of "source identification." While this Committee member understood the expert's inability to claim infallibility, he expressed confusion about how the DOJ testimony allowed for a "source identification" without "individualizing" the opinion. He emphasized the logical inability to identify one source *without excluding other sources*.

> might form an expectation of whether an arrangement comes from the same source. The [DOJ Uniform Standard] fails to acknowledge the uncertainty that exists regarding the rarity of particular fingerprint patterns. Any such expectations that an examiner asserts necessarily rest on speculation, rather than scientific evidence.
>
> *As there is no empirical basis for examiners to estimate the frequency of any particular pattern observable in a print, the term identification or, in [the] proposed language source identification, should not be used.*

The AAAS report suggests the following testimony by a fingerprint examiner:

> The latent print on Exhibit ## and the record print bearing the name XXX have a great deal of corresponding ridge detail with no differences that would indicate they were made by different fingers. There is no way to determine how many other people might have a finger with a corresponding set of ridge features, but it is my opinion that this set of features would be unusual.

The 2018 Report of the American Statistical Association on Statistical Statements for Forensic Evidence supports the argument that the DOJ-sanctioned statement of "identification" raises the possibility of a problematic overstatement of an expert's conclusions. The Association states as follows:

> The ASA strongly discourages statements to the effect that a specific individual or object is the source of the forensic science evidence. Instead, the ASA recommends that reports and testimony make clear that, even in circumstances involving extremely strong statistical evidence, it is possible that other individuals or objects may possess or have left a similar set of observed features. We also strongly advise forensic science practitioners to confine their evaluative statements to expressions of support for stated hypotheses: e.g., the support for the hypothesis that the samples originate from a common source and support for the hypothesis that they originate from different sources.

The ASA report is addressing, in the above passage, the very concerns that support an amendment prohibiting overstatement. The ASA further states that "a comprehensive report by the forensic scientist should report the limitations and uncertainty associated with measurements, and the inferences that could be drawn from them" --- again, directed straight to the concerns that animate an amendment prohibiting overstatement.

In sum, even if the DOJ Guidelines are perfectly implemented, an argument remains for an amendment to Rule 702 that would specifically preclude an expert from overstating a conclusion.

Side Issue on the Validation of Ballistics Testimony

The validity of ballistics testimony was questioned by the PCAST report. PCAST concluded that ballistics lacked empirical data supporting its reliability. PCAST recognized that one black box study had been conducted on ballistics identification, but recommended that another black box study be conducted. The DOJ has reported that another study, which it claims meets PCAST's requirements, has been conducted, and that it establishes an extremely low rate of error for ballistics identification --- indeed a zero rate of error.

That study is called the Keisler study. I don't have the expertise to determine whether the study meets the requirements of a black box study, as defined by PCAST. I sought advice from Dr. Timothy Lau of the Federal Judicial Center, and this is what he concludes:

> In response to your question about whether Keisler 2018 (the study you forwarded me) satisfies the standard of a black box validation study as defined within the PCAST Report, my answer is no. Please understand that I can only provide an informational response based on my training as a scientist and engineer, applying the standard defined within the PCAST Report. I am not an expert in firearm analysis, and I offer no opinion about the propriety of the standard itself.

The PCAST Report states in relevant part:

> The central question with respect to firearms analysis is whether examiners can associate spent ammunition with a *particular* gun, not simply with a particular *make* of gun. To answer this question, studies must assess examiners' performance on ammunition fired from different guns of the *same make* ("within-class" comparisons) rather than from guns of *different makes* ("between-class" comparison); the latter comparison is much simpler because guns of different makes produce marks with distinctive "class" characteristics (due to the design of the gun), whereas guns of the same make must be distinguished based on "randomly acquired" features of each gun (acquired during rifling or in use). p.112 n.335 (emphasis original).

> According to Table 1 of Keisler 2018, the study involved six models of guns from three different manufacturers:

Make	Model	Caliber	Serial number
Glock	22	40	BTK137
Glock	23	40	ACZ682
Glock	23	40	BZR800
Glock	27	40	DGV668
HK	USP Compact	40	26-011212
Smith & Wesson	SW40V	40	PAZ5764
Smith & Wesson	SW40V	40	PAW6619
Smith & Wesson	SW40VE	40	PAY4932
Smith & Wesson	SW40V	40	PAM5409

Table 1: Firearms used in research

While Keisler 2018 did involve two Glock 23's and three Smith & Wesson SW40V's, it did not separately report examiners' performance on analyzing ammunition fired from guns of these two makes. Instead, the study lumps all results together, regardless of the make of the gun. Accordingly, on this factor alone, I would say that Keisler 2018 does not qualify as a black box validation study as defined within the PCAST Report. *See also* PCAST Report p.112 n.335 (stating that a study did not meet the standard of a black box validation study for using "a mixture of within- vs. between-class comparisons, with the substantial majority being the simpler between-class comparisons" and for "not distinguish[ing] between within- and between-class comparisons").

I also asked Dr. Karen Kafadar, an expert on statistics and forensics at the University of Virginia, for her take on the statistical analysis in the Keisler study:

I have my doubts about the statistical analysis. This research included eighteen within-class comparisons and two out-of-class comparisons in each kit. So far as I can tell, the "statistical analysis" did not account for "within-class comparisons." Nor did it account for the effect of the 126 different examiners. They are assuming you can just collapse everything together.

The report states: "A confidence interval could not be tabulated for the results due to non-normal distributions observed in reported data." That sentence virtually proves lack of statistical understanding. A confidence interval for a binomial proportion is easily calculated - even if they don't account for effects of class and examiner. Students in their very first statistics class learn how to do this.

There is no information on the level of difficulty of the tests - except these lines:

> "The sample kits that the two examiners used were also completed by other participants who came to definitive conclusions, indicating that the level of difficulty of the sample kits was not the issue."
>
> But how does that confirm "level of difficulty"?
>
> and
>
> "The two out-of-class comparisons contained an easy exclusion for examiners based on a difference in class characteristics (ex: hemispherical firing pin impression versus an elliptical firing pin impression)."
>
> But how many other "easy cases" were there (just not acknowledged]?

So, in sum, I am not impressed.

So there is at least some doubt that ballistics has been properly validated in such a way that there would be no risk of overstatement if the expert testified to a match and an infinitesimal error rate. And in any case, even if ballistics has been validated, that leaves many other forensic disciplines subject to a risk of overstatement.

4. Cross-examination as a Solution to the Overstatement Problem

At previous meetings, it has been asserted that the question of overstatement of expert opinion can be adequately handled by cross-examination. For example, if a forensic expert says that he has determined, by a reasonable degree of scientific certainty, that there is a match between a trace substance and the defendant, the defense counsel can attack that testimony on cross-examination --- defense counsel can contradict the conclusion by referring to the PCAST report, or the DOJ standards; counsel might establish through cross-examination the subjective choices that the expert made. And so forth.

Whether cross-examination is a sufficient device to regulate overstatement is a difficult question to assess. There are few data points to rely on, although at least one empirical study has indicated that cross-examination has little impact on the jury when a forensic expert overstates a conclusion. See Dawn McQuiston-Surrett & Michael J. Saks, *Communicating Opinion Evidence in the Forensic Identification Sciences: Accuracy and Impact,* 59 Hastings L.J. 1159, 1167-69 (2008) (explaining that "[w]hether or not jurors were informed about the limitations of microscopic hair examination on cross-examination or by the judge had little measurable or meaningful impact on their judgments about the likelihood that the defendant was the source of the crime-scene hair or their perceived understanding of the expert's testimony").

Perhaps another data point is all the criminal convictions in which forensic experts overstated their conclusions (including the hair identification scandal in which the DOJ admitted that experts overstated their results in hundreds of cases that resulted in conviction). Apparently, cross-examination was *not* a sufficient regulator in all of these cases --- including the very recent cases set forth in the case digest.

Moreover, reviews of cases involving forensic evidence indicate that *forensic experts often don't get cross-examined at all.* For example, forensic experts were not cross-examined in almost half of the wrongful convictions that have been documented by the Innocence Project. So if cross-examination is the answer to overstatement, it hasn't often been employed that way.

Perhaps another way to think about cross-examination as a remedy is to compare the overstatement issue to the issues of sufficiency of basis, reliability of methodology, and reliable application of that methodology. As we know, those three factors must be shown by a preponderance of the evidence. The whole point of Rule 702 --- and the *Daubert*-Rule 104(a) gatekeeping function --- is that these issues *cannot* be left to cross-examination. The underpinning of *Daubert* is that an expert's opinion could be unreliable and the jury could not figure that out, *even given cross-examination and argument*, because the jurors are deferent to a qualified expert (i.e., the white lab coat effect). The premise is that cross-examination cannot undo the damage that has been done by the expert who has power over the jury. This is because, for the very reason that an expert is needed (because lay jurors need assistance) the jury may well be unable to figure out even after cross-examination whether the expert has a sufficient basis, is using reliable methodology, and it reliably applying it.

The real question, then, is whether the dangers of juror mistakes regarding overstatement are any different from the dangers of being unable to assess insufficient basis, unreliability of methodology, and unreliable application. Why would cross-examination be insufficient for the latter yet sufficient for the former?

It is hard to see any difference between the risk of overstatement and the other risks that are regulated by Rule 702. When an expert says that they are certain of a result --- when they cannot be --- how is that easier for the jury to figure out than if an expert says something like "I relied on four scientifically valid studies concluding that PCB's cause small lung cancer."[6] When an expert says he employed a "scientific methodology" when that is not so, how is that different from an expert saying "I employed a reliable methodology" when that is not so?

Judge Rakoff, in *United States v. Glynn,* 578 F.Supp.2d 567, 574 (S.D.N.Y. 2008), when evaluating the admissibility of ballistics evidence, directly addressed the need for a gatekeeper when it comes to overstatement:

[6] That was the expert's testimony in *Joiner* and the Supreme Court held that the trial judge correctly exercised the gatekeeping function in excluding the testimony, because the studies did not actually support a conclusion of causation. But why wasn't it sufficient that the lack of support could have been brought up on cross-examination? The answer is, the gatekeeping function assumes that cross-examination will be insufficient when there is an analytical gap between the expert's methodology and the expert's conclusion.

> The problem is how to admit [the expert opinion] into evidence without giving the jury the impression—always a risk where forensic evidence is concerned—that it has greater reliability than its imperfect methodology permits. The problem is compounded by the tendency of ballistics experts . . . to make assertions that their matches are certain beyond all doubt, that the error rate of their methodology is "zero," and other such pretensions. *Although effective cross-examination may mitigate some of these dangers, the explicit premise of Daubert and Kumho Tire is that, when it comes to expert testimony, cross-examination is inherently handicapped by the jury's own lack of background knowledge, so that the Court must play a greater role, not only in excluding unreliable testimony, but also in alerting the jury to the limitations of what is presented.*

It should also be noted that cross-examination has its work cut out for it when it comes to experts expressing unjustified confidence in an opinion. Research on juries (including post-trial interviews) indicates that the greater the expert's confidence in her conclusion, the more the expert's testimony is likely to sway the jury. If this confidence is unfounded, the risk of inaccurate verdicts runs high.[7] Moreover, there is research on juries demonstrating that even when jurors are apprised of the problems with forensic evidence on cross-examination, that information has little impact on their decisionmaking.[8]

In sum, it seems difficult to argue that cross-examination is the solution for overstatement, while gatekeeping is required for the related questions of reliable methodology and reliable application.

5. Fortified Discovery?

Perhaps the effectiveness of cross-examination would be increased --- and the argument for including a prohibition on overstatement accordingly less compelling --- if criminal discovery were improved.[9] The question of the adequacy of criminal discovery was addressed by Judge

[7] See, e.g, Vidmar, *Expert Evidence, the Adversary System, and the Jury,* 95 American J. of Pub. Health, S137 (2005) (finding that an expert's confidence in an opinion was a critical factor in assessing the weight of the expert's testimony).

[8] See, e.g., McQuiston-Surrett & Saks, *Communicating Opinion Evidence in the Forensic Identification Sciences: Accuracy and Impact,* 59 Hastings L.J. 1159, 1167-69 (2008) ("Whether or not jurors were informed about the limitations of microscopic hair examination on cross-examination or by the judge had little measurable or meaningful impact on their judgments about the likelihood that the defendant was the source of the crime-scene hair or their perceived understanding of the expert's testimony.").

[9] This whole issue of cross-examination as the remedy is based on the premise that defense counsel, if adequately notified, will in fact cross-examine effectively. To hear many judges tell it, that premise is not empirically supported.

Grimm at the 2017 Symposium at Boston College. Judge Grimm argued that because criminal discovery is so truncated, and late in the day, defense counsel are unduly hampered in cross-examining forensic experts.

Judge Grimm and Judge Rakoff both proposed that the Criminal Rules Committee undertake efforts to amend Criminal Rule 16 to provide for greater and more timely discovery related to expert testimony in criminal cases. The Criminal Rules Committee has proposed changes that would, according to the draft Committee Note, address "two shortcomings of the prior provisions: the lack of adequate specificity regarding what information must be disclosed, and the lack of an enforceable deadline for disclosure." The Criminal Rules Committee's proposed amendment is currently out for public comment.

Currently the prosecution must provide only a summary of the expert's testimony. The proposed amendment requires disclosure of a complete statement of all opinions that the government will elicit from the witness in its case-in-chief as well as the bases and reasons for those opinions. It also adds to the current rule a requirement of a disclosure of the witness's publications and prior cases in which the expert testified. Finally, it requires that the witness approve and sign the disclosure, unless the government states that it could not obtain the witness's signature.

As to timeliness, the amendment requires that the court or a local rule must set a time for the government to make the disclosure. The time must be "sufficiently before trial to provide a fair opportunity for the defendant to meet the government's evidence."

At a miniconference on Rule 16 held by the Criminal Rules Committee, the DOJ representative argued that whatever changes might be made to Rule 16, none were necessary in the forensic area. That was because, under DOJ policy, the prosecutor ordinarily has an obligation to turn over the forensic report. This is due to a 2017 memorandum issued by Sally Yates. That memorandum states that the prosecution must obtain the forensic expert's lab report and that "[i]n most cases the best practice is to turn over the forensic expert's report to the defense if requested." The Yates memo also sets forth further requirements:

> ● "The prosecutor should disclose to the defense, if requested, a written summary for any forensic expert the government intends to call as an expert at trial. This statement should summarize the analyses performed by the forensic expert and describe any conclusions reached."
>
> ● "[I]f requested, the prosecutor should provide the defense with . . . the laboratory or forensic expert's 'case file' . . . . This information . . . normally will describe the facts or data considered by the forensic expert, include the underlying documentation of the examination or analysis performed, and contain the material necessary for another expert to understand the expert's report. The exact material contained in a case file varies depending on the type of forensic analysis performed. It may include such items as a chain-

And it is also based on the assumption that even the most effective cross-examination of forensic testimony will have an impact on the jury --- which, as discussed above, is subject to doubt.

of-custody log; photographs of physical evidence; analysts' worksheets or bench notes; a scope of work; an examination plan; and data, charts and graphs that illustrate the results of the tests conducted."

● "[T]he prosecution should provide to the defense information on the expert's qualifications. Typically, this material will include such items as the expert's curriculum vitae, highlighting relevant education, training and publications, and a brief summary that describes the analyst's synopsis of experience in testifying as an expert at trial or by deposition."

So there will probably in the future be improvements in disclosure of information that will be relevant to cross-examination of experts generally; and there are already internal standards at the DOJ in place for disclosure pertinent to cross-examination of forensic experts.[10]

There are strong arguments, however, that even assuming that cross-examination is a remedy for overstatement, the discovery obligations imposed by the Yates memo are insufficient to guarantee effective cross-examination. In a reply email to me, Chris Fabricant of the Innocence Project came up with a list of information that would be necessary for effective cross-examination of a forensic expert, beyond what is currently provided under the Yates memo:

> Going into a cross-examination, I would want the analyst's bench notes, their personnel file, all proficiency tests, prior transcripts, validation/calibration documentation of any instrument used, a list of publication that support's the analyst's opinion - OSAC standards should provide a list of publications; "peer review" info (expert disagreement), and all communication between the prosecution and the forensic analyst, as it relates to contextual bias influencing expert opinion). From the lab, I would want accreditation audits (on-sight assessments and self-reported) and any/all "corrective actions" related to expert testifying and the specific unit within the lab. Note that sometimes labs claim these last two items are confidential accreditation documents. But the Houston crime lab posts these online, so the confidentiality claim is simply a policy to avoid disclosure.

It should also be noted that a number of states require a more robust disclosure for forensic experts than would be required by the Yates memo or an amended Rule 16. For example, New York requires disclosure not only of the forensic expert's report but also "all proficiency tests and results administered or taken within the past ten years." N.Y. Crim. Pro. 245.20 (1)(f). Proficiency records are especially important because, given the subjectivity of most forensic comparisons, the expert's proficiency needs to be disclosed to the jury for it to properly weigh the expert's opinion.

[10] Of course, the internal regulations are not legally enforceable and they can be abrogated.

Also note that the DOJ argued that *no* changes to Rule 16 were necessary because internal efforts were being made to provide more effective discovery than required by the existing Rule 16. That is the same argument that the DOJ has made to the Evidence Rules Committee regarding overstatement by forensic experts. It appears that the Criminal Rules Committee was not persuaded by that argument in the context of criminal discovery.

See Brandon Garrett and Gregory Mitchell, *The Proficiency of Experts,* 166 Univ. Penn. L.Rev. 901, 909 (2018):

> An expert who uses a subjective method is a "black box" into which data is fed and out of which magically pops an answer. Such an expert can never be shown definitively to have erred in applying a method because that method cannot be observed and applied by others. However, if proficiency data for such "black-box experts" exists, then we can assess their basic levels of proficiency, which provides important information about their ability to provide accurate and reliable information. Experts reaching conclusions using subjective methods may be highly reliable. But walking through the courtroom door is unlikely to transform an "expert" who regularly receives low scores on proficiency tests into a highly reliable source of information in the case at hand.

Thus, even if cross-examination is the answer, and discovery standards are being fortified, there is still debate about whether defense counsel will get enough information, in sufficient time, to effectively cross-examine a forensic expert. This is not to criticize the admirable efforts being taken by the Criminal Rules Committee and the DOJ. It is just to say that there is debate on whether these discovery advances are the complete answer to the overstatement problem.

Most importantly, even perfect discovery does not guarantee that cross-examination of expert overstatement will be effective, for reasons and data discussed in the previous section.

It can surely be argued that it is not one or the other, i.e., better and faster discovery *or* an amendment to the Evidence Rules to prohibit overstatement. There is a good argument that *both* changes are necessary. Better and faster discovery will allow the defense an improved chance at convincing the judge at a *Daubert* hearing that the government's expert is overstating the conclusion that can be fairly drawn from the methodology employed. An amendment to Rule 702 will highlight to defense lawyers that they should look for "overstatements" while an amendment to Rule 16 will give them the information to make that argument, and better discovery will arm the trial judge with the specific basis for excluding overstated testimony.

C. Isn't an Overstatement Limitation Already in the Rule?

One argument against an overstatement amendment that has been expressed at a prior Committee meeting is that an amendment is not necessary because overstatement is simply an aspect of existing requirements in the rule: reliable methodology reliably applied. For example, an expert who testifies that "I am certain that there is a match" might be using a reliable methodology (e.g., ballistics), but is not applying it reliably (because the methodology is subjective and so not error-free). So why add a requirement to the rule that can already be teased out of the existing language?

The response to that question might be that it could be useful to break overstatement out as a separate factor, in order to draw attention to it --- because the case digest shows that courts

are *not* regulating overstatement as seriously as they are the three reliability factors set forth in the text of Rule 702. This appeared to be the conclusion of most of the panelists at the Vanderbilt conference.

I asked Professor Ed Imwinkelried, the greatest living scholar on Evidence, for his thoughts on an overstatement amendment --- specifically directed to its necessity given that it can likely be teased out of the existing requirements. This is what he had to say:

> Given the fact that in the past so many courts have tolerated and admitted overstated opinions, I agree that it would be helpful to explicitly send trial judges a message that as part of their admissibility analysis, they need to police the manner in which the expert expresses his or her degree of confidence in the opinion.
>
> I see the counterargument that it's technically unnecessary to amend 702 to explicitly include the limitation if you can tease the limitation out of the current wording of (d). However, that counterargument isn't persuasive here. After decades in which judges had to merely count noses under *Frye*, we're now asking judges to roll up their sleeves and learn the rudiments of expert methodology. You could argue that in 2000 it was unnecessary to insert 702(c); that requirement was surely implicit in *Daubert's* reliability test which purported to derive from the original rule's simple reference to "scientific . . . knowledge." However, the judicial treatment of expert testimony is evolving. Your Committee proposed adding 702(c) to nudge the evolution in the right direction and help judges refine their analysis under *Daubert* and 702. Similarly, this amendment would signal the judges that as "gatekeepers," they have to scrutinize the level of confidence stated in any opinions they admit through the gate. In these situations I tend to fall back on the wisdom: "When in doubt, be insultingly explicit."

D. Support for a Proposal to Regulate Overstatement

As discussed in prior memos, the Reporter contacted some individuals involved with the PCAST report to determine whether the working draft amendment addressed to overstatement --- developed over the last few meetings --- was on the right track. They were asked their thoughts about whether the proposed amendment will effectively address at least some of the concerns expressed about forensic expert testimony. (There was no attempt to be comprehensive in this outreach, because broader input is part of the public comment process).

Professor Brandon Garrett, an expert on forensic evidence at Duke Law School, reviewed the proposed amendment on overstatement and submitted this opinion:

> I write to strongly endorse the revision presently under consideration to Rule 702, regarding the testimony of expert witnesses. My research includes work in law and in psychology, as well as collaborations with statisticians, and with forensic crime laboratories, regarding scientific evidence. I should note that the views expressed in this letter do not reflect those of Duke University or Duke School of Law, where I work, or that of the Center for Statistics and Applications to Forensic Evidence (CSAFE), a research center that I participate in.
>
> The proposed revision would add a new subsection (e), providing that an expert may not overstate the conclusions that may reasonably be drawn from the principles and methods used. I strongly favor this proposal. The central problem that this proposal addresses is that experts may reach conclusions that are not supported by the facts or by the method employed and that there has been a tendency in many disciplines to overstate conclusions.
>
> Testimonial overstatement has contributed to large numbers of wrongful convictions. Experts have made such claims of infallibility, together with other unscientific and invalid claims, in a disturbing number of cases in which persons were later exonerated by post-conviction DNA testing. Brandon L. Garrett & Peter J. Neufeld, *Invalid Forensic Science Testimony and Wrongful Convictions*, 95 Va. L. Rev. 1, 1 (2009) (exploring "the forensic science testimony by prosecution experts in the trials of innocent persons, all convicted of serious crimes, who were later exonerated by post-conviction DNA testing").
>
> Nor is it an isolated problem. Entire disciplines have been plagued by testimonial overstatement. A massive FBI review of almost 3,000 cases involving microscopic hair comparison found that over 96% involved testimony flawed by overstatement of several different types. FBI/DOJ Microscopic Hair Comparison Analysis Review, at https://www.fbi.gov/services/laboratory/scientific-analysis/fbidoj-microscopic-hair-comparison-analysis-review. Indeed, 33 of those cases involving testimonial overstatement had been death penalty cases; in nine of those cases, the defendants had already been executed and five died of natural causes, as of March 2015.
>
> Moreover, when such testimonial overstatement has occurred and has been brought to the attention of judges, in response, judges have often viewed their responsibility to regulate expert testimony as limited to the methods used and the admissibility of the type of expertise. Judges have sometimes viewed (incorrectly, in my view) the conclusions reached and how those conclusions are expressed as a matter for the jury to assess, rather than an integral feature of the expert's work. In my view, the ultimate conclusion reached is an integral feature of the expert's work and it must be reviewed as part of the judge's

gatekeeping responsibilities. This proposal valuably addresses what has become, in practice, a very important and troubling gap in the coverage of Rule 702.

Obviously more could be done to address the problem that experts may draw conclusions that are overstated and do not follow from the facts or their methods. However, I also want to highlight the importance of the notes accompanying this proposal, which help to explain the concept of non-overstatement of conclusions. Perhaps most important is what the Committee Note says regarding failure to mention error rates. No conclusion can be reached about a method without qualification or discussion of error rates, because there is no type of expertise that does not have some error rate. No technique that involves human interpretation or judgment is error free. And if a type of analysis was so reliable that no human judgment was involved, one would likely not need an expert to explain it and reach conclusions about it. The entire purpose of an expert is to contribute judgment, experience, and use of sound scientific methods to analysis of facts relevant in a case. In research conducted in collaboration with Greg Mitchell, we have found that error-rate information is highly salient to lay jurors. See, e.g. Brandon L. Garrett and Gregory Mitchell, *How Jurors Evaluate Fingerprint Evidence: The Relative Importance of Match Language, Method Information and Error Acknowledgement*, 10 J. Empirical Legal Stud. 484 (2013).

In the past, unfortunately, experts have made false and startling statements, like that there was a "zero error" rate in their type of expert work. See, e.g. Simon A. Cole, *More Than Zero: Accounting for Error in Latent Fingerprint Identification*, 95 J. Crim. L. & Criminology 985, 1043, 1048 (2005). For example, the American Association for the Advance of Science (AAAS) report descried "decades of overstatement by latent print examiners." Am. Ass'n for the Advancement of Sci., *Latent Fingerprint Examination: A Quality and Gap Analysis* 11 (2017). Zero error rates do not exist but asserting infallibility would predictably impact the jury powerfully.

Not only should experts be barred from claiming infallibility, but they must disclose the actual error rates, if they have been adequately measured. If error rates for a method have not been adequately measured using sound "black box" studies under realistic conditions, then experts must disclose that their technique is of unknown validity and reliability (and in such situations, other prongs of Rule 703 and Rule 403 may each bar admissibility of the expert testimony).

Expert evidence should never be presented in court without evidence of its error rates and of the proficiency or reliability of not just the method, but the particular examiner using the method. *See* President's Council of Advisors on Sci. & Tech., Exec. Office of the President, *Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods* 9–11 (2016). Such proficiency testing should involve tests of realistic difficulty and such testing should be done blind, so that the participant does not know that it is a test. Jonathan J. Koehler, *Proficiency Tests to Estimate Error Rates in the Forensic Sciences*, 12 Law, Prob. & Risk 89, 94 (2013) ("Blind proficiency testing has been used in some forensic science areas, including the Department of Defence's forensic

urine drug testing programme and the HIV testing programme."); Joseph L. Peterson et al., *The Feasibility Of External Blind DNA Proficiency Testing. II. Experience With Actual Blind Tests*, 48 J. Forensic Sci. 1, 8 (2003).

Jurors should hear about the proficiency of the particular expert, and of that person's reliability in reaching conclusions using a method. Brandon L. Garrett and Gregory Mitchell, *The Proficiency of Experts*, 166 U. Penn. L. Rev. 901 (2018); see also Gary Edmond, *Forensic Science Evidence and the Conditions for Rational (Jury) Evaluation*, 39 Melb. U. L. Rev. 77, 85-86 (2015) ("[R]egardless of qualifications and experience, rigorous proficiency testing tells us whether the forensic analyst performs a task or set of tasks better than non-experts or chance. A significantly enhanced level of performance is precisely what it means to be an expert.").

* * *

In the past, scientific experts have also used vague terminology like "identification" or "match" – and the Committee Note could valuably note that there are additional types of problematic conclusion testimony apart from the use of terms like "reasonable scientific certainty." The AAAS report, for example, noted that terms like "match," "identification," "individualization," and other synonyms should not be used by examiners, nor should they make any conclusions that "claim or imply" that only a "single person" could be the source of a print. AAAS Report at 11.

The Committee Note could also address claims of experience – which can be used to bolster statements that something the expert observes is rare or common based on one's experience, without citing to any empirically valid support. The Department of Justice's Model Uniform Language on Latent Fingerprint Evidence, for example, explicitly cautions against the use of such experience-based claims to suggest probabilities connected with a conclusion, as does the protocol for the FBI's review of microscopic hair evidence. FBI/DOJ Microscopic Hair Comparison Analysis Review, at https://www.fbi.gov/services/laboratory/scientific-analysis/fbidoj-microscopic-hair-comparison-analysis-review.

I also note that some experts testify about general research, and are therefore cautious about connecting general research to the facts in a case, and therefore may be much less likely to risk overstatement. For example, experts may also testify about more general scientific research to provide a "framework" to educate factfinders, and they may explain industry or professional norms as well. *See* Laurens Walker & John Monahan, *Social Frameworks: A New Use of Social Science in Law*, 73 VA. L. REV. 559, 570 (1987).

I hope that these views are of use as you consider this important proposal. Please feel free to contact me at your convenience if I can be of further assistance.

Other PCAST Participants

In addition, a number of experts involved in the PCAST report have reported that the amendment, and especially the Committee Note, would be useful in regulating what that PCAST found to be a significant problem of overstatement. Among those who have reviewed the draft amendment are Dr. Eric Lander (who provided some suggestions on the Committee Note), Judge Patti Saris, and Dr. Karen Kafadar. All thought that the amendment and the Note would be an important tool in addressing a real problem.

Other Jurisdictions

Some support for an amendment regarding overstatement can be found in the United Kingdom. U.K. Rule of Criminal Procedure 19 governs the procedural and evidentiary aspects of expert witness testimony in British criminal trials.

Rule 19.4 states that the expert report must include:

> (f) where there is a range of opinion on the matters dealt with in the report— (i) summarise the range of opinion, and (ii) give reasons for the expert's own opinion;
>
> (g) if the expert is not able to give an opinion without qualification, state the qualification;[11]

On the other hand, it should be noted that none of the state versions of Rule 702 contain language addressed to the problem of overstatement. The closest that the states get to regulating forensic expert testimony is Ohio Rule 702, which has language specifically addressed to reports of a procedure, test or experiment (that would presumably cover forensic expert testimony). Ohio 702 provides as follows:

> A witness may testify as an expert if all of the following apply:
>
> (A) The witness' testimony either relates to matters beyond the knowledge or experience possessed by lay persons or dispels a misconception common among lay persons;
>
> (B) The witness is qualified as an expert by specialized knowledge, skill, experience, training, or education regarding the subject matter of the testimony;
>
> (C) The witness' testimony is based on reliable scientific, technical, or other specialized information. *To the extent that the testimony reports the result of a procedure, test, or experiment, the testimony is reliable only if all of the following apply:*

[11] Thanks to Dr. Tim Lau for drawing the UK rule to my attention.

(1) The theory upon which the procedure, test, or experiment is based is objectively verifiable or is validly derived from widely accepted knowledge, facts, or principles;

(2) The design of the procedure, test, or experiment reliably implements the theory;

(3) The particular procedure, test, or experiment was conducted in a way that will yield an accurate result.

E. Trial Court Evaluations of an Expert's "Credibility"

At the Fall, 2018 meeting, during the discussion of the proposed amendment on overstatement, the thought was expressed that the amendment might lead to the court assessing the "credibility" of an expert, and that this was inappropriate. The example discussed was an expert testifying that he was "certain" of his opinion; under the draft amendment, it was thought that the trial judge might have to exclude the testimony if she found that the testimony of "certainty" was an overstatement given the underlying data and method that the expert used. The thought was expressed that such an exclusion would amount to a credibility determination, and the credibility of the expert is to be left to the jury.

But the process that the judge used in this hypothetical would be no different than that used to judge any of the other admissibility requirements currently in Rule 702. For example, if an expert states that he relied on sufficient data, and the judge finds that the data is not sufficient to support the opinion, the judge must exclude the evidence. Is the judge in that case wrong because she does not believe the expert's assertion? If "credibility" assessments are prohibited in that circumstance, then logically the judge cannot disagree with *any* of the expert's assertions or conclusions, because to do so would challenge the expert's credibility.

In fact a *Daubert* hearing today is rife with "credibility" determinations --- as Judge Vance pointed out at the Vanderbilt conference. If an expert states that he relied on a report, but the judge determines that the expert could not have so relied and come to the opinion he did, then the judge should disregard the expert's assertion and review the expert's basis accordingly. Similarly, under the proposed amendment, if the expert states that there is a zero rate of error when a forensic methodology applies, that assertion is demonstrably untrue --- incredible --- and the expert should be prohibited from testifying to that overstatement.

The role of "credibility" determinations at a *Daubert* hearing is complicated, but credibility determinations are clearly not always barred. If the expert says that he employed a reliable method, or that his conclusion is not an overstatement, it may be that the expert did not in fact employ reliable methods, or did in fact overstate the conclusion. If the trial judge does not intervene, this would mean that the jury would hear unreliable expert testimony, contrary to the principle of *Daubert*.

Judge Becker considered the complex relationship between expert credibility and reliability in *Elcock v. Kmart Corp.*, 233 F.3d 734, 750–751 (3d Cir. 2000). The trial judge in *Elcock* held a *Daubert* hearing and determined that one of the plaintiff's experts did not pass the reliability threshold. The judge relied in part on the fact that the expert had engaged in criminal acts involving fraud, and so was not a credible witness; the fraudulent activity was not in any way related to the expert's professional life, however. Judge Becker found the trial court's reliance on these bad acts to be error, and stated that on remand "the district court should not consider Copemann's likely credibility as a witness when assessing the reliability of his methods." Judge Becker added, however, the following important qualification:

> We do not hold … that a district court can never consider an expert witness's credibility in assessing the reliability of that expert's methodology under Rule 702. ***Such a general prohibition would be foreclosed by the language of Rule 104(a), which delineates the district court's fact-finding responsibilities in the context of an in limine hearing on the Daubert reliability issue. Indeed, consider a case in which an expert witness, during a Daubert hearing, claims to have looked at the key data that informed his proffered methodology, while the opponent offers testimony suggesting that the expert had not in fact conducted such an examination. Under such a scenario, a district court would necessarily have to address and resolve the credibility issue raised by the conflicting testimony in order to arrive at a conclusion regarding the reliability of the methodology at issue.*** We therefore recognize that, under certain circumstances, a district court, in order to discharge its fact-finding responsibility under Rule 104(a), may need to evaluate an expert's general credibility as part of the Rule 702 reliability inquiry.

While Judge Becker properly concluded that credibility determinations would have to be made at a *Daubert* hearing, he emphasized that those determinations are limited to testimony *about how the expert reached her opinion*, as opposed to witness-credibility more generally:

> Although *Daubert* assigns to the district court a preliminary gatekeeping function—requiring the court to act as a specialized fact-finder in determining whether the methodology relied upon by an expert witness is reliable—it does not necessarily follow that the court should be given free rein to employ its assessment of an expert witness's *general credibility* in making the Rule 702 reliability determination. To conclude otherwise would be to permit the district court, acting in its capacity as a *Daubert* gatekeeper, to improperly impinge on the province of the ultimate fact-finder, to whom issues concerning the general credibility of witnesses are ordinarily reserved.

Thus the distinction as articulated by Judge Becker is between credibility determinations bearing *directly* on the expert's methods and application, and general credibility issues that apply to all witnesses. Judge Becker posited the following example:

> For instance, in situations involving an attempt to attack an expert witness's credibility on the basis of prior bad acts or convictions, at least one prominent evidence commentator has noted that an expert's prior dishonesty or misconduct should not qualify

> as an appropriate factor in assessing methodological reliability *when the acts are wholly unrelated to the expert's use of a particular methodology*, but that a court should take such dishonesty or misconduct into account when the nexus between the acts and the expert's methodology is more direct, e.g., when the prior dishonest acts involve fraud committed in connection with the earlier phases of a research project that serves as the foundation for the expert's proffered opinion. *See* Edward J. Imwinkelreid, *Trial Judges—Gatekeepers or Usurpers? Can the Trial Judge Critically Assess the Admissibility of Expert Testimony Without Invading the Jury's Province to Evaluate the Credibility and Weight of the Testimony*, 84 Marq. L. Rev. 1, 39 (2000). Under this approach, for instance, the fact that an expert witness falsely reported his salary on an income tax return has little if any bearing on the reliability of a diagnostic test he frequently employs, but the fact that the expert lied about whether his methodology had been subjected to peer review, or ***intentionally understated the test's known rates of error, is a different matter entirely.***

It would seem that the Becker quote above is spot-on for answering concerns about "credibility" determinations made by a judge ruling on possible overstatement of an expert's conclusions. If the expert overstates the certainty of a conclusion (understates the rate of error) then *Daubert* obligates the judge to prohibit such an unreliable assertion from being made at trial.

On the other hand, if the attack on credibility has nothing to do with the expert's methods, but only with a general character for truthfulness, the issue of credibility should be left to the jury—the opponent can bring impeachment evidence before the jury by way of cross-examination as with any witness. As applied to the facts of *Elcock*, the credibility evidence should not have been used by the trial court, because it related to acts of dishonesty and fraud completely outside the expert's work in the particular case.[12] In contrast, if the expert in *Elcock* were found to have misstated or even lied about doing a test in this particular case, the trial court must disregard the expert's conclusion that is purportedly based on the test. If that is a "credibility" determination, then so be it.

It should be noted that while a trial court is considering credibility when evaluating an admissibility requirement under Rule 702 (such as sufficiency of basis), the addition of an overstatement requirement would not, and should not, be a vehicle allowing the trial judge to nitpick an expert into oblivion. Nothing in an amendment limiting overstatement requires the judge to get into the difference between "highly likely" and "very likely" for example. The preponderance standard of Rule 702 does not require that the expert be absolutely correct or completely precise. The draft Committee Note, infra, emphasizes this point.

In sum, the proposed amendment limiting overstatement is no different from any of the existing admissibility requirements of 702 insofar as there is concern that trial judges will

[12] *See also Cruz-Vazquez v. Mennonite Gen. Hosp. Inc.,* 613 F.3d 54 (1st Cir. 2010) (error to exclude expert because he was biased in favor of plaintiffs in medical cases and was generally affiliated with plaintiffs' lawyers; those considerations are for the jury in assessing the weight of the expert's testimony).

improperly make "credibility" determinations. If the judge finds that the expert overstated the opinion, then the trial judge should prohibit the opinion.

F. Should a Rule on Overstatement Apply Beyond Forensics?

While overstatement by experts in areas other than forensics is less publicized, there are arguments that any amendment regulating overstatement should apply to all expert testimony. Those arguments are:

1) the term "forensic" is hard to define in rule text, as it goes beyond feature-comparison (for example to arson investigations) and there are disputes about just which disciplines are forensic;

2) there is no other Federal Rule of Evidence that focuses specifically on a subset of witnesses;

3) if it is a good idea to require a court to regulate overstatement, it could be a good idea to have that tool available outside the forensic disciplines;

4) There is an incentive for an expert to overstate a conclusion in a civil case --- they are financially beholden to the party. *Judge Kaplan explains it like this:*

> Lawyers want experts who will express unwavering certainty about their conclusions: Eighty-four percent of lawyers surveyed in a recent study said that the adamancy of an expert's support for the lawyer's position was an important consideration in the expert selection process. Experts are well aware of this overwhelming preference. The same study showed that sixty-four percent of experts believe that the willingness to draw firm conclusions was important to being retained. ***The desire to please lawyers often leads experts to overstate the certainty of their conclusions and to gloss over important nuances in an effort to present the most uncompromising support for the lawyers' position.***[13]

5) ***Most importantly, there are a number of reported cases in which an expert appears to have gotten away with a conclusion that overstates what they could fairly say based on the methodology employed. That is, there is a problem of overstatement outside the forensic area. And while it is not as evident as in the forensic area, overstatement does exist. What follows is a case digest of some representative cases***:

[13] Hon. Lewis Kaplan, *Experts in the Courthouse: Problems and Opportunities,* 2006 Colum. Bus. L.Rev. 247 (2006). The study Judge Kaplan cites is by Daniel Shurman et. al., *An Empirical Examination of the Use of Expert Witnesses in the Courts --- Part II: A Three-City Study,* 34 Jurimetrics 193 (1994).

Case Digest on Overstatement by Non-Forensic Experts[14]

1. Expert Overstatement Permitted

In some federal cases, non-forensic expert opinion testimony is admitted that appears to overstate the conclusions that reliably flow from the expert's methodology. Here are some recent examples:

- ***United States v. Chikvashvili***, 859 F.3d 285, 292-93 (4th Cir. 2017) (government expert in prosecution for healthcare fraud resulting in death was permitted to testify that the misreading of patient x-rays was the "but-for cause" of two patients' deaths and that standard medical procedures "would have averted" their deaths. Doctor also opined that one patient's elective surgery "would have been postponed" with an accurate reading of his x-ray).
- ***United States v. Campbell,*** 963 F.3d 309 (4th Cir. 2020) (expert allowed to testify categorically that "the cause of [the victim's death] was heroin intoxication" and that "but for the heroin, she would have lived").
- ***Puga v. RCX Solutions, Inc.,*** 922 F.3d 285 (5th Cir. 2019) (police officer who arrived at an accident was properly permitted to testify that a truck driver "must have been driving too fast" even though he did not examine the truck, the brakes, the weight of the truck, or attempt to estimate his speed).
- ***United States v. Tingle,*** 880 F.3d 850, 855 (7th Cir. 2018) (no error in allowing law enforcement expert to testify that the amount of drugs found in the defendant's residence was "definitely for distribution" and that the gun found in residence "was utilized by [the defendant] to protect himself and/or the methamphetamine and the currency.").
- ***United States v. Johnson,*** 916 F.3d 579 (7th Cir. 2019): In a trial on charges of possessing a handgun in furtherance of a drug trafficking crime, an expert on drug dealers was allowed to testify that "where there's guns, there's drugs, and where there's drugs, there's guns."
- ***Adams v. Toyota***, 867 F.3d 903, 916 (8th Cir. 2017) (affirming admission of expert testimony in which an engineer "ruled out" pedal misapplication as a potential cause of a sudden acceleration accident).
- ***United States v. Lopez***, 880 F.3d 974 (8th Cir. 2018) (affirming admission of a DEA agent's expert testimony that "illegal drugs entering the market are of such high purity that it has

[14] This digest is not intended to be comprehensive. It collects a representative example of cases. The digest was prepared with the substantial help of Professor Liesa Richter.

become physically impossible even for seasoned addicts to consume large amounts of methamphetamine").

- ***Wendell v. Glaxo Smith Kline***, LLC, 858 F.3d 1227 (9th Cir. 2017) (the district court erred in excluding medical expert's opinions that prescription drug caused the plaintiff's rare cancer even though the expert testified to "a one in six million chance" that the plaintiff would have developed the cancer without exposure to the drug).
- ***United States v. Wells,*** 879 F.3d 900 (9th Cir. 2018) (affirming the admission of expert testimony by a tire expert to refute a murder defendant's alibi that he was not at work at the time of the murders because he got a flat tire; the expert concluded that the nail in the tire "had been inserted" in the tire "manually" rather than picked up while driving).
- ***United States v. Lozano***, 711 Fed. App'x 934 (11th Cir. 2017) (permitting the government's drug trafficking expert to testify that the defendant's "blind mule theory" had "no factual basis").
- ***U.S. Information Systems, Inc. v. International Broth. of Elec. Workers Local Union No. 3, AFL-CIO,*** 313 F.Supp.2d 213 (S.D.N.Y. 2004): An expert in antitrust economics testified to damages, and the opponent argued that the claims were overstated, because he used a discounting factor that was unsupported. The court held that the expert could testify, concluding that while "the accuracy of Dr. Dunbar's figures may be open to dispute, his methodology with respect to damages is sound."
- ***Flavel v. Svedala Indus.,*** 875 F.Supp. 550 (E.D.Wi. 1994) (in an age discrimination action, the fact that a statistics expert artificially inflated his findings by using employee ages as of a certain date raised a question for the jury, not the court).
- ***Etherton v. Owners Ins. Co***., 35 F. Supp.3d 1360, 1364, 1368 (D. Colo. 2014), aff'd 829 F.3d 1209 (10th Cir. 2016) (rejecting a challenge to expert testimony that the plaintiff's many injuries "were entirely caused" by a collision and that "every single rear-end collision that has ever occurred" is a plausible mechanism for causing lumbar disc injury).
- ***In re Trasylol Prod***. ***Liab. Litig.,*** 2010 WL 8354662 (S.D.Fla.) (the expert was allowed to testify, on the basis of a differential diagnosis, that the use of a drug was a contributor "in all medical certainty" to a kidney injury, despite conceding "scientific unknowns").

2. Expert Overstatement Regulated

There are a number of reported cases in which it appears that courts are regulating expert attempts to overstate their results (sometimes by appellate court correction):

- ***United States v. Machado-Erazo,*** 901 F.3d 326 (D.C. 2018): The government offered an expert on cellphone location. The disclosure under Rule 16 was deficient, because the "report" was nothing but pictures of cellphone towers. (!) At a hearing the government assured the trial judge that the expert would offer testimony about only the "general location" of cell phones, rather than precise locations. At trial, before a different judge, the expert testified to precise locations. The court of appeals found that it was error to admit this testimony --- and that there was a violation of Rule 16 --- but found the error to be harmless.

- ***United States v. Naranjo-Rosaro***, 871 F.3d 86, 96 (1st Cir. 2017) (the trial court erred in allowing the agent handling a drug-sniffing dog to testify as a lay witness, but the error was harmless where the agent's testimony would have been admissible expert opinion and where the agent conceded that the dog's alerts to drugs "did not establish the presence of drugs in the house").

- ***In re Vivendi Sec. Litig***., 838 F.3d 223, 256 (2nd Cir. 2016) (affirming admissibility of expert testimony based upon an event study about artificial inflation in a company's stock price due to misapprehension of a company's liquidity risk; emphasizing that the expert did not purport to establish that the company's fraud *caused* the misapprehension).

- ***Nease v. Ford Motor Co.,*** 848 F.3d 219, 225 (4th Cir. 2017) (reversing a verdict for the plaintiff in a product liability action due to the district court's erroneous admission of testimony by the plaintiff's expert "to a reasonable degree of engineering certainty" that the throttle on the plaintiff's truck contained a design defect that caused an acceleration accident; the expert's opinion was not supported by the information he had and the methodology he used).

- ***Rheinfrank v. Abbott Labs, Inc.,*** 680 Fed. App'x 369, 376 (6th Cir. 2017) (finding no error in the district court's ruling refusing to allow the plaintiff's regulatory expert to testify that "DepoKote was known to be the most teratogenic drug"; the expert was not in a position to evaluate the relative risks of epilepsy drugs).

- ***Abrams v. Nucor Steel Marion, Inc.,*** 694 Fed. App'x 974 (6th Cir. 2017) (affirming exclusion of an opinion by a toxicological expert that persons who reside ".25 to .50 miles" from the defendant's plant "for a period of ten years or more" will suffer harm from chronic exposure to manganese; the opinion was an overstatement).

- ***United States v. Pembrook***, 876 F.3d 812 (6th Cir. 2017) (affirming admission of expert testimony regarding cell tower location analysis because the government did not attempt to put defendant's cell phone in a very "specific" or "precise" location, but rather attempted to show the general geographical proximity to the locations of the robberies at the pertinent times; the court stated that the disclaimers about the limits of the methodology would have been good fodder for cross-examination of the expert).

- ***United States v. Reynolds,*** 626 Fed. App'x 610 (6th Cir. 2015) (affirming admission of expert testimony concerning cell tower location analysis because the agent did not purport

to rely on data to place the defendant *in* the home when child pornography was downloaded, but rather used data to *exclude* the presence of other members of the household during relevant times, because the cell phones of other individuals connected to cell towers were far away from home during downloads).

- ***Krik v. Exxon Mobile Corp***., 870 F.3d 669, 675 (7th Cir. 2017) (affirming exclusion of a toxicological expert's testimony that asbestos exposure is "either zero or it's substantial; there's no such thing as not substantial exposure," as unsupported by dose-dependent causation of cancer).

- ***United States v. Lewisbey***, 843 F.3d 653, 659-60 (7th Cir. 2016) (affirming admission of expert testimony about the general location of the defendant's cell phone based on call records and cell tower data, where the district court appropriately barred the agent "from couching his testimony in terms that would suggest that he could pinpoint the exact location of Lewisbey's phones.").

- ***United States v. Hill***, 818 F.3d 289, 295 (7th Cir. 2016): The court held that cell site analysis expert testimony should include a "disclaimer" regarding accuracy. The expert should not "overpromise on the technique's precision or fail to account for its flaws." The court affirmed the admission of cell site analysis testimony by an FBI agent where the agent made it clear that the defendant's phone records were "consistent" with him being at or near relevant locations at relevant times, but clarified that he could not state whether a phone was "absolutely at a specific address."

- ***Murray v. Southern Route Maritime, S.A., et al.,*** 870 F.3d 915 (9th Cir. 2017) (affirming the district court's admission of expert testimony about the theory of low-voltage diffuse electrical injury, where the district court highlighted the narrow nature of the expert's opinion about the theory, and did not permit the expert to testify that the plaintiff's injuries were *caused* by low-voltage shock).

3. The "Reasonable Degree of Certainty" Standard in Civil Cases

A rule prohibiting overstatement in forensic evidence cases would likely result in prohibiting an expert from testifying to a "reasonable degree of [field] certainty" of a feature-comparison match. As stated above, the DOJ has abandoned the standard, it has been rejected by scientific panels, and it is a classic example of overstatement --- but many courts are still using it.

In civil cases, there is a complication in rejecting the reasonable degree of certainty standard. Civil litigants frequently object that the expert testimony offered by their opponents is unreliable and insufficient due to the experts' *failure* to opine "to a reasonable degree of certainty." Moreover, some states appear to require a reasonable certainty standard as a matter of state substantive law --- which is controlling in diversity cases, assuming that in fact it is substantive.

See, e.g., Antrim Pharmaceutical LLC v. Bio-Pharm., Inc., 310 F. Supp.3d 934 (N.D. Ill. 2018) (explaining that Illinois law permits plaintiffs to recover lost profits only if they can establish them "to a reasonable degree of certainty"; finding expert testimony sufficient to establish lost profits to the requisite degree of certainty); *Miranda v. Count of Lake,* 900 F.3d 335 (7th Cir. 2018) ("In Illinois, proximate cause must be established by expert testimony to a reasonable degree of medical certainty."); *Day v. United States*, 865 F.3d 1082 (8th Cir. 2017) (Under Arkansas law, a medical expert must testify that "the damages would not have occurred" without the defendant's negligence; expert's opinion "must be stated within a reasonable degree of medical certainty or probability.").

At the Spring, 2019 meeting, the Committee resolved that if anything is specifically said about the reasonable degree of certainty standard in a Committee Note, it should be limited to the topic of forensic evidence. The Committee Notes set forth in Part Three of this memo are written with the intent to be so limited.

G. How Would a Rule Regulating Overstatement Affect Experience-Based Experts?

One concern expressed by some Committee members at previous meetings is that an amendment regulating overstatement would be difficult to apply to the testimony of some experts who testify on the basis of experience. To address this concern, and to consider how a bar on overstatement could operate on experience-based experts, it might be best to proceed by example.

Let's take the facts of *Maryland Cas. Co. v. Therm-O-Disc., Inc.,* 137 F.3d 780 (4th Cir. 1998), a case involving a dispute over what caused a fire in a building. An electrician was allowed to testify that the fire was "caused by a malfunction in a thermostat" manufactured by the defendant. The expert stated that his opinion was based on "examination of the conditions inside the disputed switch and the application of principles of electrical engineering to those conditions." He also cited numerous works of technical literature in support of his methodology and explained how his experience led to his conclusion. The court of appeals found this testimony properly admitted. Would there be a different result under an amendment prohibiting overstatement? Specifically, would the statement "in my opinion, the fire was caused by a malfunction in a thermostat" be an overstatement?

It seems unlikely that such an opinion is an overstatement if it is properly grounded in a sufficient basis of information and based on accepted principles in the field --- as the court found. The whole point of the grounding of the opinion in experience and supporting literature is that the expert has a sufficient basis and proper methodology to opine on causation of an event.

So what would be the role of a prohibition on overstatement for such experience-based testimony? Let's take the same example, with the same grounding, but the expert tacks on extravagant claims, such as "without a doubt," or "to a scientific certainty," or "there is no

possibility of an alternate cause." Without knowing much about the area of expertise, it's still probably safe to assume that the expert's grounding in experience and supporting literature is not enough to opine on causation with absolute certainty (just as a forensic expert's grounding in experience is not enough to allow a conclusion of "scientific certainty").

Here is another example: *Kieffer v. Weston Land, Inc.,* 90 F.3d 1496 (10th Cir. 1996), in which the plaintiff alleged that he received an electrical shock from a Pepsi machine, that resulted in a burn and a broken shoulder. The Pepsi machine was removed from the site, and the plug removed, so it could not be tested by the plaintiff. The plaintiff's expert electrical engineer testified that if the wrong type of plug had been attached to the machine, "it could have produced a shock sufficient to cause" the plaintiff's injuries. The court found that testimony properly admitted under *Daubert*. It noted that the expert did not testify that the soda machine *actually* caused the injuries, (because the expert did not have a sufficient factual basis to make that conclusion). Rather, the expert merely theorized circumstances under which the machine could have created an electrical shock sufficient to cause the injuries. That opinion was permissible *because* it did not overstate the results. Given what the expert knew (and did not know), the only thing he could say was that the wrong type of plug could have caused the injuries. If he had stated, given his limited basis of information, that "the plaintiff's injuries had to be caused by the wrong type of plug on the Pepsi machine," that would have been an overstatement and excludable as such.

These examples show that an overstatement amendment can be usefully employed to reject extravagant claims by an experience-based expert. The court can look at principles, methods, and basis, and then determine whether the opinion as expressed by the expert goes beyond the foundation. Of course there will be line-drawing involved. But that can't be the sole reason for rejecting an amendment. Virtually all questions of evidentiary admissibility require some kind of line-drawing.

The Committee Notes to the drafting alternatives below add a paragraph discussing how a regulation on overstatement might apply to experience-based testimony.

H. Suggestion for a Change to Rule 702(d)

Judge Kuhl, the Liaison from the Standing Committee, has suggested a change to Rule 702(d) (reliable application) that is directed toward the problem of overstatement. That suggestion is as follows:

> (d) the ~~expert has reliably applied~~ expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Here is Judge Kuhl's explanation for her suggestion:

> It's not a large change to subpart (d), obviously. But by making the expert's conclusion the subject of the sentence, the language more clearly empowers the court to pass judgment on that conclusion. It seems clear (to me) that overstatement cannot be said to arise from *reliable* application of acceptable principles and methods.

Judge Schroeder has suggested a slightly different fix to Rule 702(d) based upon the same reasoning. His proposed language reads:

> (d) the ~~expert has reliably applied~~ testimony [opinion] is limited to a reliable application of the principles and methods to the facts of the case.

Reporter's Comment:

A change along these lines could be a helpful emphasis not only to get the court to focus on the overstatement problem, but more generally about the importance of looking at the expert's conclusion as well as the methodology --- the point made by the Supreme Court in *Joiner*. It could also serve to emphasize that the supportability of the conclusion is an admissibility requirement rather than a question of weight.

It is, as Judge Kuhl states, a minor change, so there is a question of whether it will be enough to address the problem of overstatement. But at a minimum it seems to be a very good complement to any new subdivision that addresses overstatement. On that possibility, it is included within the drafting alternatives at the end of this memo.

The difference between "reflects" and "is limited to" is, I think, largely one of style preference. Arguably "limited to" emphasizes that the language is, in fact, limiting, and so that might be useful.

II. A Discussion of the Admissibility/Weight Problem

As stated above, the Committee has been considering the possibility of an amendment to Rule 702 that would emphasize that the questions of sufficiency of basis (subdivision (b)) and reliability of application (subdivision (d)) are questions of admissibility and not weight. The Chair appointed a Rule 702 Subcommittee to study this matter and report to the Committee. That report was submitted to the Committee at the Fall, 2018 meeting.

The Committee's inquiry was in response to a law review article highlighting a number of cases that appear not to have read the Rule as it is intended. The Rule provides that the requirements of sufficient basis and reliable application must be treated as questions of admissibility, and so must be established by a preponderance of the evidence under Rule 104(a). But the cases cited in the law review article appeared to be treating these admissibility requirements as questions of weight.

A previous memo to the Committee on this subject took a deep dive into the cases that have been cited as the leading examples of courts ignoring the Rule 104(a) standard for questions of sufficiency of basis and reliability of application. The takeaway points from the case law survey were as follows:

● A court's declaration that sufficiency of basis and reliability of application are "questions of weight" is not necessarily a misapplication of Rule 702/104(a) in a particular case. That is because even under 104(a) there are disputes that will go to weight and not admissibility. When the proponent has met the preponderance standard and the opponent responds with some deficiency that does not sufficiently detract from the proponent's showing of a preponderance, then that deficiency is a question of weight and not admissibility --- under the preponderance standard.

● Because there remain questions of weight under Rule 104(a), one must be cautious in jumping to the conclusion that a court is ignoring Rule 702/104(a) when it states something like "the defendant's challenges to the expert's opinion present questions of weight and not admissibility." That is a different statement than a *broader* one such as "challenges to the sufficiency of an expert's basis raise questions of weight and not admissibility" (a misstatement made by circuit courts in a disturbing number of cases). But even where that broader statement is made, it does not mean that an error is being made in the specific case. It depends on what the challenges are and what the court *actually* has found in terms of the expert's basis and application. A court that makes the broader statement might actually have found both basis and application by a preponderance, even if the court does not say so. The fact that the court makes an overbroad, generalized statement is not ideal, but it's only dictum if the court actually ended up finding the standards to be met by a preponderance. Though, it could be argued that broad misstatements of the law can have a pernicious effect beyond the specific case.

● There is no doubt that in some circuits the courts routinely state the misguided notion that arguments about sufficiency of basis and reliability of application almost always go to weight and not admissibility. But in many of the reviewed cases, the expert arguably satisfied the Rule 104(a) standard anyway, so the court's cavalier treatment of Rule 702(b) and (d) appears to make no difference to the result. In other cases, it cannot be determined whether the court used the 104(a) or the 104(b) standard in assessing sufficiency of basis and application. Evaluation of the cases is muddled by two complications: 1) courts rarely specifically articulate the standard of proof that they are employing; and, more importantly, 2) there will be a line to draw for admissibility and weight no matter what standard of proof is employed.[15]

●That said, there are certainly a number of cases in which the court not only misstates the appropriate standard, but also misapplies it in the specific case--- by allowing experts to testify even though the proponent has not established more likely than not that there is a sufficient basis for the opinion and/or that the methodology has been reliably applied.

● While there surely are courts that are applying the Rule 104(b) standard to questions of basis and application, there are also courts that apply Rule 104(a) faithfully. For example, in *In re Wholesale Grocery Products Antitrust Litig.,* 946 F.3d 995 (8th Cir. 2019), the appellant argued that the trial court erred in evaluating the basis that the expert used to make a conclusion. The appellant argued that once the trial court found the methodology to be reliable (in this case, multiple regression analysis) any remaining issues were for the jury. But the court disagreed, stating that the gatekeeper must find that the expert had a proper factual foundation, and also had "an obligation to discern whether this particular methodology and reasoning, as it was being applied to these facts, passed muster." The court found no error in the trial court's exclusion of the expert testimony for failure to satisfy Rule 702(b) and (d). *See also Perez v. K & B Transportation, Inc.* (7th Cir. 2020) (expert on accident reconstruction was properly excluded --- *sua sponte* ---- because the report cited "barely any case specific evidence" and so was not supported by sufficient facts or data).

[15] A rough count of the cases highlighted in the law review article as being problematic (along with a number of recent cases decided after its publication) found the following: 1. Five circuit court opinions in which the court appeared to apply a Rule 104(b) standard to the questions of sufficiency of basis and reliable application; 2. Six circuit opinions in which the court used inappropriate Rule 104(b) language, but actually appeared to apply the Rule 104(a) standard to those questions; 3. Three district court opinions that wrongly applied the Rule 104(b) standard; 4. Four district court opinions that used Rule 104(b) language but actually appeared to review under Rule 104(a); and 5. Three district court opinions in which Rule 104(b) language was used and there is not enough to determine from the opinion which standard was actually applied.

Since the last meeting, the defense bar has submitted to the Committee several lengthy studies, as well as a number of letters, analyzing the case law and concluding that the admissibility requirements of Rule 702(b) and (d) have been ignored by many courts --- both in terms of statements of the law, and in application. Those reports and letters are attached to this memorandum.

Discussion at Previous Committee Meetings:

At previous meetings a number of Committee members observed that it would be useful to educate the courts that it is incorrect to make broad statements that sufficiency of basis and reliable application are questions of weight and not admissibility. Members also stated that it would be useful if courts could be encouraged to articulate the standard of proof that they were actually applying. But Committee members have not to date voted in favor of amending the text of the Rule to emphasize that the Rule 104(a) standard applies to all admissibility requirements of Rule 702.

The confounding problem of amending the text is that the Rule 104(a) standard *already* applies to these admissibility requirements --- as the court itself makes clear in *Daubert* and *Bourjaily.* Adding the preponderance standard to the text of the rule may raise questions about its applicability to all the other rules --- the Rule 104(a) standard applies to almost all the admissibility requirements in the Federal Rules, but it is not specifically stated in the text of any of them.

But there is also a counterargument: While Rule 104(a) applies to most FRE admissibility requirements, there is nothing in Rule 702 *itself* that directs the parties or the court to the preponderance standard. Indeed, there is *nothing in Rule 104(a) itself* that speaks to a preponderance standard --- that construct of Rule 104(a) comes from *Bourjaily* and from a footnote in *Daubert.* So a lot of thinking (and reading outside the Rules) needs to be done to get to applying the preponderance standard to the Rule 702(b) and (d) admissibility requirements. And while it is true that Rule 104(a) applies well beyond the admissibility requirements of Rule 702, it is in applying Rule 702 that most of the problems have occurred. (There is not much in the reported cases about disputes over the standard of proof in the admissibility requirements of the excited utterance exception, for example). So, if there is a problem that the courts are having in applying the general requirement to Rule 702 specifically, it makes sense to change the specific rule to remind the courts that the general requirement applies. And a proviso could be put in the Committee Note to say that no change is intended for any other rule, and that the Committee simply found it necessary to remind courts about the Rule 702 admissibility requirement because many courts have ignored them.

In previous meetings, the Committee seemed more receptive to the possibility that if Rule 702 were amended to deal with overstatement, the Committee Note to that amendment could provide instruction on the Rule 104(a) question --- including encouraging courts to specify that they are applying that standard.

Accordingly, the drafts set forth in Part Three below add Rule 104(a)-related instructions to the Committee Note that would accompany an amendment regarding overstatement. And, to continue discussion and in light of changes in Committee personnel, one of the drafting alternatives is to add language to Rule 702 specifically incorporating the Rule 104(a) standard.

Possible Confusion About the Helpfulness Standard in Rule 702

Beyond the issues surrounding the reliability requirements of Rule 702 (b)-(d), discussed above, there is a question in the case law about the application of the "helpfulness" standard of Rule 702(a). Rule 702(a) requires the court to find that the expert's testimony will "help the trier of fact to understand the evidence or determine a fact in issue." The operative word is "help". But there are some courts that have read into the rule a requirement that the testimony not only help, but "appreciably help" the trier of fact. *See, e.g., Cunningham v. Wong*, 704 F.3d 1143, 1167 (9th Cir. 2013) ("Admissible expert testimony is meant to provide the jury with 'appreciable help' in their determinations."); *United States v. Amaral,* 488 F.2d 1148 (9th Cir. 1973) (expert testimony on the unreliability of identifications was properly excluded as it did not "appreciably help" the jury). Courts following this potentially higher standard have cited to Wigmore's treatise on evidence to establish the "appreciable help" requirement as the "essential question" of expert admissibility. See *Keys v. Wash. Metro. Area Transit Auth.,* 577 F. Supp. 2d 283, 286 (D.D.C. 2008) ("As Professor Wigmore stated, the admissibility of expert testimony is guided by one essential question: 'On this subject can a jury from this person receive appreciable help?'") (citing WIGMORE ON EVIDENCE § 1923 (3d ed. 1940)). *See also Sullivan v. Alcatel-Lucent USA, Inc.,* 2014 U.S. Dist. LEXIS 97011, at *15 (N.D. Ill.*)* ("[T]he crucial question is, on this subject can a jury from this person receive appreciable help?'"); *Cage v. City of Chicago*, 979 F. Supp. 2d. 787, 834 (N.D. Ill. 2013) (expert must appreciably help).

Other courts, however, have found that there is no heightened standard of helpfulness for expert testimony that satisfies the other requirements of the rule. *See, e.g., United States ex rel. Morsell v. Symantec Corp.,* 2020 U.S. Dist. LEXIS 54847, *12 (D.D.C. 2020) ("[T]he 'help' requirement [from Rule 702] is satisfied where the expert testimony advances the trier of fact's understanding to any degree.") (quoting 29 Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure § 6264.1 (2015)); *United States v. Lamarre*, 248 F.3d 642, 648 (7th Cir. 2001) (testimony of the defendant's mental disability was helpful in a fraud case: "Trial courts are not compelled to exclude all expert testimony merely because it overlaps with matters within the jury's experience."); *United States v. King,* 898 F.3d 797, 805–06 (8th Cir. 2018) (in a pill mill case, the court uses the "to any degree" standard, and states: "While Dr. Roman acknowledged that he could not definitively state that any particular prescription was illegitimate absent more information, his opinion on the general operation of the clinic based on the accumulated evidence was still relevant. On the whole, Dr. Roman's opinion on the PMP charts advanced the trier of

fact's understanding of the clinical practices at KJ and Artex and how they differed from ordinary medical facilities."); *United States v. Archuleta*, 737 F.3d 1287, 1297 (10th Cir. 2013) (expert testimony about the operation of a gang was properly admitted: "At bottom, Archuleta simply fails to explain how relevant evidence, which no other witness covered, was unhelpful to the jury's understanding of the implications of his membership in the Tortilla Flats. See 29 Charles Alan Wright & Victor James Gold, Federal Practice and Procedure: Evidence § 6265, at 250 (1997) ("[T]he 'assist' requirement is satisfied where expert testimony advances the trier of fact's understanding to any degree.").").

There is some doubt about whether there is any daylight between "help" and "appreciably help" in the case results. For example, in *Keys,* the court quoted the Wigmore "appreciably help" language but ultimately excluded the expert's testimony because it was "irrelevant" --- it was offered to prove a fact that the opponent had conceded. And in *Sullivan, supra,* the "appreciably help" standard was employed but it was quite clear that the expert's testimony was not helpful at all --- as he just read out documents and applied his interpretation without any indication of how he came to those interpretations. The "conflict" appears to be more about what treatise a court uses rather than a real difference in the standard. The "appreciable help" cases quote Wigmore, while the "any help" cases quote Wright and Gold.

I haven't seen a case where a court held the following: "I find that the expert's testimony is helpful, but not appreciably so, and therefore I am excluding the evidence." Nor have I seen a case in which the court declared the reverse: "I am admitting the evidence because I find it helpful, though I cannot say it is appreciably helpful." In some sense, the problem of figuring out whether there is any difference in the standards as applied is similar to the admissibility/weight question: different standards are bandied about but in many cases it makes no difference to the result.

That said, it is troublesome that courts say they are applying a standard that is not supported by the text of the rule. The wayward language problem that applies to the admissibility/weight question is also an issue here. It is probably not problematic enough to justify an amendment to Rule 702 on its own, but it may be something to address as an "add-on." As discussed in the Rule 615 memo, an "add-on" is often a good idea because otherwise a mild improvement to a rule might never be made --- and if you get essentially one shot at a particular rule every decade or so, you might as well try to improve what you can.

So let us assume that the Committee finds it worthwhile to address the "help vs. appreciable help" question. Which of the two is the correct standard? It seems clear that the correct standard is "help" rather than "appreciably help" --- the obvious reason being that "appreciably" is not in the text of the Rule. Wigmore is the fountainhead of the "appreciably help" line of cases, and the problem with Wigmore as a source is that he was not construing the text of Rule 702 (unlike Wright

and Gold). The original Committee Note to Rule 702, while citing Wigmore, pointedly does not give any imprimatur to an "appreciably help" standard. The Committee Note states that the standard is whether the opinion "assist[s] the trier" and states that when expert opinions are excluded, "it is because they are unhelpful and therefore superfluous and a waste of time." So there is nothing in the text or note that supports a higher standard than "helpfulness."

Moreover, as a matter of policy, it would appear that an "appreciably help" standard is too strict (if actually applied as a higher threshold). It would allow a court to exclude reliable and helpful expert testimony on the mushy ground that it wasn't helpful *enough.* That would leave a lot to the discretion of a trial judge, and would make review quite difficult. Given all the other requirements for expert testimony (especially if Rule 104(a) is correctly applied to them), there is a risk that an "appreciable help" standard could operate as an extra hurdle that could make it too difficult to admit relevant and reliable expert testimony.

Now let us assume that something in the amendment should reject the "appreciable help" standard. How should the issue be addressed? It is pretty clear that it *cannot* be addressed in the text of the amendment. That is because the "appreciably help" courts have *added* a word that is not in text. So you can't cut anything out. And you definitely do not want to take out the word "help" for some other word, as there is a lot of case law on that word. And you definitely don't want to add something like:

> the expert's . . . knowledge will help . . . but it need not appreciably help.

It should be noted here that the problem to be addressed is not exactly the same as with the admissibility/weight question. As found above, some courts have read a preponderance of the evidence requirement out of Rule 702(b) and (d). But in fact there is nothing explicit about the standard of proof in Rule 702. To get to the preponderance of the evidence requirement, you have to read *Daubert, Bourjaily,* etc. So, adding text that specifies the preponderance of the evidence requirement can be thought to be a clarifying improvement. In contrast, as to the "appreciable help" requirement, courts are adding a requirement that is not in the text. There seems to be little to do in the text to clarify its meaning or to correct the error.

What this means is that if the "appreciable help" standard is to be addressed, it should probably be in the Note. **Here is some language that might work in the Note.**

> Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.

This language appears in brackets in the drafting alternatives below.

III. Drafts of a Possible Amendment to Rule 702

Part III sets forth a number of drafting options. Part III.A includes three draft amendments that would deal with the overstatement issue only. Part III.B contains two drafts that would address the Rule 104(a) weight/admissibility issue in rule text. Finally, Part III.C puts the preceding drafts together into a potential amendment that would address both the overstatement issue and the weight/admissibility issue.

A. Draft Amendments Addressing Overstatement

There are three drafts addressing overstatement. All three drafts would limit overstatement for all expert witnesses. Draft One attempts to limit overstatement with minor changes to the language in existing Rule 702(d) (the suggestion from Judge Kuhl and Judge Schroeder). Draft Two seeks to prevent an expert from "overstating" the conclusions that reliably may be drawn from his methods with the addition of a new subsection (e). Draft Three would preclude an expert from expressing a "degree of confidence" that is not supported by a reliable application of principles and methods in an alternate new subsection (e). Drafts Two and Three contain the minor change to Rule 702(d) included in Draft One.

The Committee Notes are slightly different given the different language addressed to overstatement. But each Committee Note provides the same guidance on the Rule 104(a)/104(b) question.

1. Draft One --- Modifying Rule 702(d) Only

Draft One would attempt to regulate expert overstatement through subtle changes to the language of Rule 702(d):

Rule 702. Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and~~and~~

(d) the ~~expert has reliably applied~~ expert's opinion [reflects] [is limited to] a reliable application of the principles and methods to the facts of the case.

Reporter's Note:

As stated above, "reflects" and "is limited to" are both nicely directed to overstatement, because they focus on the opinion as opposed to the application of a method; the latter, "is limited to" sounds slightly more proscriptive.

Draft Committee Note

Rule 702(d) has been amended to provide that a trial judge should exercise gatekeeping authority with respect to the opinion ultimately expressed by a testifying expert to ensure that it stays within the bounds of what can be concluded by a reliable application of the expert's methodology. Testimony that overstates the conclusion that an expert's methods can reliably support undermines the purposes of the Rule and requires intervention by the judge. Just as jurors are unable to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors lack a basis for assessing critically the conclusions of an expert that go beyond what the expert's methodology may reliably support.

The amendment is especially pertinent to testimony of forensic experts. Forensic experts often (explicitly or implicitly) express opinions about probabilities – for example, when comparing features to assess the possible origin of an evidence sample. It is important that the expert accurately inform the factfinder of the meaning of the results that are reached. A forensic expert who states or implies that a method or conclusion is "infallible," "certain," or "error-free" will by definition be stating an opinion that cannot reasonably be drawn, because such statements cannot be empirically supported. Also, many forensic processes do not comport with the scientific method, so testimony that such a process is "scientific" is not supported --- and is prohibited under this amendment. Under the amendment the expert must accurately state the meaning of the results found by the expert. Accurate testimony will ordinarily include a fair assessment of the rate of error of the methodology employed, based where appropriate on empirical studies of how often the method produces correct results, as well as other relevant limitations inherent in the methodology. Claims of a match, or of probabilities based only on the expert's experience, without empirically valid support, would not be admissible because they are not reasonably drawn from the method used.

Claims that a forensic expert expresses an opinion to a "reasonable degree of [scientific/forensic] certainty" should be strictly scrutinized under the amendment. That phrase has no scientific meaning; it was developed by lawyers, not scientists. See National Commission on Forensic Science, *Testimony Using the Term "Reasonable Scientific Certainty", https://www.justice.gov/ncfs/file/795146/download* ("Rather than use 'reasonable…certainty' terminology, experts should make a statement about the examination itself, including an expression of the uncertainty in the measurement or in the data. The expert should state the bases for that opinion (e.g., the underlying information, studies, observations) and the limitations relating

to the results of the examination."). Examples of properly verified conclusions, when supported by the data and methodology, include statements such as "cannot be ruled out" or "more likely than not." Of course this amendment does not bar testimony that satisfies a state law standard of proof in cases where state law provides the rule of decision.

Nothing in the amendment requires the court to nitpick an expert's opinion in order to reach a perfect expression of what the basis and methodology can support. The Rule 104(a) standard does not require perfection. On the other hand, it does not permit the expert to make extravagant claims that are clearly unsupported by the expert's basis and methodology.

The admissibility requirements of Rule 702, are evaluated by the court under Rule 104(a), so the proponent must establish that the admissibility standards are met by a preponderance of the evidence. *See Bourjaily v. United States,* 483 U.S. 171 (1987). Unfortunately many courts have held or declared that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a).

Of course some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds by a preponderance of the evidence that an expert has relied on sufficient studies to support an opinion, the fact that the expert has not read every single study that exists will likely raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis *generally* go to weight and not admissibility. Rather it means that once the court has found the admissibility requirement to be met by a preponderance of the evidence, any remaining attack by the opponent will go only to the weight of the evidence. In order to avoid confusion on this subject, it is useful for the trial court to specify that it is applying the Rule 104(a) preponderance standard to all the admissibility requirements of Rule 702.

[Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.]

2. Draft Two -- "Overstatement" Limitation in New Rule 702(e)

Draft Two would seek to limit "overstatement" more overtly through the addition of a new subsection (e):

Rule 702. Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; ~~and~~

(d) the ~~expert has reliably applied~~ expert's opinion [reflects] [is limited to] a reliable application of the principles and methods to the facts of the case; and

(e) the expert does not overstate the conclusions that reasonably may be drawn from a reliable application of the expert's principles and methods.

Draft Committee Note

Rule 702 has been amended to provide that an expert may "not overstate" the conclusions that reasonably may be drawn from a reliable application of the expert's principles and methods, and emphasizes that the court must regulate conclusions of experts even if they are employing a reliable method. Testimony that inaccurately states the conclusion that an expert's methods can reliably support undermines the purposes of the Rule and requires intervention by the judge as gatekeeper. Just as jurors are unable to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors lack a basis for assessing critically the claims of an expert that overstate what that the expert's methodology may reliably support.

The amendment is especially pertinent to testimony of forensic experts. Forensic experts often (explicitly or implicitly) express opinions about probabilities – for example, when comparing features to assess the possible origin of an evidence sample. It is important that the expert accurately inform the factfinder of the meaning of the results that are reached. A forensic expert who states or implies that a method or conclusion is "infallible," "certain," or "error-free" will by definition be stating an opinion that cannot reasonably be drawn, because such statements cannot be empirically supported. Also, many forensic processes do not comport with the scientific method, so testimony that such a process is "scientific" is not supported --- and is prohibited under this amendment. Under the amendment the expert must accurately state the meaning of the results found by the expert. Accurate testimony will ordinarily include a fair assessment of the rate of error of the methodology employed, based where appropriate on empirical studies of how often the method produces correct results, as well as other relevant limitations inherent in the

methodology. Claims of a match, or of probabilities based only on the expert's experience, without empirically valid support, would not be admissible because they are not reasonably drawn from the method used.

Claims that a forensic expert expresses an opinion to a "reasonable degree of [scientific/forensic] certainty" should be strictly scrutinized under the amendment. That phrase has no scientific meaning; it was developed by lawyers, not scientists. See National Commission on Forensic Science, *Testimony Using the Term "Reasonable Scientific Certainty", https://www.justice.gov/ncfs/file/795146/download* ("Rather than use 'reasonable…certainty' terminology, experts should make a statement about the examination itself, including an expression of the uncertainty in the measurement or in the data. The expert should state the bases for that opinion (e.g., the underlying information, studies, observations) and the limitations relating to the results of the examination."). Examples of properly verified conclusions, when supported by the data and methodology, include statements such as "cannot be ruled out" or "more likely than not." Of course this amendment does not bar testimony that satisfies a state law standard of proof in cases where state law provides the rule of decision.

Nothing in the amendment requires the court to nitpick an expert's opinion in order to reach a perfect expression of what the basis and methodology can support. The Rule 104(a) standard does not require perfection. On the other hand, it does not permit the expert to make extravagant claims that are clearly unsupported by the expert's basis and methodology.

A requirement of a conclusion that does not overstate the results is integrally related to the admissibility requirements of Rule 702(b)-(d), all of which are intended to assure that an expert's opinion is helpful. In this regard, Rule 702(d) has been amended slightly to emphasize that the trial court has an obligation to assure that an expert's conclusion must be soundly based in sufficient facts or data and a reliable methodology, reliably applied.

The admissibility requirements of Rule 702, are evaluated by the court under Rule 104(a), so the proponent must establish that the admissibility standards are met by a preponderance of the evidence. *See Bourjaily v. United States,* 483 U.S. 171 (1987). Unfortunately many courts have held or declared that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a).

Of course some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds by a preponderance of the evidence that an expert has relied on sufficient studies to support an opinion, the fact that the expert has not read every single study that exists will likely raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis *generally* go to weight and not admissibility. Rather it means that once the court has found the admissibility requirement to be met by a preponderance of the evidence, any remaining attack by the opponent will go only to the weight of the evidence. In order to avoid confusion on this subject, it is useful for the trial court to specify that it is applying the Rule 104(a) preponderance standard to all the admissibility requirements of Rule 702.

[Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.]

Reporter's Comment:

If there is a separate subdivision on overstatement, is it useful to retain the proposed change to (d) --- that the opinion reflects or is limited to the reliable application of the method? Arguably the answer is yes, for purposes of emphasis, and also as a reminder more broadly that a court must police conclusions as well as methodology, as *Joiner* instructs. So a paragraph was added to the note, above, to explain why it is in the rule in addition to the language on overstatement.

3. Draft Three – "Degree of Confidence" Limit in New Rule 702(e)

Draft Three would also add a new subsection (e) to Rule 702, this time focused on the "degree of confidence" expressed by an expert:

Rule 702. Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; ~~and~~

(d) the ~~expert has reliably applied~~ expert's opinion [reflects] [is limited to] a reliable application of the principles and methods to the facts of the case; and

(e) the expert does not express a degree of confidence that is unsupported by a reliable application of the principles and methods.

Draft Committee Note

Rule 702 has been amended to provide that an expert may not express a degree of confidence in an opinion that is unsupported by a reliable application of the expert's principles and methods, and emphasizes that the court must regulate opinions of experts even if they are

employing a reliable method. Testimony that inaccurately states the conclusion that an expert's methods can reliably support undermines the purposes of the Rule and requires intervention by the judge as gatekeeper. Just as jurors are unable to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors lack a basis for assessing critically the claims of an expert that overstate what the expert's methodology may reliably support.

The amendment is especially pertinent to testimony of forensic experts. Forensic experts often (explicitly or implicitly) express opinions about probabilities – for example, when comparing features to assess the possible origin of an evidence sample. It is important that the expert accurately inform the factfinder of the meaning of the results that are reached. A forensic expert who states or implies that a method or conclusion is "infallible," "certain," or "error-free" will by definition be stating an opinion that cannot reasonably be drawn, because such statements cannot be empirically supported. Also, many forensic processes do not comport with the scientific method, so testimony that such a process is "scientific" is not supported --- and is prohibited under this amendment. Under the amendment the expert must accurately state the meaning of the results found by the expert. Accurate testimony will ordinarily include a fair assessment of the rate of error of the methodology employed, based where appropriate on empirical studies of how often the method produces correct results, as well as other relevant limitations inherent in the methodology. Claims of a match, or of probabilities based only on the expert's experience, without empirically valid support, would not be admissible because they are not reasonably drawn from the method used.

Claims that a forensic expert expresses an opinion to a "reasonable degree of [scientific/forensic] certainty" should be strictly scrutinized under the amendment. That phrase has no scientific meaning; it was developed by lawyers, not scientists. See National Commission on Forensic Science, *Testimony Using the Term "Reasonable Scientific Certainty", https://www.justice.gov/ncfs/file/795146/download* ("Rather than use 'reasonable…certainty' terminology, experts should make a statement about the examination itself, including an expression of the uncertainty in the measurement or in the data. The expert should state the bases for that opinion (e.g., the underlying information, studies, observations) and the limitations relating to the results of the examination."). Examples of properly verified conclusions, when supported by the data and methodology, include statements such as "cannot be ruled out" or "more likely than not." Of course this amendment does not bar testimony that satisfies a state law standard of proof in cases where state law provides the rule of decision.

Nothing in the amendment requires the court to nitpick an expert's opinion in order to reach a perfect expression of what the basis and methodology can support. The Rule 104(a) standard does not require perfection. On the other hand, it does not permit the expert to make extravagant claims that are clearly unsupported by the expert's basis and methodology.

A requirement that testimony does not overstate an expert's degree of confidence is integrally related to the admissibility requirements of Rule 702(b)-(d), all of which are intended to assure that an expert's opinion is helpful. In this regard, Rule 702(d) has been amended slightly to emphasize that the trial court has an obligation to assure that an expert's conclusion must be soundly based in sufficient facts or data and a reliable methodology, reliably applied.

The admissibility requirements of Rule 702, are evaluated by the court under Rule 104(a), so the proponent must establish that the admissibility standards are met by a preponderance of the evidence. *See Bourjaily v. United States,* 483 U.S. 171 (1987). Unfortunately many courts have held or declared that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a).

Of course some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds by a preponderance of the evidence that an expert has relied on sufficient studies to support an opinion, the fact that the expert has not read every single study that exists will likely raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis *generally* go to weight and not admissibility. Rather it means that once the court has found the admissibility requirement to be met by a preponderance of the evidence, any remaining attack by the opponent will go only to the weight of the evidence. In order to avoid confusion on this subject, it is useful for the trial court to specify that it is applying the Rule 104(a) preponderance standard to all the admissibility requirements of Rule 702.

[Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.]

B. Clarifying the Applicability of the Rule 104(a) Preponderance Standard to the Rule 702 Admissibility Requirements in Rule Text

Let's assume that the Committee decides to specify in text that a preponderance standard applies to its admissibility requirements. How best to implement the change?

It would seem that the most effective way to highlight the standard of proof is to put it at the beginning or the end of the Rule, so that it clearly applies to *all* the Rule's admissibility requirements. Adding the preponderance standard only to subdivisions (b) and (d) could create the negative inference that the standard does *not* apply to the other requirements, such as qualifications, helpfulness, and reliable methodology.

On the other hand, restating the Rule 104(a) preponderance standard at the beginning of all other requirements would significantly alter the existing structure of Rule 702 by taking the expert's qualification out of the introductory sentence and placing it in its own new subsection at the very end of the Rule. As an alternative, adding language to the existing introductory sentence immediately following the qualification requirement would target only the current (a)-(d) requirements (thus excluding the qualification requirement from the clarified standard of proof) and would result in less disruption in the familiar structure of the Rule. Because the preponderance standard already applies to all the requirements of Rule 702 via Rule 104(a), emphasizing the standard only with respect to requirements (a)-(d) for which federal courts have failed to apply it would not necessarily create a negative inference with respect to the qualification requirement and could be a viable alternative. Two draft amendments that follow reflect these alternatives.

1. Draft One – Adding Preponderance Language to All Rule 702 Requirements

If the Committee wanted to pursue a preponderance amendment that captures all Rule 702 requirements, , it would seem optimal to locate the amended language at the beginning of the Rule. Placing the standard at the beginning provides a stronger highlight, and moreover placing the standard at the end would mean that it would probably have to be in its own hanging paragraph. And restylists hate a hanging paragraph.

Placing the preponderance standard at the beginning would look like this:

Rule 702. Testimony by Expert Witnesses.

> For a witness to testify as an expert in the form or an opinion or otherwise, the court must find the following requirements to be established by a preponderance of the evidence: ~~A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form or an opinion or otherwise, if:~~

(a) the ~~expert's~~ witness's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; ~~and~~

(d) the ~~expert~~ witness has reliably applied the principles and methods to the facts of the case~~.~~ ; and

(e) the witness is qualified as an expert by knowledge, skill, experience, training, or education.

Comments:

1. The change has the collateral benefit of clarifying that qualification is an admissibility requirement governed by Rule 104(a). The current rule buries the qualification requirement in the introductory sentence to the rule.

2. As an admissibility requirement, we placed qualifications at the end. Logically, perhaps, it should go in the front. That's what the restylist suggested. But to do so would disrupt electronic searches on a rule that has been cited hundreds of times. Specifically, since 2000, appellate cases only: more than 800 citations to 702(a); more than 600 citations to Rule 702(b); more than 400 citations to 702(c); and more than 150 citations to Rule 702(d).

Draft Committee Note

Rule 702 has been amended to clarify and emphasize that the admissibility requirements set forth in the Rule must be established by a preponderance of the evidence. *See* Rule 104(a). Of course the Rule 104(a) standard applies to most of the admissibility requirements set forth in the Evidence Rules. *See Bourjaily v. United States,* 483 U.S. 171 (1987). But unfortunately many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a), and are rejected by this amendment.

There is no intent to raise any negative inference as to the applicability of the Rule 104(a) standard of proof for other rules. The Committee concluded that emphasizing the preponderance standard in Rule 702 specifically was made necessary by the courts that have ignored it when applying that Rule.

Of course some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds by a preponderance of the evidence that an expert has relied on sufficient studies to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis *generally* go to weight and not admissibility. Rather it means that once the court has found the admissibility requirement to be met by a preponderance of the evidence, any attack by the opponent will go only to the weight of the evidence.

[Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.]

2. Draft Two – Emphasizing the Preponderance Standard for Subsections (a)-(d) Only (Excluding Expert Qualification from Clarified Standard)

Rule 702. Testimony by Expert Witnesses.

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates by a preponderance of the evidence that:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Comments:

1. The benefit of this draft is that the qualification requirement remains at the very beginning of the Rule where it logically belongs and that the clarified standard is added without disrupting the existing structure of Rule 702 with which courts and litigants are familiar.
2. The downside of this amendment is that the textual preponderance standard does not apply to the qualification requirement that precedes it. If this draft were chosen, the Committee

note would need to emphasize the trial judge's continuing obligation to determine qualification by a preponderance pursuant to Rule 104(a).

Draft Committee Note

Rule 702 has been amended to clarify and emphasize that the admissibility requirements set forth in the Rule must be established by a preponderance of the evidence. *See* Rule 104(a). Of course the Rule 104(a) standard applies to most of the admissibility requirements set forth in the Evidence Rules. *See Bourjaily v. United States,* 483 U.S. 171 (1987). But unfortunately many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a), and are rejected by this amendment.

Although the clarifying amendment emphasizes the application of the preponderance standard to the requirements of sufficiency of basis and application of the expert's methodology where some courts have failed to apply it, the Rule 104(a) preponderance standard continues to govern a trial judge's determination of the expert's qualifications as well. Likewise, there is no intent to raise any negative inference as to the applicability of the Rule 104(a) standard of proof for other rules by clarifying the standard with respect to Rule 702. The Committee concluded that emphasizing the preponderance standard as to Rule 702(b)-(d) specifically was made necessary by the courts that have ignored it when applying those provisions.

Of course some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds by a preponderance of the evidence that an expert has relied on sufficient studies to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis *generally* go to weight and not admissibility. Rather it means that once the court has found the admissibility requirement to be met by a preponderance of the evidence, any attack by the opponent will go only to the weight of the evidence.

[Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.]

C. Regulating Overstatement And Articulating the Preponderance Standard in Rule Text

Finally, the Committee could propose an amendment to Rule 702 that would regulate the problem of expert overstatement and add an explicit preponderance standard to the text of the Rule. There are several possibilities for combining the above-described drafts. The two drafts below illustrate the ways in which both changes could be combined in a proposed amendment.

1. Draft One – Making the Preponderance Standard Applicable to All Rule 702 Admissibility Requirements and Adding an Overstatement Limitation

Rule 702. Testimony by Expert Witnesses.

For a witness to testify as an expert in the form or an opinion or otherwise, the court must find the following requirements to be established by a preponderance of the evidence: ~~A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form or an opinion or otherwise, if:~~

(a) the ~~expert's~~ witness's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; ~~and~~

(d) the ~~expert~~ witness's ~~has reliably applied~~ opinion [reflects] [is limited to] a reliable application of the principles and methods to the facts of the case~~.~~ ;

(e) the witness does not overstate the conclusions that reasonably may be drawn from a reliable application of the principles and methods [or the expert does not express a degree of confidence that is unsupported by a reliable application of the principles and methods];and

(f) the witness is qualified as an expert by knowledge, skill, experience, training, or education.

Draft Committee Note

Rule 702 has been amended in two respects. First, the Rule has been amended to clarify and emphasize that the admissibility requirements set forth in the Rule must be established by a preponderance of the evidence. *See* Rule 104(a). Of course the Rule 104(a) standard applies to most of the admissibility requirements set forth in the Evidence Rules. *See Bourjaily v. United States,* 483 U.S. 171 (1987). But unfortunately many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a), and are rejected by this amendment. There is no intent to raise any negative inference as to the applicability of the Rule 104(a) standard of proof for other rules. The Committee concluded that emphasizing the preponderance standard in Rule 702 specifically was made necessary by the courts that have ignored it when applying that Rule.

Of course some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds by a preponderance of the evidence that an expert has relied on sufficient studies to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis *generally* go to weight and not admissibility. Rather it means that once the court has found the admissibility requirement to be met by a preponderance of the evidence, any attack by the opponent will go only to the weight of the evidence.

Rule 702 has also been amended to provide that an expert may "not overstate" the conclusions that reasonably may be drawn from a reliable application of the expert's principles and methods [or "to provide that an expert may not express a degree of confidence that cannot be supported by a reliable application of the expert's principles and methods."], and emphasizes that the court must regulate conclusions of experts even if they are employing a reliable method.. Testimony that inaccurately states the conclusion [or "the degree of confidence"] that an expert's methods can reliably support undermines the purposes of the Rule and requires intervention by the judge as gatekeeper. Just as jurors are unable to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors lack a basis for assessing critically the conclusions that an expert's methodology may reliably support [or "for assessing critically the degree of confidence an expert's methodology can support"].

The amendment is especially pertinent to testimony of forensic experts. Forensic experts often (explicitly or implicitly) express opinions about probabilities – for example, when comparing features to assess the possible origin of an evidence sample. It is important that the expert accurately inform the factfinder of the meaning of the results that are reached. A forensic expert who states or implies that a method or conclusion is "infallible," "certain," or "error-free" will by definition be stating an opinion that cannot reasonably be drawn, because such statements cannot be empirically supported. Also, many forensic processes do not comport with the scientific method, so testimony that such a process is "scientific" is not supported --- and is prohibited under this amendment. Under the amendment the expert must accurately state the meaning of the results found by the expert. Accurate testimony will ordinarily include a fair assessment of the rate

of error of the methodology employed, based where appropriate on empirical studies of how often the method produces correct results, as well as other relevant limitations inherent in the methodology. Claims of a match, or of probabilities based only on the expert's experience, without empirically valid support, would not be admissible because they are not reasonably drawn from the method used.

Claims that a forensic expert expresses an opinion to a "reasonable degree of [scientific/forensic] certainty" should be strictly scrutinized under the amendment. That phrase has no scientific meaning; it was developed by lawyers, not scientists. See National Commission on Forensic Science, *Testimony Using the Term "Reasonable Scientific Certainty", https://www.justice.gov/ncfs/file/795146/download* ("Rather than use 'reasonable…certainty' terminology, experts should make a statement about the examination itself, including an expression of the uncertainty in the measurement or in the data. The expert should state the bases for that opinion (e.g., the underlying information, studies, observations) and the limitations relating to the results of the examination."). Examples of properly verified conclusions, when supported by the data and methodology, include statements such as "cannot be ruled out" or "more likely than not." Of course this amendment does not bar testimony that satisfies a state law standard of proof in cases where state law provides the rule of decision.

Nothing in the amendment requires the court to nitpick an expert's opinion in order to reach a perfect expression of what the basis and methodology can support. The Rule 104(a) standard does not require perfection. On the other hand, it does not permit the expert to make extravagant claims that are clearly unsupported by the expert's basis and methodology.

A requirement of a conclusion that does not overstate the expert's results [or "A requirement that testimony does not overstate an expert's degree of confidence"] is integrally related to the admissibility requirements of Rule 702(b)-(d), all of which are intended to assure that an expert's opinion is helpful. In this regard, Rule 702(d) has been amended slightly to emphasize that the trial court has an obligation to assure that an expert's conclusion must be soundly based in sufficient facts or data and a reliable methodology, reliably applied.

[Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.]

2. Draft Two -- Emphasizing Preponderance Standard for Subsections (a)-(d) Only (Excluding Expert Qualification from Clarified Standard) And Regulating Overstatement

Rule 702. Testimony by Expert Witnesses.

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates by a preponderance of the evidence that:

(a) the ~~expert's~~ witness's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the ~~expert~~ witness's ~~has reliably applied~~ opinion [reflects] [is limited to] a reliable application of the principles and methods to the facts of the case; and

(e) the witness does not overstate the conclusions that reasonably may be drawn from a reliable application of the principles and methods [or the witness does not express a degree of confidence that is unsupported by a reliable application of the principles and methods].~~.~~

Draft Committee Note

Rule 702 has been amended in two respects. First, the Rule has been amended to clarify and emphasize that the admissibility requirements set forth in the Rule must be established by a preponderance of the evidence. *See* Rule 104(a). Of course the Rule 104(a) standard applies to most of the admissibility requirements set forth in the Evidence Rules. *See Bourjaily v. United States,* 483 U.S. 171 (1987). But unfortunately many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are generally questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a), and are rejected by this amendment. Although the clarifying amendment emphasizes the application of the preponderance standard to the requirements of sufficiency of basis and application of the expert's methodology where some courts have failed to apply it, the Rule 104(a) preponderance standard continues to govern a trial judge's determination of the expert's qualifications as well. Likewise, there is no intent to raise any negative inference as to the applicability of the Rule 104(a) standard of proof for other rules by clarifying the standard with respect to Rule 702. The Committee concluded that emphasizing the preponderance standard in Rule 702 specifically was made necessary by the courts that have ignored it when applying that Rule.

Of course some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds by a preponderance of the evidence that an expert has relied on sufficient studies to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis *generally* go to weight and not admissibility. Rather it means that once the court has found the admissibility requirement to be met by a preponderance of the evidence, any attack by the opponent will go only to the weight of the evidence.

Rule 702 has also been amended to provide that an expert may "not overstate" the conclusions that reasonably may be drawn from a reliable application of the expert's principles and methods [or "to provide that an expert may not express a degree of confidence that cannot be supported by a reliable application of the expert's principles and methods."], and emphasizes that the court must regulate conclusions of experts even if they are employing a reliable method.. Testimony that inaccurately states the conclusion [or "the degree of confidence"] that an expert's methods can reliably support undermines the purposes of the Rule and requires intervention by the judge as gatekeeper. Just as jurors are unable to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors lack a basis for assessing critically the conclusions that an expert's methodology may reliably support [or "for assessing critically the degree of confidence an expert's methodology can support"].

The amendment is especially pertinent to testimony of forensic experts. Forensic experts often (explicitly or implicitly) express opinions about probabilities – for example, when comparing features to assess the possible origin of an evidence sample. It is important that the expert accurately inform the factfinder of the meaning of the results that are reached. A forensic expert who states or implies that a method or conclusion is "infallible," "certain," or "error-free" will by definition be stating an opinion that cannot reasonably be drawn, because such statements cannot be empirically supported. Also, many forensic processes do not comport with the scientific method, so testimony that such a process is "scientific" is not supported --- and is prohibited under this amendment. Under the amendment the expert must accurately state the meaning of the results found by the expert. Accurate testimony will ordinarily include a fair assessment of the rate of error of the methodology employed, based where appropriate on empirical studies of how often the method produces correct results, as well as other relevant limitations inherent in the methodology. Claims of a match, or of probabilities based only on the expert's experience, without empirically valid support, would not be admissible because they are not reasonably drawn from the method used.

Claims that a forensic expert expresses an opinion to a "reasonable degree of [scientific/forensic] certainty" should be strictly scrutinized under the amendment. That phrase has no scientific meaning; it was developed by lawyers, not scientists. See National Commission on Forensic Science, *Testimony Using the Term "Reasonable Scientific Certainty", https://www.justice.gov/ncfs/file/795146/download* ("Rather than use 'reasonable…certainty' terminology, experts should make a statement about the examination itself, including an expression of the uncertainty in the measurement or in the data. The expert should state the bases

for that opinion (e.g., the underlying information, studies, observations) and the limitations relating to the results of the examination."). Examples of properly verified conclusions, when supported by the data and methodology, include statements such as "cannot be ruled out" or "more likely than not." Of course this amendment does not bar testimony that satisfies a state law standard of proof in cases where state law provides the rule of decision.

Nothing in the amendment requires the court to nitpick an expert's opinion in order to reach a perfect expression of what the basis and methodology can support. The Rule 104(a) standard does not require perfection. On the other hand, it does not permit the expert to make extravagant claims that are clearly unsupported by the expert's basis and methodology.

A requirement of a conclusion that does not overstate the expert's results [or "A requirement that testimony does not overstate an expert's degree of confidence"] is integrally related to the admissibility requirements of Rule 702(b)-(d), all of which are intended to assure that an expert's opinion is helpful. In this regard, Rule 702(d) has been amended slightly to emphasize that the trial court has an obligation to assure that an expert's conclusion must be soundly based in sufficient facts or data and a reliable methodology, reliably applied.

[Rule 702 requires that the expert's knowledge must "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.]

TAB 2B

THIS PAGE INTENTIONALLY BLANK

FORENSIC CASE DIGEST

2008-Present

Prepared by Daniel J. Capra

Several Committee members have expressed an interest in development of a case digest on forensic expert testimony, as a way to evaluate the scope of the problem --- particular the problem of an expert opinion that overstates the conclusion that can reliably be drawn from the methodology. The Reporter has prepared a digest on federal appellate cases and federal district court cases. The digests run from 2008 to date --- 2008 was picked because that was when the first challenges in the scientific community were voiced. (I threw in a couple of older cases that I wrote up for other projects).

The case digest has gotten so large that I decided to put it in its own file.

A. Federal Appellate Cases on Forensic Evidence

Acid-phosphate testing: *United States v. Rodriguez,* 581 F.3d 775 (8th Cir. 2009): The court affirmed a conviction for kidnapping resulting in death, finding no abuse of discretion in permitting a government pathologist to testify about acid-phosphate tests on the victim's body, indicating the presence of semen. The pathologist "did not invent acid-phosphate testing; he testified to attending national medical conferences and reviewing scientific literature on the topic." The expert's conclusion was based on living people, and the defendant pointed out that there was uncertainty about the timing of the chemical process on a corpse. But the court found that this variable went to weight and not admissibility.

Ballistics --- Overstatement Problem: *United States v. Williams,* 506 F.3d 151 (2nd Cir. 2007): The court found no abuse of discretion in allowing a ballistics expert to testify to a "match." The court found that the district court was not required to hold a *Daubert* hearing on the admissibility of ballistics evidence, as the district court had relied on precedent:

> We think that *Daubert* was satisfied here. When the district court denied a separate hearing it went through the exercise of considering the use of ballistic expert testimony in other cases. Then, before the expert's testimony was presented to the jury, the government provided an exhaustive foundation for Kuehner's expertise including: her service as a firearms examiner for approximately twelve years; her receipt of "hands-on training" from her section supervisor; attendance at seminars on firearms identification, where firearms examiners from the United States and the international community gather to present papers on current topics within the field; publication of her writings in a peer review journal; her obvious expertise with toolmark identification; her experience examining approximately

> 2,800 different types of firearms; and her prior expert testimony on between 20 and 30 occasions. Under the circumstances, we are satisfied that the district court effectively fulfilled its gatekeeping function under *Daubert.*

The court did impose a qualification on admitting ballistics testimony:

> We do not wish this opinion to be taken as saying that any proffered ballistic expert should be routinely admitted. *Daubert* [did not] "grandfather" or protect from *Daubert* scrutiny evidence that had previously been admitted under *Frye*. Thus, expert testimony long assumed reliable before Rule 702 must nonetheless be subject to the careful examination that *Daubert* and *Kumho Tire* require. * * * Because the district court's inquiry here did not stop when the separate hearing was denied, but went on with an extensive consideration of the expert's credentials and methods, the jury could, if it chose to do so, rely on her testimony which was relevant to the issues in the case. We find that the gatekeeping function of *Daubert* was satisfied and that there was no abuse of discretion.

Ballistics: *United States v. Mikos,* 539 F.3d 706 (7th Cir. 2008): The court found no error in admitting the testimony of a ballistics expert that the defendant's revolver was one of the models that could have been the murder weapon. The expert disclosed that at least 15 other models could have fired the bullets, *so he did not overstate his findings*. The expert reliably applied the data he obtained to conclude that the rifling on the bullets did not rule out the defendant's make and model of gun.

Ballistics --- testimony of a match allowed without comment: *United States v. Brown*, 2020 WL 5088074 (7th Cir. Aug. 28, 2020): Here is the court's description of the testimony of four ballistics experts (three state experts and one from the FBI):

> Pomerance examined 9mm cartridge casings that were recovered from the area where Cordale Hampton and his uncle were shot. He compared them to 9mm cartridge casings from an October 2005 shooting. The individual characteristics ***were the same on both, and so he determined that they were fired by the same firearm***. Pomerance also compared a 5.7 x 28mm cartridge casing from the Eddie Jones shooting to a 5.7 x 28mm cartridge casing from the Simmons shooting. ***The markings matched.*** Murray ***found a match*** between 5.7 x 28mm casings from the Jonte Robinson shooting and comparable casings from the Simmons shooting. Murray also found that a firearm seized from Bush's storage locker ***fired the cartridge casings*** from the Eddie Jones shooting. Stevens ***found a match*** between .40 caliber cartridge casing from the Wilber Moore murder and the same type from the October 2005 shooting. ***Jiggets testified that the .45 caliber cartridge casings recovered from the Bluitt/Neeley murder scene matched casings*** found at the Daniels murder scene.

The defendants challenged the ballistics match testimony by relying on the PCAST report. The Court of Appeals stated that the trial court "chose not to give it dispositive effect, and that choice was within its set of options."

As to the reliability of ballistics testing, the court declared that it has "almost uniformly accepted by federal courts." See, *e.g.*, *Cazares*, 788 F.3d at 989. It noted that "several reliability studies have been conducted on it" and although the error rate varies from study to study, "overall it is low—in the single digits." So the court found no abuse of discretion in admitting the testimony. The court did not comment at all on the overstatements made by the experts.

Ballistics --- some limitation on overstatement: *United States v. Parker*, 871 F.3d 590 (8th Cir. 2017): In a trial on charges of illegal possession of firearms, the defendant argued that the trial court erred in allowing testimony of a ballistics expert. The trial court prohibited the expert from testifying that she was "100% sure" or "certain" that the relevant guns matched the relevant shell casings. The defendant argued that the expert violated that restriction by describing the general reliability of the ballistics testing process. But the court, after reviewing the trial transcript, concluded that the expert's testimony "stayed within the bounds set by the district court."

Ballistics --- Overstatement--- reasonable degree of ballistics certainty: *United States v. Johnson,* 875 F.3d 1265 (9th Cir. 2017): In a felon-gun possession case, the expert testified that two bullets matched to a "reasonable degree of ballistics certainty." The court found that this "qualification" was sufficient to justify admission of the expert testimony – i.e., the expert did not state, categorically that there was a match. The court rejected the defendant's argument --- based on a report and recommendation from National Commission of Forensic Science --- that the "reasonable degree of ballistics certainty" test was itself insupportable and misleading. The court did not address the Commission report but instead simply relied on lower court cases employing the standard and stated that there was "only one case in which a 'reasonable degree of ballistics certainty' was found to be too misleading." That case is *United States v. Glynn*, 578 F.Supp.2d 567 (S.D.N.Y. 2008). Finally, the court rejected the defendant's argument that ballistics is inherently unreliable and fails to satisfy the *Daubert* factors. But instead of rebutting the defendant's attack on ballistics as unscientific, the court simply relied on precedent and stated that the defendant had not cited a case in which ballistics testimony was "excluded altogether."

Cell Site Location --- regulation of overstatement: *United States v. Hill,* 818 F.3d 289 (7th Cir. 2017): The court held that the science and methods supporting historical cell site location are understood and well-documented. But the court found it important that the trial expert "emphasized that Hill's cell phone's use of a cell site did not mean that Hill was right at that tower or at any particular spot near that tower." It concluded that the expert's disclaimer "save[d] his testimony" because historical cell-site analysis can only "show with sufficient reliability that a phone was in a general area, especially in a well-populated area."

Because the *Hill* court was concerned that a jury might overestimate the meaning of the information provided by historical cell-site analysis, it cautioned the Government "not to present historical cell-site evidence without clearly indicating the level of precision—or imprecision—with which that particular evidence pinpoints a person's location at a given time." And it warned that "[t]he admission of historical cell-site evidence that overpromises on the technique's precision—or fails to account adequately for its potential flaws—may well be an abuse of discretion."

Comparative bullet lead analysis: *Kennedy v. Peele*, 552 Fed. Appx. 787 (10th Cir. 2014): The plaintiff sought damages for suffering a wrongful conviction. The defendant, an agent with the FBI, conducted comparative bullet-lead analysis ("CBLA") linking the plaintiff to multiple murders. The plaintiff argued that CBLA is unreliable (an argument since validated), and that the defendant knew "there was a question regarding the scientific reliability of the lead matching theory," but failed to disclose that the CBLA method lacked a statistical and scientific basis. The court held that the defendant was entitled to qualified immunity. It stated that it could not "ignore the fact that CBLA was widely accepted at the time of the events at issue." And the plaintiff's attack was on CBLA in general rather than any specific misconduct by the defendant.

DNA mixed source sample: *United States v. Kelsey*, 917 F.3d 740 (D.C. Cir. 2019): In a prosecution for sexual assault, the government relied at trial on a DNA match taken from the victim's sexual assault kit. One witness, Shana Mills, testified as to the processing of DNA swabs from the kit – i.e., taking cuttings from swabs, placing them in test tubes, and loading them into a machine called a genetic analyzer which produced electropherograms (charts that list the alleles present at different locations of a length of DNA). The data that Mills generated was transferred to another lab and analyzed by an expert, Hope Parker. Mills testified and compared the information in a report she wrote with the information that Parker used. Mills also testified that she identified a male profile in the DNA sample, which helped to explain why the electropherogram analysis was sent to Parker for a mixture analysis. The court held that Mills's testimony was properly admitted and that the trial judge did not abuse discretion in precluding cross-examination of Mills as to alleged deficient mixture analyses at the Department of Forensic Sciences' Laboratory. The court reasoned that any problems were irrelevant to Mills's credibility, because the benchwork in this case predated the problems with mixture analysis in the lab.

DNA Mixed Source Sample --- FST Outmoded Method Sufficiently Reliable: *United States v. Jones,* 965 F.3d 149 (2nd Cir. 2020): The court upheld the admission of a DNA identification from a multi-source sample, where the process used --- known as FST --- had been abandoned by the only lab that had ever used it (the New York City Medical examiner). This was referred to by the court as OCME using "its internally-developed, then-usual methodology for this type of mixed DNA sample, called the Forensic Statistical Tool ("FST")."

The court explained that in 2017, OCME stopped using FST for new cases. At that time, the Combined DNA Index System ("CODIS")--the FBI's national database, to which OCME

contributes its data--raised the minimum number of loci that must be amplified during the preliminary stage of analysis. FST, which had conformed to CODIS's prior standards, became incompatible because it did not comply with the higher standard. Rather than altering the FST codes to comply with these new standards, and be forced to go through another rigorous validation process, OCME opted to switch to a DNA testing program that was commercially available.

The court found that the trial court did not abuse its wide discretion in admitting the FST-based expert testimony. Here is the court's analysis:

> We see no error, much less any manifest error, in the decision of the district court in the present case. * * * [T]he five-day *Daubert* hearing exhaustively dissected FST's development, methodology, and implementation. The court permissibly found that the only two *Daubert* factors that were meaningfully in dispute were the known rate of error in FST analysis, and the question of general acceptance of FST in the scientific community. It permissibly found that both factors favored denial of Jones's motion to exclude the Glove DNA evidence.
>
> While the hearing testimony indicated that FST does not have what experts would describe as a "known error rate," the court had leeway to find it appropriate to substitute consideration of the rate at which FST would produce false positive results. And in considering the false-positive rate, there was no abuse of discretion in the court's decision to focus on FST's overall rate of false positives instead of, as urged by Jones, limiting its focus to one single early element in the process--the estimation of quant, where there is a 30-percent rate of error. Notably, all DNA analysis involves quantitation, and the *Daubert* hearing testimony indicated that the quantitation method OCME uses is considered the "gold standard." Further, to the extent that FST integrates quantitation more directly into its analysis than other programs do (i.e., in estimating drop-out), the false-positive rate takes this into account. Thus, despite the rate of error in determining quant, the evidence showed that FST's overall false-positive rate is 0.03 percent, a mere three-hundredths of one percent; and that for "very strong support" likelihood ratios (i.e., those more than 1,000)--including that for the Glove DNA here, which was 1,340--the false-positive rate is a mere 0.0009 percent. We see no abuse of discretion in the district court's conclusion that this evidence indicated reliability sufficient to support admission of the Glove DNA evidence.
>
> [T]he district court clearly explained its finding that FST is sufficiently accepted--both in its admission in scores of New York State cases and in "the fact that the FST has been approved for use in casework by members of the relevant scientific community and subjected to peer review" to warrant its admission here.

DNA mixed source sample --- procedure subsequently determined unreliable was properly admitted: *United States v. Barton,* 909 F.3d 1323 (11th Cir. 2018): The defendant was convicted of felon-firearm possession, in part on the basis of testimony by a DNA expert who extracted a sample from a gun. The defendant did not challenge the process of DNA identification itself, but argued that the identification was from a sample that was a mixture from a number of

individuals, and that the expert used a flawed process in extracting the DNA that she tested. The court held that the trial court "rightly reached its decision based on an evaluation of the foundations of Zuleger's testimony and the failure of the defense to rebut it with anything but the testimony of a competing expert, who employed the same general methodology." The court concluded that "[t]he issues raised by Johnson's competing testimony went to the weight owed Zuleger's expert opinion, and were properly left to the jury."

The defendant pointed up that between the time of his conviction and the appeal, a scientific body published new guidelines concluding that the prosecution expert's methods of extraction from the mixed source were not reliable. (The prosecution expert was relying on guidelines that were primarily designed to cover single-source samples and two-person mixtures, while the sample in the case was a mixture of DNA from at least three persons.). According to the court, "the updated SWGDAM guidelines support Barton's claim that analysis of a low-quantity three-person mixture should be based on interpretation guidelines drawn from validation studies performed on low-quantity three-person mixtures. Validation studies go to the heart of reliability." The court found that the new guidelines are "potentially important evidence cutting against reliability." But because they were not presented to the trial court, the court held that they could not be considered on appeal. The remedy, if any, would lie in a motion for a new trial under Fed.R.Crim.P. 33.

DNA single source samples --- typographical error: *United States v. Silva,* 889 F.3d 704 (10th Cir. 2018): In a felon-firearm possession case, the government called a DNA expert who testified on the basis of "single source samples" (i.e., no problem of extraction of one source from multiple sources), that she could not exclude the defendant's profile as the donor of the samples collected from a truck and a house. The defendant argued that the testimony should have been excluded because the numbers of the samples on her digital record did not match up with the numbers on the tubes. The expert recognized the error but said it was a typo, and that the error "had nothing to do with what's labelled on the actual tube." The court found no error in admitting the expert's testimony because the errors "were typographical only and did not affect her analysis and its result." The court then stated that "errors in the implementation of otherwise-reliable DNA methodology typically go to the weight that the trier of fact should accord to the evidence and not to its admissibility."

> **Comment:** It is surely true that the typographical error should not render the testimony inadmissible, because the actual test was reliably conducted. Therefore the court did not need to state as a general proposition --- twice --- that errors in application are questions of weight and not admissibility. This wasn't even an error in application. Or if it was, the trial judge could easily have found, by a preponderance of the evidence, that the test was reliably conducted even given the typo.

DNA—PCR methodology: ***United States v. Eastman***, 645 Fed. Appx. 476 (6th Cir. 2016): The defendant argued that polymerase chain reaction (PCR)—the process used to identify Eastman as the likely major DNA profile found on three dust masks—has no known error rate or accepted procedure for determining an error rate, and therefore should be rejected. But the court

found no abuse of discretion in admitting the DNA identification. The court relied almost exclusively on precedent.

> The defendant's argument confuses the error-rate factor with an admissibility requirement. More than ten years ago, we noted that "[t]he use of nuclear DNA analysis as a forensic tool has been found to be scientifically reliable by the scientific community for more than a decade." *United States v. Beverly*, 369 F.3d 516, 528 (6th Cir. 2004). Eastman presents no groundbreaking evidence that leads us to question that decision. At least one of our sister circuits even permits trial courts to take judicial notice of PCR's reliability. See *United States v. Beasley*, 102 F.3d 1440, 1448 (8th Cir. 1996). Of course, a defendant may challenge sound scientific methodology by showing that its reliability is undermined by procedural error—failure to follow protocol, mishandling of samples, and so on. But Eastman did not do so here.

DNA identification: *United States v. Preston,* 706 F.3d 1106 (9th Cir. 2013): In a sexual assault prosecution, the defendant argued that the expert's testimony regarding DNA identification should have been excluded. The court analyzed and rejected this argument in the following passage:

> The district court properly applied Rule 702 to determine whether to admit the testimony of the DNA analyst. The trial judge fulfilled his "gatekeeper" role pursuant to *Daubert* and allowed the expert's testimony based on the foundation laid by the prosecutor that established the relevance and reliability of the testimony and the scientific method by which the DNA was analyzed; the DNA was subjected to a common procedure for analysis. * * * Preston argues that the "analyst went below her lab's quality threshold." However, the expert explicitly stated that while the test conducted may have fallen below the lab's "reporting threshold," the analysts are "allowed to go below that level to try and eliminate or exclude someone." This is exactly what the expert did. * * *

Drug identification --- Testimony about an "infinitesimal" error rate: *United States v. Mire,* 725 F.3d 665 (7th Cir. 2013): The court found no error in the admission of testimony by a chemist that the defendant was carrying the controlled substances cathinone and cathine. The court found the forensic testing process to be reliable. The expert relied on published literature and peer-reviewed studies to support the reliability of the methodology. The expert stated that the rate of error was "infinitesimal" --- and while that ought to raise some concern, the court found that conclusion to be a factor *supporting* reliability.

Drug identification: *United States v. Carlson,* 810 F.3d 544 (8th Cir. 2016): The court affirmed convictions for selling misbranded synthetic drugs, finding no abuse of discretion in the admission of testimony from a DEA chemist regarding the substantial similarity in chemical structure between scheduled controlled substances and the products sold by the defendants. The entirety of the court's analysis is as follows:

The district court did not abuse its discretion by permitting Dr. Boos to testify. He testified that his conclusion was based on relevant evidence he had observed, his specialized knowledge in the field, his review of the scientific literature, and discussions with other scientists at the DEA. Although the defendants contend that Dr. Boos's testimony did not flow naturally from disinterested research, that his methodology was not subject to peer review or publication, and that his theory had no known rate of error, these objections go to the weight of Dr. Boos's testimony, not to its admissibility.

Comment: Charges of suspect motivation, lack of peer review, and no known rate of error clearly do not go to weight. The *Daubert* Court itself says that these matters affect admissibility.

Drug identification: ***United States v. Gutierrez*****,** 2020 U.S. App. LEXIS 12679 (11th Cir.): The defendant was convicted of conspiracy to distribute methamphetamine and argued, on appeal, that the government failed to prove the reliability of the methodology used by the government's two forensic experts, who testified as to the nature, weight, and purity of the substances found. The court found no abuse of discretion, even though the experts provided no rate of error and could not identify any studies that supported their methods. The court relied heavily on the general acceptance factor. Its analysis was as follows:

The district court did not abuse its discretion in admitting the testimony of the government's experts. Gutierrez does not question the experts' experience or background, but he argues that their testimony was unreliable because they did not know the rate of error regarding the techniques they used and were unable to identify any experts or studies that supported or discredited the methods they used. But as we have explained, expert testimony does not necessarily need to meet all or most of the *Daubert* factors to be admissible.

And here, * * * the "general acceptance" *Daubert* factor was met. Shire testified that the various techniques he and Conde used in the DEA labs to identify substances—including gas chromatography, mass spectrometry, and infrared spectroscopy—were "commonly used in the industry for identifying compounds." The district court was permitted to credit this testimony that the experts' testing methods were generally accepted and to conclude that the methods were, therefore, sufficiently reliable to be considered by the jury. The reliability of the expert testimony was further supported by Shire's testimony that DEA chemists employed "multiple testing using a variety of techniques," as well as testing multiple samples of the substance, which provided multiple results that could be compared with "authenticated reference materials from an outside source" and which permitted identification with confidence. Given the flexible nature of the gatekeeping inquiry, Gutierrez has not shown that the court abused its discretion in admitting the expert testimony as to the nature, purity, and weight of the substances.

EDTA testing offered by the defendant, rejected: ***Cooper v. Brown*****,** 510 F.3d 870 (9th Cir. 2007): In a habeas challenge to a conviction for multiple murders, the defendant argued that

a forensic test for the preservative agent ethylene-diamine tetra-acetic acid (EDTA) on a bloody T-shirt would show that blood had been taken from a vial and planted on the shirt. The court found no abuse of discretion in the trial judge's conclusion that the EDTA testing lacked sufficient indicia of reliability to be admissible, because it had not been subjected to peer review, "there has been no discussion of forensic EDTA testing in scientific literature since a 1997 article that headlines the need for a better analytical method," and it is not possible to determine the error rate of EDTA testing because of the widespread presence of EDTA in the environment.

Fabric-impression analysis found unreliable in part by trial court: *United States v. Williams,* 576 F.3d 385 (7th Cir. 2009): The defendants challenged the trial court's admission of an expert's conclusion that an impression on a glass door at the robbery scene was left by a non-woven fabric and could have been made by a glove. The expert also sought to testify that the impression was consistent with the pair of gloves containing Williams's DNA, but the district court excluded that testimony because it considered the underlying science, fabric impression analysis, unreliable under *Daubert*. The defendants argued that the admitted testimony relied on the same science as the excluded testimony--fabric impression analysis--and therefore also should have been excluded. The court of appeals did not rule on the argument, finding any error to be harmless.

Fingerprint identification: Overstatement --- zero rate of error --- *United States v. Straker,* 800 F.3d 570 (D.C.Cir. 2015): The court rejected the defendant's argument that fingerprint identification, using the ACE-V method, was unreliable. The expert testified that there are two different types of error—the error rate in the methodology and human error. She further testified that there is a "zero rate of error in the methodology." She did not articulate the rate of human error, though she acknowledged the potential for such error. The defendant argued that the failure to articulate the rate of human error in the ACE–V methodology rendered her testimony based on that methodology inadmissible. But the court disagreed, arguing that "the factors listed in *Daubert* do not constitute a definitive checklist or test" and that "[n]o specific inquiry is demanded of the trial court." The court stated that the reliability of the ACE-V methodology was "properly taken for granted" because courts routinely find fingerprint identification based on the ACE–V method to be sufficiently reliable under *Daubert.*

Fingerprint Identification: Overstatement – infinitesimal error rate --- *United States v. Casanova*, 886 F.3d 55 (1st Cir. 2018): The court held that it was not plain error to allow a latent print examiner to testify to an identification. The expert, Truta, a senior criminalist in the Latent Print Unit of the Boston Police Department, testified about the history of fingerprint examinations in criminal investigations, the "ACE-V" method (analysis, comparison, evaluation, and verification) used to compare fingerprints and perform identifications, and the results of analyses he performed on prints collected from the scene of the shooting. Truta identified one particular palm impression, located on a straw wrapper found in the back seat of the car in which the victim was shot, as belonging to Casanova. Witnesses had testified that Casanova was in that back seat. On cross-examination, Truta testified, "[a]s far as I know, in the United States the[re] are not more than maybe 50 erroneous identification[s], which comparing with identification[s] that are made daily, thousands of identification[s], the error rate will be very small." Truta had previously

testified that it would be inappropriate to claim that the rate of false-positive identifications is zero. Truta emphasized that his testimony was based on what he had read in the literature, and acknowledged that at the time of his testimony, there was "no known database of latent prints" that would permit a statistical analysis of false-positive rates for fingerprint identifications.

The defendant argued that Truta "claimed falsely that the error rate in fingerprint comparisons was effectively zero." But the court stated that "Truta never testified that the error rate for fingerprint examinations was 'effectively zero.' * * * Rather, Truta testified that in light of the number of recorded errors he knew of from his own review of the literature, and the number of fingerprint identifications made daily, he expected the error rate to be 'very small.' He did not calculate or assert any particular error rate and he specifically cautioned that whatever the rate may be, it would not be zero. On redirect he acknowledged that there was no statistical method generally accepted in the field for determining actual statistical probabilities of erroneous identifications. This is the classic stuff of cross-examination and redirect."

The defendant relied on the PCAST report, and the court had this to say about that:

> Casanova grounds his entire challenge on a single post-trial report that provided recommendations to the executive branch regarding the use of fingerprint analysis as forensic evidence in the courtroom. See President's Council of Advisors on Sci. and Tech., Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods (2016). The report, issued after Casanova's trial had already ended, is not properly before this court, and in any event it does not endorse a particular false-positive rate or range of such rates.
>
> > **Comment:** Saying "I have read some stuff and it is, uh, about 50 mistakes in all the fingerprints ever done" is not much different from saying that the error rate is effectively zero. The court makes a big deal about the distinction but what else is a jury to take from the testimony? It's a clear case of overstatement. Note that the testimony was from a state expert, not from the FBI, and so the DOJ standards are not directly applicable.

Fingerprint identification: Overstatement --- testimony of a match --- *United States v. Pena,* 586 F.3d 105 (1st Cir. 2009): The trial judge expressed doubts about the reliability of an expert's fingerprint identification, because the governing protocol used no specific minimum number of points for an identification. The defendant argued that the ACE-V method was unreliable because it involved merely a visual comparison of the two prints, the trooper conducting the initial analysis knew that the inked print was taken from a suspect, and the trooper made no diagrams, charts, or notes as part of his evaluation. But the judge relied on precedent, describing the case law as "overwhelmingly in favor of admitting fingerprint experts under virtually any circumstance." The trial judge essentially imposed the burden on the defendant to present data to overcome the uniform precedent, and held that the defendant did not satisfy that burden by producing a (Fordham) law review article questioning latent fingerprint identification as being

impermissibly subjective. The court of appeals found no abuse of discretion, given the precedent allowing the use of fingerprint identification.

Fingerprint identification: Testimony of a match --- limitation of cross-examination: ***United States v. Muhanad Mahmoud Al-Farekh,*** 956 F.3d 99 (2nd Cir. 2020): A fingerprint expert concluded that 18 latent prints recovered from the adhesive packing tape in an undetonated bomb "matched" the defendant's fingerprints. The defendant sought to cross-examine the expert by raising the famous error in fingerprint identification that occurred in the investigation of the bombing of a train in Madrid (in which a fingerprint expert incorrectly identified a latent print as a "match" for Brandon Mayfield, a lawyer in Portland). The trial judge precluded the cross-examination under Rule 403, concluding that the Mayfield misidentification was not very probative to this expert's conclusion, and would create a risk of jury confusion. The court found no error. It found that "the misidentification of Mayfield is only marginally relevant" because "the fingerprint examiners in the Mayfield incident were not involved in the instant case." It concluded that "a defendant may attack the subjectivity of fingerprint examinations as a category of evidence, but is not entitled without more to rely on a fingerprint examiner's mistakes in a wholly unrelated case to undermine the testimony of a different examiner." ***Accord, United States v. Bonds,*** 922 F.3d 343 (7th Cir. 2019) (upholding trial court's exclusion of the Mayfield incident when offered to impeach a different examiner); ***United States v. Rivas,*** 831 F.3d 931 (7th Cir. 2016) (same).

Fingerprint identification: Overstatement --- testimony of a match ---*United States v. John,* 597 F.3d 263 (5th Cir. 2010): The court found no abuse of discretion in allowing a fingerprint expert to testify to a "match." It recognized that the methodology is subjective, because "there is no universally accepted number of matching points that is required for proper identification." But it relied on precedent holding that the method was "testable, generally accepted, and sufficiently reliable and that its known error rate is essentially zero." The defendant pointed out that the expert's opinion had not been subjected to blind verification, but the court responded that no case law holds that blind verification is required.

> **Note: The DOJ says this entry is misrepresentative because, while the court used the term "match" the witness never did. Rather the witness "identified" the print as coming from the defendant, in accordance with DOJ standards. But this only shows that courts (like pretty much everyone else) do not get the DOJ's fine distinction between a match and an identification. And if courts don't understand it, how are juries supposed to?**

Fingerprint testimony: Overstatement --- testimony that the methodology was error-free: *United States v. Watkins*, 450 Fed. Appx. 511 (6th Cir. 2011): The defendant relied on the 2009 NAS report to argue that latent fingerprint identification (the ACE-V method) is unreliable and should have been excluded. The examiner had testified that the method was 100% accurate. But the court found no error. It stated that the error rate "is only one of several factors that a court should take into account when determining the scientific validity of a methodology. These factors include testing, peer review, publication, error rates, the existence and maintenance of standards

controlling the technique's operation, and general acceptance in the relevant scientific community." At the *Daubert* hearing in this case, the fingerprint examiner testified about custody-control standards, generally accepted standards for latent fingerprint identification, peer review journals on fingerprint identification, and the system of proficiency testing within her lab. The court "decline[d] to hold that her allegedly mistaken error-rate testimony negates the scientific validity of the ACE-V method given all the other factors that the district court was required to consider."

> **Comment:** The court seems to say that because the methodology is sufficiently reliable, it is a question of weight when the expert says it is error-free. This makes no sense. Surely a methodology can be reliable by a preponderance of the evidence and yet have a rate of error. Why can't the court allow the testimony about the procedure, but preclude the expert from testifying that it is error-free? It would seem that highlighting the problem of overstatement --- as an admissibility requirement --- might get courts to focus more on it and not leave it to the jury to sort out.

Fingerprint identification: Limitations on cross-examination: *United States v. Bonds,* 922 F.3d 343 (7th Cir. 2019): The defendant argued that his right to confront an FBI fingerprint expert was impaired when the trial judge prohibited him from cross-examining the expert about an error that the FBI lab had made in the Brandon Mayfield (Madrid bombing) case. The court found no error in prohibiting this cross-examination. The court stated that the defendant had "ample opportunity to supply the jury with evidence about the reliability of the ACE-V method" --- specifically the analysis provided in the NAS and the PCAST reports. The court specifically noted that the summary on fingerprint identification provided in the PCAST report "provides the defense bar with paths to cross-examine witnesses who used the ACE-V approach. Have they avoided confirmation bias? Have they avoided contextual bias? Has their proficiency been confirmed by testing?" The court noted that Bonds was not arguing that he was precluded from using the NAS and PCAST reports on cross. His only complaint was that he was not allowed to raise the Mayfield error.

Fingerprint identification: *United States v. Herrera*, 704 F.3d 480 (7th Cir. 2013): upholding the use of latent fingerprint matching, the court noted that the expert received "extensive training" and that "errors in fingerprint matching by expert examiners appear to be very rare." It conceded that latent fingerprint matching is "judgmental rather than scientifically rigorous because it depends on how readable the latent fingerprint is and also on how distorted a version of the person's patent fingerprint it is." But it compared fingerprint-matching favorably to another form of subjective matching --- eyewitness identification. It stated that "[o]f the first 194 prisoners in the United States exonerated by DNA evidence, none had been convicted on the basis of erroneous fingerprint matches, whereas 75 percent had been convicted on the basis of mistaken eyewitness identification."

> **Comment:** The comparison of fingerprint-matching and eyewitness identification is a false one, as Judge Edwards has pointed out. They are not comparable because a fingerprint-matcher touts his experience and training, and testifies to a match.

Fingerprint identification: *United States v. Calderon-Segura,* 512 F.3d 1104 (9th Cir. 2008): This is an unusual case in which the defendant challenged fingerprint identification testimony which found a match when comparing two inked thumb-print exemplars. The court noted that the defendant's challenge related to questions about *latent* fingerprints, whereas the reliability and admissibility of comparison of two inked fingerprints is "well-established." The court emphasized that the defendant made no showing that the exemplars "lacked clarity, were fragmented, or contained any other defects or artifactual interference that might call into question the accuracy or reliability of their identification."

Fingerprint identification --- Bench trial: *United States v. Flores*, 901 F.3d 1150 (9th Cir. 2018): The court affirmed the defendant's conviction for attempting to reenter the United States after being deported. It held that the trial judge did not abuse discretion in admitting the testimony of a government fingerprint expert. The defendant presented evidence that the expert failed to consult with other professionals, had taken no certification test in forty years, had no verification of his work done in this case, and had no regular continuing education in the field. But the court found this not troubling at all. It first noted that this was a bench trial, and that the trial court's gatekeeping function is less stringent when it also acts as the trier of fact. It further noted that the witness had over 25 years' experience in fingerprint comparison, had worked as a FBI fingerprint technician, and had been qualified as an expert in federal and state court more than thirty times. It finally declared that "fingerprinting is far from junk science—it can be tested and peer reviewed and is generally accepted by the relevant scientific community." In making that assessment it relied on precedent, specifically *United States v. Calderon-Segura*, 512 F.3d 1104, 1109 (9th Cir. 2008) ("[F]ingerprint identification methods have been tested in the adversarial system for roughly a hundred years.").

Fingerprint identification --- Abdicating the gatekeeper function: *United States v. Ruvalcaba-Garcia*, 923 F.3d 1183 (9th Cir. 2019): In an illegal reentry case, a government expert was called to testify that the fingerprint he took from the defendant matched the fingerprint on an order of removal. The expert's methodology was ACE, but not –V: meaning that he did not have his conclusion of a match validated in any way. The expert was not a member of the International Association for Identification ("IAI") or the Scientific Working Group on Friction Ridge Analysis, Study, and Technology ("SWGFAST"). The trial judge essentially ruled that the expert's qualifications and methodology were questions for the jury. The court found error, because qualifications and reliability of methodology are clearly admissibility questions for the court under Rule 702 and *Daubert.* The court concluded as follows:

> Here, the district court abused its discretion by failing to make any findings regarding the reliability of Beers's expert testimony and instead delegating that issue to the jury. Indeed, the district court made this error three times during Ruvalcaba's * * * trial. After the government conducted an initial voir dire of Beers and "move[d] to have [him] qualified as an expert fingerprint technician," the court responded, "That's a determination for the jury." After Ruvalcaba cross-examined Beers and the government again "move[d] to qualify him as an expert," the court responded, "Again, that's an issue for the jury." And when Ruvalcaba "object[ed] to the qualifying [of Beers] as an expert," the court overruled

the objection and told the jury that it was up to them "to decide whether the witness by virtue of his experience and training is qualified to give opinions." * * * The district court's failure to make an explicit reliability finding before admitting Beers's expert testimony in this case constituted an abuse of discretion.

Fingerprint identification --- Overstatement, testimony of a match: *United States v. Baines,* 573 F.3d 979 (10th Cir. 2009): The court found that the trial court did not abuse discretion in admitting expert testimony that a latent fingerprint *matched* the fingerprint of the defendant that was taken when he was arrested. The defendant argued that fingerprint analysis is unreliable under *Daubert*, because comparison of a latent print to a known print is essentially a subjective evaluation, with no rate of error established, and the only verification is done by a second investigator who is usually closely associated with the first investigator. The court recognized that there are "multiple questions regarding whether fingerprint analysis can be considered truly scientific in an intellectual, abstract sense" but declared that "nothing in the controlling legal authority we are bound to apply demands such an extremely high degree of intellectual purity." The court stated that "fingerprint analysis is best described as an area of technical rather than scientific knowledge." Turning to the *Daubert/Kumho* factors, the court recognized that fingerprint analysis was subjective, and that there was really no peer review of the process. As to rate of error, the court concluded that whatever the flaws in the studies conducted on false positives, "the known error rate remains impressively low." As to the factor of general acceptance, the defendant argued that fingerprint analysis had not been accepted in any unbiased scientific or technical community, and that its acceptance by law enforcement and fingerprint analysts should be considered irrelevant. But the court disagreed, noting that the Court in *Kumho* "referred with apparent approval to a lower court's inquiry into general acceptance into the relevant expert community" and also referred to testing "by other experts in the industry." The court concluded that while acceptance by a community of unbiased experts "would carry greater weight, we believe that acceptance by other experts in the field should also be considered. And when we consider that factor with respect to fingerprint analysis, what we observe is overwhelming acceptance."

Fingerprint identification: *United States v. Watkins,* 880 F.3d 1221 (11th Cir. 2018): In an illegal reentry prosecution, the government called an expert to testify to a fingerprint identification. The court of appeals found that the trial court "likely erred" in admitting the testimony but found any error to be harmless. The court did not discuss the particulars. It simply concluded that the fingerprint analyst's testimony was "probably not reliable" because the analyst "did not specifically testify about her scientific methods and her testimony may not have been based on sufficient facts or data."

Fingerprint identification: Overstatement, testimony of a match: *United States v. Scott,* 403 Fed. Appx. 392 (11th Cir. 2010): The defendant challenged the expert's use of the ACE-V method. The court simply relied on precedent to reject the challenge. In *United States v. Abreu*, 406 F.3d 1304, 1307 (11th Cir. 2005), the court had concluded that the error rate of latent fingerprint examination was infinitesimal, and that latent fingerprint examiners follow a uniform methodology. The *Abreu* court also gave significant weight to the fact that latent fingerprint

methodology was generally accepted --- by the field of latent fingerprint examiners (which is not a large surprise). The *Scott* court concluded as follows:

> Although there is no scientifically determined error rate, the examiner's conclusions must be verified by a second examiner, which reduces, even if it does not eliminate, the potential for incorrect matches. The ACE-V method has been in use for over 20 years, and is generally accepted within the community of fingerprint experts. Based on this information, the district court did not commit an abuse of discretion by concluding that fingerprint examination is a reliable technique.
>
> **Reporter's Note: The term "match" is used by the court. It is unknown what the witness testified to. But the fact that a court thinks it is a "match" is cause for concern.**

Footwear-impression testimony allowed --- Overstatement, zero error rate: *United States v. Mahone,* 453 F.3d 68 (1st Cir. 2006): The court found no abuse of discretion when a government witness was permitted to testify as an expert on footwear-impression identification, even though she was not qualified through the International Association for Identification --- and despite the fact that the expert testified that the methodology had a zero error rate. The expert relied on the ACE-V method (analysis, comparison, evaluation, and verification) for assessing footwear impressions. The defendant argued that the ACE-V method "utterly lacks objective identification standards" because: 1) there is no set number of clues which dictate a match between an impression and a particular shoe; 2) there is no objective standard for determining whether a discrepancy between an impression and a shoe is major or minor; and 3) the government provided "absolutely no scientific testing of the premises underlying ACE-V." The court essentially relied on precedent to find no abuse of discretion:

> From the outset, it is difficult to discern any abuse of discretion in the district court's decision, because other federal courts have favorably analyzed the ACE-V method under *Daubert* for footwear and fingerprint impressions. See *United States v. Allen*, 207 F.Supp.2d 856 (N.D.Ind.2002) (footwear impressions), aff'd, 390 F.3d 944 (7th Cir.2004); *United States v. Mitchell*, 365 F.3d 215, 246 (3d Cir.2004) (favorably analyzing ACE-V method under *Daubert* in latent fingerprint identification case); *Commonwealth v. Patterson,* 445 Mass. 626, 840 N.E.2d 12, 32-33 (2005) (holding ACE-V method reliable under *Daubert* for single latent fingerprint impressions).

Footwear-impression analysis --- Overstatement--- testimony of a match--- *United States v. Turner*, 287 Fed. Appx. 426 (6th Cir. 2008): the defendant appealed the district court's denial of his motion to exclude the boot-print analysis of the government's expert. The court found no error. The court noted that both the government and defense expert testified that photographic analysis was recognized as a valid method of shoe-print analysis within the scientific community. The government expert testified that the government lab methods were tested by an independent agency once during the year, and that he had never failed a proficiency test. Also, the government presented evidence indicating that a book entitled *Footwear Impression Evidence* by William J.

Bodziak stated that "[p]ositive identifications may be made with as few as one random identifying characteristic." The court rejected arguments that an electrostatic method should have been used, and that the four points of comparison used by the government expert were insufficient to conclude that the boot and the print on the glass matched. It stated that "the government and defense experts disagreed as to whether the photographic or the electrostatic method would be better to use on the boot print at issue--not whether the photographic method was a valid method, tested and accepted by the larger scientific community. In addition, the record reveals that the experts also disagreed about the number of points of comparison necessary for a positive match between the boot and the print. These disputes go to the weight of the evidence rather than its admissibility."

> **Comment:** Shouldn't a question of the necessary number of points of comparison be decided by the judge? That is the critical aspect of the methodology itself; if not that, it is at least a critical question about the application of the methodology. The court, in throwing up its hands and leaving questions about the methodology to the jury, appears to be using the Rule 104(b) standard, in violation of Rule 702.

Footwear-impression testimony: *United States v. Smith*, 697 F.3d 625 (7th Cir. 2012): The defendant argued that the trial court erred in admitting footwear-impression testimony by an FBI examiner. The expert testified that the left Nike shoe worn by the defendant at the time of the robbery made the partial impression on the piece of paper recovered from the tellers' counter at the bank and that the impressions left on the bank carpet were "consistent with" the shoes worn by defendant Smith at the time of his arrest. The court found no error. It relied on prior precedent predating the scientific reports that challenge the reliability of footprint identification methodology. See *United States v. Allen*, 390 F.3d 944, 949–50 (7th Cir. 2004). The court stated that "In *Allen*, we affirmed the admission of footprint analysis testimony where the expert testified that 'accurate comparisons require a trained eye; the techniques for shoe-print identification are generally accepted in the forensic community; and the methodologies are subject to peer review.'" In this case the FBI Examiner testified that the four-step approach he used is employed by forensic laboratories throughout the United States, in Canada, and in thirty other countries. He also explained that there have been peer reviews of the methodology published in several books and articles. And he explained in detail how he applied this methodology to the footprint impressions recovered at the bank. This was enough to establish that the testimony met the criteria of Rule 702.

> **Comment: Assuming the footprint methodology is reliable, the fact that subjective judgment is required means that there is a rate of error. Therefore, while it seems correct to allow the expert to testify that a footprint is "consistent with" the defendant's shoe, it is surely an overstatement to say that the defendant's shoe is the one that made a partial impression on a piece of paper.**

Gun residue testing upheld: *United States v. Stafford*, 721 F.3d 380 (6th Cir. 2013): In a felon-firearm prosecution, the defendant challenged gunshot-residue evidence. He argued that the testing is imprecise and that there is no consensus in the discipline as to how many particles must be identified in order to find a positive for residue. But the court found that the expert's test had revealed five particles, and that this was more than the minimum required by the most stringent

standard used by experts in the field. The defendant also argued that he could have been exposed to gunshot residue without ever having fired a gun. The court conceded that this was so, but concluded that this affected the probative value of the test result, not the reliability of the conclusion that five particles of gunshot residue were found on the defendant's hands.

Hair identification – overstatement – violation of constitutional rights by government presentation of overstated, "false" expert testimony: *United States v. Ausby,* 916 F.3d 1089 (D.C.Cir. 2019): At the defendant's trial on rape and murder in 1972, the government's forensic expert testified that hairs found at the crime scene were "microscopically identical" to the defendant's hair, and that hair is "unique to a particular individual." The defendant was convicted and sentenced to life in prison. In 2012, the FBI concluded that the expert in Ausby's case "misled the jury by implying that he could positively identify the hairs taken from the crime scene as belonging to Ausby." The government conceded error, but in this proceeding argued that the error was not material to the conviction. The court, in light of the government's concession, found that the government had violated *Napue v. Illinois,* 360 U.S. 264 (1959) by presenting false testimony. The court concluded that the false testimony was material, and held that Ausby should be granted relief under §2255, and that the trial court erred in refusing to vacate Ausby's conviction. ***See also United States v. Butler,*** 955 F.3d 1052 (D.C. Cir. 2020) (conviction vacated where hair identification expert testified that the defendant's hair sample was "the same" as the hair found at the crime scene; the government itself conceded that hair comparison testimony "exceeded the limits of science").

Handwriting: *United States v. Mallory*, 902 F.3d 584 (6th Cir. 2018): Defendants were convicted on charges arising from a scheme to steal Fewlas's sizeable estate by forging a signature on his will. On appeal, the defendants objected to the trial court's admission of testimony by government handwriting expert Olson, who testified that the signature on the forged will was "probably" not Fewlas's, but instead a "simulation" performed by someone else. The court held that the district court did not abuse its discretion in admitting Olson's handwriting analysis. Citing *Daubert*, *Kumho Tire*, and Sixth Circuit precedent, the court found that the district court faithfully applied these legal standards in deeming Olson's handwriting analysis to be reliable, and affirmed the general reliability of expert handwriting analysis.

The court relied most heavily on *United States v. Jones,* the handwriting case that was cited in the Committee Note to the 2000 amendment to Rule 702 --- the citation that some people have argued opened the gate to admission of unreliable forensic evidence. The court's analysis of *Jones, Daubert,* and *Kumho* is as follows:

> The reliability of expert handwriting analysis has come before our court before. In *United States v. Jones*, our court upheld the admissibility of such testimony. 107 F.3d 1147, 1161 (6th Cir. 1997). In so holding, *Jones* explained that handwriting analysis is not a science *per se.* Handwriting analysts "do not concentrate on proposing and refining theoretical explanations about the world," as scientists do. Instead, handwriting analysts "use their knowledge and experience to answer the extremely practical question of whether a signature is genuine or forged." Handwriting analysts see things in handwriting that

> laypeople do not—both because of analysts' training in the minutiae of loops, swoops, and dotted 'i's, and because of the volume of handwriting they inspect—and therefore assist the trier of fact by bringing their training and experience to bear. Thus, while handwriting analysis may not boast the "empirical' support underpinning scientific disciplines, it is nevertheless "technical" or "specialized" knowledge that, subject to thorough gatekeeping, is a proper area of expertise.
>
> Our court decided *Jones* without the benefit of *Kumho Tire*. In *Kumho Tire*, the Supreme Court clarified that the *Daubert* factors may also be useful in scrutinizing non-scientific expertise. * ** [T]he *Kumho* Court referenced handwriting analysis as an area where strict *Daubert*-type analysis might be less appropriate, indicating that "the relevant reliability concerns may focus upon personal knowledge or experience." Since *Jones* predated *Kumho Tire*, it did not apply the *Daubert* factors in evaluating the handwriting analysis at issue. Still, *Jones*'s focus on handwriting analysts' experience-based expertise is consistent with *Kumho Tire*, even though *Daubert*-type inquiries may also be appropriate in evaluating such testimony.

The court then proceeded to consider the trial court's review of the handwriting expert's opinion in this case.

> Here, the district court faithfully applied *Daubert, Jones*, and *Kumho Tire* in deeming Olson's handwriting analysis admissible. The court conducted thorough *voir dire* to ascertain Olson's experience and methodology. Olson testified to his thirty-one years' experience as an ink chemist and forensic document examiner at the IRS National Forensic Laboratory, during which he has performed countless handwriting analyses and testified in court on multiple occasions. He explained that his laboratory is accredited by an international organization that polices general standards practiced throughout the discipline. In addition, Olson walked through the principles and basic approach he used in performing his analysis. To perform the analysis, Olson studied approximately ninety-one known examples of Fewlas's signature. From those samples, he discerned various unique characteristics, many of which he then found lacking in the signature on the forged will. As Olson explained, this approach embodies two precepts—no two people write exactly alike, and no one person writes exactly the same every time—which he represented as having been tested in various studies and experiments. *See United States v. Prime*, 431 F.3d 1147, 1153 (9th Cir. 2005) (affirming admission of handwriting expert citing one of the same studies). Those studies and experiments, according to Olson, further establish that his mode of analysis is highly accurate. Moreover, Olson testified that his laboratory requires document examiners to review each other's work, and that in this case, another document examiner not only reviewed his work but independently verified his opinion. *See Prime*, 431 F.3d at 1153 (highlighting similar review and verification); *accord United States v. Crisp*, 324 F.3d 261, 271 (4th Cir. 2003). Based on this testimony, the district court did not abuse its discretion in deeming Olson's testimony reliable.

The defendants argued that the trial court erred in referring to handwriting as a "science." But the court had this to say about that:

> Handwriting analysis, of course, is not a science—*Jones* makes that much clear. The district court's loose language in describing handwriting analysis as a science, however, was more of an afterthought to otherwise thorough gatekeeping. The court's *voir dire* demonstrates that, rather than viewing handwriting analysis as a science, it sought to ascertain whether Olson's experience-based expertise was reliable. * * *

Reporter's comment: The court's analysis indicates that the reference to *Jones* in the Committee Note is not the gateway to disaster. That is because *Kumho* itself paves the way for admission of handwriting testimony as a technical rather than scientific skill. The Committee Note essentially tracks *Kumho* to that effect. One can argue that the real problem of handwriting evidence is the distinct possibility of *overstatement* --- for example, testifying that it is scientific, or has a zero rate of error. In this case, no such testimony was given. The expert only testified that a forgery was "probable."

Handwriting Identification --- error to admit in the absence of verification: *Crew Tile Distribution, Inc. v. Porcelanosa L.A., Inc.*, 2019 U.S. App. LEXIS 4988 (10th Cir.): In an appeal of a judgment in a contract dispute, the appellant argued that the trial court erred in admitting the testimony of a handwriting expert, Carlson, because she did not complete the verification step of the ACE-V methodology before submitting her expert report. The court agreed and found error. It explained as follows:

> [T]he district court assessed the reliability of Carlson's testimony without the aid of a *Daubert* hearing. Moreover, [the appellee] did not offer any evidence to support its contention that Carlson's ACE methodology satisfied Rule 702. As a result, the district court based its finding on one Fourth Circuit case and two district court cases in which expert testimony was admitted despite a failure to complete the verification step of the ACE-V methodology. But none of these cases explain why the ACE methodology is reliable, and certainly none discuss the lack of verification with respect to Carlson's analysis in this case.
>
> It may be that verification adds so little to the reliability of an expert's opinion that there is no real difference between the ACE and ACE-V methodologies. But it might also be true that verification adds just enough to the reliability of the ACE-V methodology to push handwriting analysis over the line from worthless pseudoscience to valuable expert testimony. [The appellee's] attempt to resolve this uncertainty was lacking. Accordingly, the district court did not have sufficient evidence to perform its gatekeeping function and its decision to admit Carlson's testimony was error.

Handwriting Identification (and fingerprinting): *United States v. Dale,* 618 Fed. Appx. 494 (11th Cir. 2015): The court found no error in admitting latent fingerprinting and handwriting identification. It relied solely on precedent. It did not consider any of the recent challenges to these methodologies:

> We have held that fingerprint analysis utilizes scientifically reliable methodology, and Dale cites to no binding authority holding that the methodology applied in this case was scientifically unreliable. See *United States v. Abreu*, 406 F.3d 1304, 1307 (11th Cir. 2005) (per curiam) (fingerprint evidence is reliable scientific evidence, satisfying the Daubert criteria for admissibility).
>
> Dale's assertion that handwriting analysis is not reliable scientific evidence is without merit and has been squarely foreclosed by this court's precedent. See *United States v. Paul,* 175 F.3d 906, 909–10 & n.2 (11th Cir. 1999) (finding that the argument that handwriting analysis does not qualify as reliable scientific evidence is meritless).

Post-Mortem Root Banding of Hair: *Restivo v. Hesseman,* 846 F.3d 547 (2nd Cir. 2017): In an unusual case, Restivo was convicted of murder, exonerated by DNA, and sued police officers for malicious prosecution. The victim's hair was found in Restivo's van and Restivo contended that an officer took hair from the victim at an autopsy and then planted it in the van. Experts testified that the hair in the van exhibited post-mortem root banding (PMBR) which will not be found unless the hair was on a dead body for a number of hours. The parties conceded that if the victim was ever in the van, she was still alive. Thus, Restivo sought through expert testimony to prove the existence of PMBR on the hairs found in the van in support of his theory that they were planted after the autopsy. The trial court found that certain aspects of PMRB had not been established to "a reasonable degree of scientific certainty" [which is a standard that scientists don't use and that the National Commission on Forensic Science has rejected]. But the trial court nonetheless admitted the testimony as non-scientific testimony that was reliable under *Kumho Tire.* The trial court found that the experts were using the same degree of intellectual rigor in reaching their opinion as they would in their real life as experts. The trial court also found that the rate of error was low, and that the experts' opinions were consistent with the academic literature. The court of appeals found no abuse of discretion.

Toolmark examination --- no error to exclude: *United States v. Smallwood,* 456 Fed. Appx. 563 (6th Cir. 2012): On interlocutory appeal, the government challenged the trial court's order excluding the proposed testimony of its toolmark examiner. The trial court reasoned that she did not have the skill and experience with knife marks to reliably make the required subjective determination. The government argued that although the Association of Firearms and Toolmark Examiners ("AFTE") theory lacks an objective standard, competent firearms toolmark examiners still operate under standards controlling their profession, and the fact that the expert had less experience with knife toolmarks than with firearms toolmarks was not a valid reason to preclude her testimony. But the court found no error in excluding the expert --- relying in part on the NAS report.

The court noted that the AFTE guidelines provide that a qualified examiner may determine that there is a match between a tool and a tool mark when there is "sufficient agreement" in the pattern of two sets of marks --- meaning that "it exceeds the best agreement demonstrated between toolmarks known to have been produced by different tools and is consistent with agreement

demonstrated by toolmarks known to have been produced by the same tool." The court noted that because toolmark determinations "involve subjective qualitative judgments" the accuracy of an examiner's assessment "is highly dependent on skill and training." The court concluded that the expert's opinion that there was sufficient agreement between her test marks and the puncture marks found in the tires of a vehicle was "unreliable under the AFTE's own standard because she has virtually no basis for concluding that the alleged match exceeds the best agreement demonstrated between tool marks known to have been produced by different tools."

Toolmarks: ***United States v. Wells***, 879 F.3d 900 (9th Cir. 2018): The court affirmed convictions for murder and use of a firearm in relation to a crime of violence resulting in death, finding no abuse of discretion in allowing a government forensic tire expert to testify that a nail in a tire found in the defendant's truck had been manually inserted into the tire, undermining the foundation of the defendant's alibi that he had run over a nail while driving to work on the morning of the murders. The defendant argued that the tire expert's testing caused destruction of the evidence, but the court found that the testing neither destroyed nor substantially altered the tire or the nail. The court stated as follows:

> In an effort to identify an alleged perpetrator for formal accusation, the Government took reasonable actions in evaluating [the defendant's] stated alibi, followed industry standards, and documented all steps in [the government's tire expert's] report. [The defendant's tire expert] then had full access to all photographs, testing, methodology, and reports from the Government's nail and tire experts, in addition to the nail and tire themselves.
>
> [The defendant's tire expert] could have, and indeed *did*, launch extensive challenges to [the government's tire expert's] tests and conclusions. As *Daubert* confirmed, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Furthermore, as found in the district court, [the defendant] can only speculate as to whether his own expert would have reached any different conclusions as to the condition, location, or angle of the nail while still in the tire.

B. Federal District Court Cases on Forensics

Ballistics and bullet trajectory: Unqualified expert with insufficient foundation: *Krause v. County of Mohave,* 2020 WL 2316091 (D.Ariz.): Krause was shot and killed after he refused to drop his gun during an interaction with a police officer. The defendants challenged the admissibility of the plaintiff's expert Lauck, a law enforcement officer, who concluded that Krause was perpendicular to the [officer] when shot and […] thus, even if Krause's firearms was raised to the ninety-degree position, it was probably not pointing directly at the [officer]." The court found Lauck to lack expertise in the area of ballistics and bullet trajectories, and that his opinion lacked sufficient foundation:

> Lauck's opinions are entirely based on his general firearms and law enforcement experience. The Court does not discount that experience. However, that experience simply does not bear on his expertise to assess ballistic evidence or judge bullet trajectories. Lauck's decades of experience as a law enforcement officer, competitive shooter, and gunsmith cannot replace qualifications in ballistic forensics and do not qualify him to opine on the highly technical area of bullet path reconstruction or ballistics. Lauck made no measurements or calculations to support his conclusions. His investigation is entirely devoid of scientific analysis for which he is unqualified to conduct. Other courts have excluded expert testimony in similar circumstances. See *Rojas Mamani v. Sanchez Berzain*, 2018 WL 2980371, at *2 (S.D. Fla.); *Lee v. City of Richmond*, 2014 WL 5092715, at *6 (E.D. Va.). Finding Lauck's general firearms expertise inadequate to support his opinions regarding bullet trajectories (and conclusions derived thereof), the Court will exclude Lauck's testimony on the topic.

Ballistics: Overstatement --- reasonable degree of ballistics certainty: *United States v. Cerna*, 2010 WL 3448528 (N.D. Cal.): The court allowed ballistics testimony that was based on a method approved by the Association of Firearms and Toolmark Examiners (AFTE). The court stated that in February 2007, it had ruled in *United States v. Diaz,* 2007 WL 485967 that the AFTE theory, as applied by the SFPD crime lab, was sufficiently reliable under *Daubert.* It concluded that "[n]o new developments since the *Diaz* ruling cast sufficient doubt on the reliability of the AFTE theory such that expert testimony must be kept from the jury simply because it is based on the AFTE theory." The court conceded that the 2009 NAS report highlighted the weaknesses and subjectivity of ballistics feature-comparison. But it concluded that these weaknesses "do not require the automatic exclusion of any expert testimony based on the AFTE theory. The weaknesses highlighted by the NAS report—subjectivity in a firearm examiner's identification of a 'match' and the absence of a precise protocol—are concerns that speak more to an individual expert's specific procedures or application of the AFTE theory, rather than the universal reliability of the theory itself." Thus, the NAS report did not "undermine the proposition that the AFTE theory is sufficiently reliable to at least be presented to a jury, subject to cross-examination."

The court reviewed Judge Rakoff's opinion in *Glynn,* which focused on the problem of overstatement and limited the expert's conclusion to "more likely than not." The court argued that the *Glynn* limitation was "not appropriate as it suggests that the expert is no more than 51% sure

that there was a match." The court concluded that the standard previously used in *Diaz*—that a bullet or casing came from a particular firearm to a "reasonable degree of certainty in the ballistics field"—would be used.

> **Reporter's Note: The DOJ memo states that this case is not problematic because "it was the court (not the witness) that ordered the witness to use the offending phrase, one that is not permitted under current Departmental policy, unless ordered by a court." But it is hard to see how it is better when it is the court rather than the witness who is responsible for the overstatement. It actually seems that it is worse when it is the court that is responsible.**

Ballistics: *United States v. Sleugh*, 2015 WL 3866270 (N.D. Cal. 2015): The court allowed a ballistics expert to testify. The defendant argued that photographs of the two shell casings appeared dissimilar to a layperson's eye. This did not trouble the court, because the defendant "conceded Smith is highly qualified and did not point out any flaws in Smith's methodology that would render his resulting opinion unreliable." The court emphasized that the expert had reached only limited conclusions, and accurately rendered those limitations — he stated that his comparison only pointed to the possibility that a firearm of the class depicted was used during the shooting, and conceded that many others may have been used instead.

> **Comment:** This seems to be a relatively rare case in which a ballistics expert seeks to keep the testimony within the bounds of what the methodology can support.

Ballistics – NAS Report – Overstatement – testimony of a match: *Jackson v. Vannoy*, 2018 U.S. Dist. LEXIS 46297 (E.D. La.): In a habeas challenge to a conviction for second degree murder, the petitioner raised a claim of actual innocence, offering the NAS Report as "new reliable evidence" not presented at trial to undermine the inculpatory toolmark evidence. The firearms expert examined two nine-millimeter cartridge casings and two nine-millimeter bullets recovered from the crime scene, and concluded that the casings and bullets were each fired from the same weapon. The petitioner argued that the NAS Report called into question the ability of toolmark analysis to individuate shell casings. The court denied the petition for writ of habeas corpus, concluding that the NAS Report was not new evidence and was insufficient to show that it was more likely than not that no reasonable juror would have convicted the petitioner.

Ballistics: Limitation on Overstatement: *United States v. Willock,* 696 F. Supp. 2d 536 (D. Md. 2010): The defendant moved to exclude the testimony of a ballistics expert. The court denied the motion, "consistent with every reported federal decision to have addressed the admissibility of toolmark identification evidence." The court noted, however, that "in light of two recent National Research Council studies that call into question toolmark identification's status as 'science,' * * * toolmark examiners must be restricted in the degree of certainty with which they express their opinions." In response to this ruling, the government stated that "it would not seek to have [its expert] state his conclusions with any degree of certainty."

Ballistics: Admissible testimony of exclusion of a gun: *Ricks v. Pauch*, 2020 WL 1491750 (E.D. Mich.): Plaintiff brought this 1983 action against three Detroit police officers after having spent 25 years in prison for a wrongful conviction of murder. One of the experts for the plaintiff examined digital photographs of the bullets entered into evidence, and stated that they were mutilated and damaged to the extent that an identification with a suspect firearm would have likely not been possible. He further testified that the evidence bullets had certain characteristics such that they could not have been fired from the type of gun that the defendant had. The defendants moved to suppress the plaintiff's expert testimony on the grounds that the "field of firearms identification overall is subjective and based on the expertise of the examiner and therefore unreliable under *Dauber* and *Kumho Tire*." They further contested the reliability of the methodology because Ricks' firearm had been destroyed following his conviction. However, the court stated that "AFTE theory does not require having a suspect weapon" and the plaintiff's experts "do not opine that the evidence bullets were fired from a specific gun, but only that the evidence bullets have 5R characteristics, and that those bullets could not have been fired from a 6R gun," which was the gun attributed to Ricks in 1992. As a result, the court emphasized that "comparison of the evidence bullets with the bullets test-fired from Ricks' Rossi handgun was not relevant or necessary" and held that the experts' proposed opinions for the plaintiff met the admissibility requirements of Rule 702.

Ballistics: *United States v. Pugh,* 2009 WL 2928757 (S.D. Miss.): The court rejected a challenge to ballistics testimony. It relied exclusively on precedent, stating that "[m]atching spent shell casings to the weapon that fired them is a recognized method of ballistics testing. Other than the argument raised by magazine articles cited by the defense and an out-of-state federal district court ruling, [Judge Rakoff's ruling in *Glynn*] the Court has not found a case from the Fifth Circuit which shows that [the ammunition expert's] findings are unreliable. On the contrary, firearm comparison testing has widespread acceptance in this Circuit."

Ballistics – generally accepted, testimony to a reasonable degree of certainty: *United States v. Hylton*, 2018 WL 5795799 (D. Nev. Nov. 5, 2018): In an armed bank robbery prosecution, the defendant moved to strike the Government's firearm expert's proposed testimony, or in the alternative, to conduct a *Daubert* hearing on the method that the expert used to identify the firearm at issue. The court denied the defendant's motion, finding that the Association of Firearm and Toolmark Examiners ("AFTE") ballistics methodology is generally accepted:

> The AFTE methodology is generally accepted by federal courts, and has repeatedly been found admissible under *Daubert* and Rule 702. *See United States v. Johnson*, 875 F.3d 1265 (9th Cir. 2017). *See also United States v. Johnson*, 2015 WL 5012949 (N.D.Cal. 2015); *United States v. Diaz*, 2007 WL 485967 (N.D.Cal. Feb. 12, 2007); *United States v. Arnett*, 2006 WL 2053880 (E.D.Cal. 2006). Defendant fails to identify a single case in which AFTE ballistics testimony was excluded under *Daubert. See Johnson*, 875 F.3d at 1282.

> [T]he Court finds that a *Daubert* hearing is neither required nor necessary in the instant matter. Further, to the extent Defendant wishes to criticize the AFTE methodology, or ballistics evidence generally, he may do so through the presentation of his own expert and cross-examination of FS Wilcox.

Note: The court stated that the government "notes that some courts have required experts to testify that casings can be matched *only* to a reasonable degree of ballistics certainty, and that FS Wilcox's testimony will comply with this directive." But under the DOJ's own guidelines, a ballistics expert is not permitted to testify to a reasonable degree of certainty, unless the court requires it, and the court did not require it in this case. The DOJ has stated that many of the cases involving overstatement in this case digest preceded the guidelines and so are to be discounted. Maybe so --- but not this one. The opinion is dated November 5, 2018. And what is especially troublesome is that the court considers the "reasonable degree of certainty" testimony to be a *tempered* form of conclusion, when in fact it is a classic form of overstatement.

Ballistics: *United States v. Romero-Lobato*, 2019 WL 2150938 (D. Nev.): In a prosecution for robbery and related offenses, the government called a ballistics expert to testify, in the court's words, "that the Taurus handgun found in the stolen Yukon following the police chase is the *same gun* that was used to fire a round into the ceiling of Aguitas Bar and Grill." The trial court held a *Daubert* hearing in which it considered the NAS and PCAST reports as applied to ballistics analysis using the Association of Firearm and Tool Mark Examiners ("AFTE") method. In its opinion, the court first summarized the case law:

> The cases surveyed by the Court indicate that some federal courts have recently become more hesitant to automatically accept expert testimony derived from the AFTE method. While no federal court (at least to the Court's knowledge) has found the AFTE method to be unreliable under *Daubert*, several have placed limitations on the manner in which the expert is allowed to testify. The general consensus is that firearm examiners should not testify that their conclusions are infallible or not subject to any rate of error, nor should they arbitrarily give a statistical probability for the accuracy of their conclusions. Several courts have also prohibited a firearm examiner from asserting that a particular bullet or shell casing could only have been discharged from a particular gun to the exclusion of all other guns in the world. These restrictions are in accord with guidelines issued by the Department of Justice for its own federal firearm examiners which went into effect in January 2019. But it is also important to note that the courts that imposed limitations on firearm and toolmark expert testimony were the exception rather than the rule. Many courts have continued to allow unfettered testimony from firearm examiners who have utilized the AFTE method.

In a lengthy analysis, the court applied the *Daubert* factors and concluded that the ballistics expert would be permitted to testify. It summed up as follows:

> Balancing the *Daubert* factors, the Court finds that Johnson's testimony derived from the AFTE method is reliable and therefore admissible. The only factor that does not support the admission of the testimony is the lack of objective criteria governing the application of the AFTE method. But this lack of objective criteria is countered by the method's relatively low rate of error, widespread acceptance in the scientific community, testability, and frequent publication in scientific journals. The balance of the factors therefore weighs strongly in favor of the admission of Johnson's testimony. The Court also notes that the defense has not cited to a single case where a federal court has completely prohibited firearms identification testimony on the basis that it fails the *Daubert* reliability analysis. The lack of such authority indicates to the Court that defendant's request to exclude Johnson's testimony wholesale is unprecedented, and when such a request is made, a defendant must make a remarkable argument supported by remarkable evidence. Defendant has not done so here.

In its analysis, the court discussed the case law, such as *Glynn,* that has sought to put limitations not on ballistics as a whole but on the overstatement of an expert's conclusion. While the court does not specifically reject those cases, ***there is nothing in the final order that appears to impose any limitation on the expert's conclusions --- which are described by the court as testimony of a match.***

Ballistics: Overstatement --- reasonable degree of ballistics certainty: *United States v. Otero*, 849 F. Supp. 2d 425 (D.N.J. 2012): The court denied a motion to exclude the government's expert on the subject of firearms and toolmark identification. The court allowed the expert to testify to a reasonable degree of ballistics certainty. It addressed the impact of the NAS report:

> The Government has demonstrated that Deady's proffered opinion is based on a reliable methodology. The Court recognizes, as did the National Research Council in *Strengthening Forensic Science in the United States: A Path Forward*, that the toolmark identification procedures discussed in this Opinion do indeed involve some degree of subjective analysis and reliance upon the expertise and experience of the examiner. The Court further recognizes, as did the National Research Council's report, that claims for absolute certainty as to identifications made by practitioners in this area may well be somewhat overblown. The role of this Court, however, is much more limited than determining whether or not the procedures utilized are sufficient to satisfy scientists that the expert opinions are virtually infallible. If that were the requirement, experience-based expert testimony in numerous technical areas would be barred. Such an approach would contravene well-settled precedent on the district court's role in evaluating the admissibility of expert testimony.

Ballistics: attempt to limit overstatement of results, but allowing testimony to a reasonable degree of certainty: *United States v. Taylor*, 663 F. Supp. 2d 1170 (D.N.M. 2009): The court allowed ballistics testimony, but limited it in several respects, relying on the NAS report. The court stated that "[b]ecause of the seriousness of the criticisms launched against the methodology underlying firearms identification, both by various commentators and by Defendant

in this case, the Court will carefully assess the reliability of this methodology, using *Daubert* as a guide." The court noted that NAS concluded that ballistics methodology was weak on the *Daubert* factor of standards and controls, because "the decision of the toolmark examiner remains a subjective decision based on unarticulated standards and no statistical foundation for estimation of error rates."

The court noted that Judge Rakoff, in *United States v. Glynn*, 578 F. Supp. 2d 567 (S.D.N.Y. 2008), resolved one of the problems of ballistics testimony "by sending the case back for retrial and ordering that the ballistics opinions offered at the retrial may be stated in terms of 'more likely than not,' but nothing more." The court adopted the reasoning in *Glynn,* concluding that the firearms identification testimony is admissible under Rule 702 and *Daubert*, but imposing limitations on that testimony.

> Because of the limitations on the reliability of firearms identification evidence discussed above, [the expert] will not be permitted to testify that his methodology allows him to reach this conclusion as a matter of scientific certainty. [The expert] also will not be allowed to testify that he can conclude that there is a match to the exclusion, either practical or absolute, of all other guns. He may only testify that, in his opinion, the bullet came from the suspect rifle to within a reasonable degree of certainty in the firearms examination field.
>
> **Note:** It is a bit sad that after all that analysis, and in a good faith attempt to prohibit the expert from overstating his conclusions, the court allows him to testify to a reasonable degree of certainty --- which is a meaningless, confusing standard that the jury may well equate with "beyond a reasonable doubt."

Ballistics: Limiting overstatement: ***United States v. White***, 2018 WL 4565140 (S.D.N.Y. Sept. 24, 2018): In a gang prosecution, the defendant moved to exclude the testimony of the government's proposed ballistics expert. Citing the NAS Report and other federal cases restricting ballistics experts' testimony, the court concluded that the proposed testimony was admissible, *subject to the limitation* that the expert could not testify to any specific degree of certainty that there was a match between the firearms seized from the defendant and those used in the various shooting incidents:

> The general admissibility of expert testimony regarding ballistics analysis has been repeatedly recognized by federal courts. *See, e.g., United States v. Glynn*, 578 F. Supp. 2d 567, 569 (S.D.N.Y. 2008); *Ashburn*, 88 F. Supp. 3d at 247. Moreover, the Second Circuit has recently affirmed the admission of this kind of expert ballistics testimony. *See Gil*, 680 F. App'x at 14. As such, White's motion to exclude Detective Fox's testimony in its entirety is denied.
>
> Still, certain restrictions to Detective Fox's testimony are warranted. Recent reports have challenged ballistics analysis as a science. For example, the National Research Council has noted the subjectivity of the analysis and the lack of any definitive error rate. *See, e.g.*, Nat'l Res. Council, Strengthening Forensic Science in the United States: A Path Forward 154-55 (2009); Nat'l Res. Council, Ballistic Imaging: Committee to Assess

the Feasibility, Accuracy, and Technical Capability of a National Ballistics Database 3 (2008). The Government's detailed description of Detective Fox's anticipated testimony is insufficient to persuade the Court that the concerns raised by such reports are unjustified. Specifically, the evidence fails to establish that the theory of uniqueness on which Detective Fox relies has been proven as a matter of empirical science, that there is any objective standard for declaring a "match," or that there is any reliable basis on which Detective Fox could state the degree to which he is certain of his conclusions.

For these reasons, consistent with other federal opinions, the Court finds that Detective Fox's testimony must be limited in certain respects. *See, e.g., Glynn*, F. Supp. 2d at 575 (restricting ballistics expert's opinion to statement that match was "more likely than not"); Order, *United States v. Barrett*, No. 12-cr-45, at 1 (S.D.N.Y. Mar. 11, 2013); *Ashburn*, 88 F. Supp. 3d at 249 (precluding expert from testifying that he is "certain" or "100%" sure of his matches); *United States v. Willock*, 696 F. Supp. 2d 536, 574 (D. Md. 2010) (prohibiting expert from stating that it was a "practical impossibility" that any other firearm fired the cartridges in question); *United States v. Green*, 405 F. Supp. 2d 104, 124 (D. Mass. 2005) (precluding expert from testifying that his methodology permits "the exclusion of all other guns" as source of certain shell casings). In particular, Detective Fox may not testify to any specific degree of certainty as to his conclusion that there is a ballistics match between the firearms seized from White and those used in the various shooting incidents. However, if pressed to define his degree of certainty during cross-examination, Detective Fox may state his personal belief on that issue.

Ballistics: Limits on Overstatement: *United States v. Shipp,* 2019 WL 6329658 (E.D.N.Y.): The court relied on the PCAST report and stated that its findings "cast considerable doubt on the reliability of the theory behind matching pieces of ballistics evidence." It concluded that the ballistics expert "will be permitted to testify only that the toolmarks on the recovered bullet fragment are consistent with having been fired from the same firearm. In other words, Detective Ring may testify that the recovered firearm cannot be excluded as the source of the recovered fragment and shell casing, but not that the recovered firearm *is,* in fact, the source of the recovered fragment and shell casing."

In reaching this conclusion preventing overstatement of the expert's results, the court made the following important points:

● A court evaluating the reliability of forensic testimony should not be precluded by precedent, given the recent studies challenging the reliability of feature-comparison testimony.

● The *Daubert* peer review factor is somewhat questionable when it comes to ballistics, because the AFTE peer review process is not rigorous --- the reviewers are all members of AFTE, and have "a vested, career-based interest in publishing studies that validate their own field and methodologies."

● The potential rate of error for matching ballistics evidence based on the AFTE theory of comparison "does not favor a finding of reliability at this time" because "the study that most closely resembles fieldwork estimated that a firearms toolmark examiner may incorrectly conclude that a revered piece of ballistics evidence matches a test fire one out of every 46 examinations."

● The AFTE theory of examination, which bases a finding of a match upon "sufficient agreement" between the compared toolmarks, is "circular and subjective" and is distinguishable from other expert testimony, such as from a psychologist, because it is not about "an ambiguous question on which experts can disagree." Rather, it is on an unambiguous question, which should be answered without subjectivity.

● On the *Daubert* question of general acceptance, the relevant scientific community cannot be limited to self-interested toolmark experts. Therefore, it is appropriate "to consider the opinions of the authors of the NRC report and the PCAST report who, while admittedly not members of the forensic ballistic community, are preeminent scientists and scholars and are undoubtedly capable of assessing the validity of a metrological method." The court consequently concluded that the AFTE theory "has not achieved general acceptance in the relevant community."

● The court recognized that the limitation on the expert's testimony--- that the firearm cannot be excluded as a source --- was more restrictive than other courts that have sought to limit overstatement. For example, Judge Rakoff in *Glynn, infra,* allowed the expert to say that it was more likely than not that the bullet came from the defendant's gun. But the court found the more restrictive limitation appropriate "given the concerns raised by the PCAST report about the lesser probative value of certain study designs and the reproducibility and accuracy of an individual examiner's application of the 'sufficient agreement' standard." The court concluded as follows:

> Placing this limitation on Detective Ring's testimony will prevent the jury from placing unwarranted faith in an identification conclusion based on the AFTE Theory, which the current research has yet to show can reliably determine, to a reasonable possibility, whether separate pieces of ballistics evidence have the same source firearm.

Note: Despite the DOJ standards that purport to limit a forensic expert's testimony, the expert in this case was prepared to testify that the cartridge casing and bullet fragment were fired from the recovered firearm. The explanation is probably that the expert was a detective, not an expert from a lab subject to the DOJ guidelines. But that shows that the DOJ guidelines are not completely effective in regulating overstatement by forensic experts.

Ballistics: *United States v. Sebbern*, 2012 WL 5989813 (E.D.N.Y.): The court denied a motion to exclude ballistics testimony. It recognized that there are legitimate questions about the validity of ballistics, and discussed the NAS report and Judge Rakoff's opinion in *Glynn*:

> The comparison of test bullets and cartridges to those of unknown origins involves "the exercise of a considerable degree of subjective judgment." *Glynn*, 578 F.Supp.2d at 573. First, some subjectivity is involved in the examination of the evidence, which is done visually using a comparison microscope. * * * In addition, the standards employed by examiners invite subjectivity. The AFTE theory of toolmark comparison permits an examiner to conclude that two bullets or two cartridges are of common origin, that is, were fired from the same gun, when the microscopic surface contours of their toolmarks are in "sufficient agreement." In part because of this reliance on the subjective judgment of the examiners, the AFTE Theory has been the subject of criticism. For example, in a 2009 report, the National Research Council of the National Academy of Sciences (the 'NRC') observed that AFTE standards acknowledged that ballistic comparisons "involve subjective qualitative judgments by examiners and that the accuracy of examiners' assessments is highly dependent on their skill and training."

In *Glynn*, Judge Rakoff found that ballistics identification had garnered sufficient empirical support as to warrant its admissibility. Accordingly, he permitted the ballistics expert to testify, but limited the degree of confidence which the expert was permitted to express with respect to his findings. Opining that the expert would "seriously mislead the jury as to the nature of the expertise involved" if he testified that he had matched a bullet or casing to a particular gun "to a reasonable degree of ballistic certainty," Judge Rakoff limited the expert to stating that it was "more likely than not" that the bullet or casing came from a particular gun. Accordingly, *Glynn* does not support the argument that the government's ballistics expert should be entirely precluded from testifying.

The court concluded that Judge Rakoff's ruling in *Glynn* "may support a request to limit the degree of confidence which the expert can express with respect to his findings." But the defendant had moved for exclusion and not limitation. Because the motion did not argue for a specific limitation, the court did not address that question. The court ultimately relied on case law to conclude that ballistics methodology is reliable.

Ballistics: Extensive analysis, discussion of overstatement: *United States v. Johnson*, 2019 WL 1130258 (S.D.N.Y.): In a prosecution of a street gang, the government offered expert testimony from a ballistics examiner. The expert report stated that the cartridge casings produced from test fires were "discharged from the SAME firearm" as the thirteen cartridge casings recovered from the scene of the Bronx Restaurant Shooting, "based on the observed agreement of their class characteristics and sufficient agreement of their individual characteristics." The court denied the defendant's motion to exclude the expert testimony.

The court discussed the NAS and PCAST reports, and summarized the federal court treatment of those reports as applied to ballistics testimony:

> All of these courts admitted expert testimony concerning toolmark identification, rejecting arguments that the 2008-2016 scientific reports had rendered such evidence inadmissible. While acknowledging that toolmark identification evidence does not feature the full rigor of a science, and suffers from subjectivity and an absence of a precise, widely accepted methodology, these courts concluded that it is nonetheless a proper subject for

expert testimony. These courts found such evidence "sufficiently plausible, relevant, and helpful to the jury to be admitted in some form," *Willock*, 696 F. Supp, 2d at 568, and reasoned that the weaknesses in toolmark identification can be effectively explored on cross-examination. These courts also precluded toolmark identification experts from expressing their opinions in terms of absolute scientific certainty. See, e.g., *Ashburn,* 88 F. Supp. 3d at 248-50; *Monteiro,* 407 F. Supp. 2d at 369; *Cerna*, 2010 WL 3448528, at *5.

Courts have also emphasized that the demanding scientific standards on display in the three reports require a level of certainty and infallibility not properly applied in a courtroom.

The court then proceeded to an application of the *Daubert* factors. As to *testability*, the court stated as follows (with many citations omitted):

There appears to be little dispute that toolmark identification is testable as a general matter. The PCAST Report observed that "[o]ver the past 15 years, the field has undertaken a number of studies that have sought to estimate the accuracy of examiners' conclusions." While the PCAST Report dismissed "many of the[se] studies [as] not appropriate for assessing scientific validity and estimating the reliability because they employed artificial designs that differ in important ways from the problems faced in casework," PCAST acknowledged that one study was appropriately designed, and called for additional such studies to be performed.

Indeed, many courts have relied on the existing scientific literature – including the studies examined in the PCAST Report — in concluding that toolmark identification analysis satisfies the "testability" factor of *Daubert*. * * * While some courts have acknowledged the limitations of these "validation studies," even the PCAST Report – which is the report most critical of toolmark identification – conceded that these studies "indicate that examiners can, under some circumstances, associate ammunition with the gun from which it was fired."

The "testability" of Detective Fox's methods and conclusions is also supported by the annual proficiency testing he undergoes. While these proficiency tests do not validate the underlying assumption of uniqueness upon which the AFTE theory rests, they do provide a mechanism by which to test examiners' ability – employing the AFTE method – to accurately determine whether bullets and cartridge casings have been fired from a particular weapon.

Finally, * * * Detective Fox testified that he is required to photograph "positive comparisons" so that "if a qualified examiner w[ere] to reexamine [his] case[,] ... he could have an idea of what [Detective Fox] was looking at and what [he] was comparing" in reaching his conclusions. Moreover, Detective Fox testified that a second microscopist reviews his conclusions, by performing "an independent verification and technical review of [Detective Fox's] findings to see if they are correct or not." The firearms examiner conducting the review is not aware of Detective Fox's conclusions when he or she conducts

the review. These procedures demonstrate that Detective Fox's methodology can be challenged and reasonably assessed for reliability.

As to *peer review,* the court noted that most of the literature concerning the AFTE theory and methodology has been published in AFTE's peer-reviewed journal, the AFTE Journal. The defendant argued that this should be discounted as peer review because the AFTE is essentially a captive journal for ballistics experts. But the court found that other courts have found the AFTE journal to be a scholarly publication. [Though not Judge Garaufis in *Shipp, supra*].

As to *standards and controls,* the court declared as follows (with many citations omitted):

> AFTE has a well-known standard for toolmark identification, which the Government and Detective Fox have repeatedly invoked – "sufficient agreement." As discussed above, both courts and the scientific community have voiced serious concerns about the "sufficient agreement" standard, characterizing it as "tautological," "wholly subjective," "circular," "leav[ing] much to be desired," and "not scientific." The Court shares some of these concerns. Having heard Detective Fox's testimony, however, the Court is persuaded that his methodology is governed by controlling standards sufficient to render it reliable.
>
> As an initial matter, several aspects of Detective Fox's methodology discussed in connection with the "testability" *Daubert* factor constitute "standards controlling ... [toolmark identification's] operation." For example, the photographic documentation and verification requirements are industry standards adhered to by most, if not all, other crime labs in the country. Similarly, the extensive AFTE training and proficiency testing Detective Fox has received — which appear to be administered to firearms examiners nationwide – also supply such standards.
>
> Moreover, Detective Fox's testimony about his methodology demonstrates the existence of standards controlling his determination as to whether "sufficient agreement" exists with respect to a particular comparison. As discussed above, the photographic comparisons included in Detective Fox's December 5, 2018 report demonstrate how he can determine – from the individual characteristics of two casings or bullets – whether striations line up or "match" one another. The photographic comparisons at issue here reflect striations that line up exactly between the test-fired cartridge casings and those recovered from the scene of the Bronx Restaurant Shooting. The "matching" of the striations is stark, even to an untrained observer. Accordingly, the issue is not whether the ballistics evidence in this case shares specific individual characteristics. Instead, the issue is at what point Detective Fox concludes that the shared individual characteristics he has observed and photographically documented are sufficient to declare that the casings or bullets were fired from the same firearm.
>
> On cross-examination, Detective Fox resisted defense counsel's efforts to have him specify the number of matching individual characteristics that are necessary before a "sufficient agreement" conclusion can be reached. Instead, Detective Fox stated that

> "[e]very single case is different," and that he employs a holistic approach incorporating his "training as a whole" and his experience "based on all the cartridge casings and ballistics that [he] ha[s] identified and compared." Detective Fox did set out certain principles that ground his conclusions, however. For example, the CMS standard – six consecutive matching striations or two groups of three matching striations – represents a "bottom standard" or a floor for declaring a match. Detective Fox will not declare that "sufficient agreement" exists unless microscopic examination reveals a toolmark impression with one area containing six consecutive matching individual characteristics, or two areas with three consecutive matching individual characteristics. Detective Fox's analysis does not end at that point, however. Instead, Detective Fox goes on to examine every impression on the ballistics evidence. "All these lines should match," as well, and if they do not, Detective Fox will not find "sufficient agreement."
>
> These criteria provide standards for Detective Fox's findings as to "sufficient agreement." While Detective Fox's ultimate findings are subjective — a fact which he readily concedes — all technical fields which require the testimony of expert witnesses engender some degree of subjectivity requiring the expert to employ his or her individual judgment, which is based on specialized training, education, and relevant work experience. Accordingly, the presence of a subjective element in a technical expert's field does not operate as an automatic bar to admissibility.

As to *rate of error,* the court recognized that no error rate for ballistics examination has been conclusively established. It also noted that based on studies conducted, PCAST concluded that the error rate is as high as 1 in 46. But it concluded that "even accepting the PCAST Report's assertion that the error rate could be as high as 1 in 46, or close to 2.2%, such an error rate is not impermissibly high. The court concludes that the absence of a definite error rate for toolmark identification does not require that such evidence be precluded."

Finally, as to *general acceptance*, the court concluded that "[t]here is no dispute here that toolmark identification analysis is a generally accepted method in the community of forensic scientists, and firearms examiners in particular." [Again, this assessment is rejected by Judge Garaufis in *Shipp, supra.]*

After finding that tool mark comparison withstood a *Daubert* challenge, the court turned to possible limitations on the ballistics expert's testimony. The defendant asked the court to limit the expert's testimony "to a factual description of the method he applied and his observations of similarities and differences he found between sets of ballistics." But the court declined to do so. It discussed the case law concerning potential overstatement of a ballistics expert's conclusion, and noted that most of it was related to testimony to a "specific degree of scientific certainty." Citing *Glynn,* the court stated that "[o]ften these limitations are imposed because of judicial or defense counsel concern that the firearms examiner intends to offer an opinion with absolute or 100% certainty." The court concluded that in this case, it was clear that the expert did not intend to assert – and the Government did not intend to elicit – "any particular degree of certainty as to his opinions regarding the ballistics match." The court stated that "Detective Fox's repeated concession at the *Daubert* hearing that his conclusions are based on his subjective opinion stands in stark contrast to the "tendency of [other] ballistics experts ... to make assertions that their matches are certain

beyond all doubt. *Glynn,* 578 F. Supp. 2d at 574." The court also emphasized that the expert stated that he "would never" state his conclusion that ballistics evidence matches to a particular firearm "to the exclusion of all other firearms in a court proceeding, because I haven't looked at all other firearms." The court concluded that "[g]iven the testimony at the *Daubert* hearing and the Government's representations as to what it will elicit from Detective Fox, there is no need for this Court to impose limitations on Detective Fox's opinions."

Ballistics: No identification of a specific gun: *United States v. Tucker*, 2020 WL 93951 (E.D.N.Y.): In a robbery case, the government offered ballistics testimony from NYPD Detective Parlo who concluded that the bullet fragments from the scene came from at least three different firearms. The defendant argued that this testimony should be excluded because toolmark identification is subjective, unreliable, and unverified, especially in light of the PCAST report. But the court distinguished the subject of the PCAST report from the case at hand – the PCAST report discusses the validity of attributing bullets to a specific firearm; whereas in this case, Parlo's testimony focuses on class characteristics. The court did note that it was troubled by Parlo's claim that the second examiner conducts their own investigation and comes to a conclusion without taking notes prior to comparing their results to those of Parlo's. Ultimately, the court found that because Parlo's analysis was routine, well-documented, and subject to cross-examination, his testimony was admissible.

Ballistics: Overstatement --- reasonable degree of ballistics certainty: *United States v. Ashburn*, 88 F. Supp. 3d 239 (E.D.N.Y. 2015): The defendant challenged ballistics testimony pursuant to the AFTE methodology. He argued for exclusion and, if not, limitation on the expert's conclusion. The court denied the motion to exclude and granted the motion to limit the conclusion. The court first addressed the findings of the NAS Report:

> In 2009, the National Academy of Sciences published a comprehensive report on the various fields of forensic science. National Research Council of the National Academies, Strengthening Forensic Science in the United States: A Path Forward (2009) [hereinafter 'NAS Report']. With respect to toolmark and firearms identification, the NAS Report found that the field suffers from certain "limitations," including the lack of sufficient studies to understand the reliability and repeatability of examiners' methods and the inability to specify how many points of similarity are necessary for a given level of confidence in the result. According to the NAS Report, "[a] fundamental problem with toolmark and firearms analysis is the lack of a precisely defined process." Still, the NAS Report concluded that "[i]ndividual patterns from manufacture or from wear might, in some cases, be distinctive enough to suggest one particular source, but additional studies should be performed to make the process of individualization more precise and repeatable."

On the *Daubert* factors, the court concluded that 1) the "AFTE methodology has been repeatedly tested"; 2) "The AFTE itself publishes within the field of toolmark and firearms identification."; 3) "Studies have shown that the error rate among trained toolmark and firearms examiners is quite low" (citing studies finding error rates between 0.9% and 1.5%); 4) "the AFTE's 'sufficient

agreement' standard is the field's established standard * * * but the fact that a standard exists does not necessarily bolster the AFTE methodology's reliability or validity, as it remains a subjective inquiry"; and 5) the AFTE theory "has been widely accepted in the forensic science community."

But the court was persuaded that given the subjectivity involved in ballistics feature-comparison, an instruction limiting the expert's testimony was appropriate. "Given the extensive record presented in other cases, the court joins in precluding this expert witness from testifying that he is 'certain' or '100%' sure of his conclusions that certain items match. * * * [T]he court will limit LaCova to stating that his conclusions were reached to a 'reasonable degree of ballistics certainty' or a 'reasonable degree of certainty in the ballistics field.'"

Comment: The court was influenced by the NAS report to put a limit on how the expert expressed his conclusion to the jury. But the court did not mention a separate NAS report that advocates abolition of the fake standard of "a reasonable degree of certainty."

DOJ points out, by way of correction of this entry, that the "reasonable degree" testimony was required by the court and not chosen by the witness. That is not quite true. The court "limited" the expert to a conclusion of reasonable degree of certainty, but did not *require* that he testify to a reasonable degree of certainty. If the Department is taking the position that authorization to testify is an order to testify, there will be many cases in which the DOJ limitations will not be applicable.

Anyway, even if it is an order, it seems especially problematic for a court to require witnesses to testify to standards that have been so widely discredited in the scientific community and by DOJ itself. This is a good indication that the DOJ standards are not the complete answer to the problem of overstatement.

Ballistics: *United States v. Glynn*, 578 F. Supp. 2d 567 (S.D.N.Y. 2008): Judge Rakoff found that the field of ballistics is not scientific because its underlying premises have not been validated empirically, and the methodology is based on subjective assessments. But he found that the methodology was sufficiently reliable to be admissible under *Kumho*. However, because of the subjectivity inherent in the field, Judge Rakoff determined that he could not permit an expert to testify that he was "certain" of a match or that there was "no rate of error." These iterations presented a risk of overstatement of the actual results. Judge Rakoff determined that the expert would be limited to testifying that the bullet "more likely than not" was fired from a particular gun. The *Glynn* opinion is discussed in many of the annotations on ballistics in this digest.

Ballistics: *United States v. Barnes*, 2008 WL 9359653 (S.D.N.Y.): The defendant challenged ballistics testimony, relying on the assertions in the NAS Report that ballistics methodology is subjective and has not been scientifically validated. The court rejected the defendant's arguments and denied the motion for a *Daubert* hearing. It stated that "ballistics evidence has long been accepted as reliable and has consistently been admitted into evidence." The court downplayed the critique in the Report, arguing that its purpose "was to assess the

possibility of developing a national ballistics database and the feasibility of capturing by computer imaging technology the toolmarks left on discharged bullets and shell casings. The report was not aimed at assessing the procedures used in firearms identification or the degree to which firearms toolmarks are unique, and the report disclaims any motive to impact the question of ballistics evidence in courts. . . . This report, while no doubt useful for the commissioned purpose and not irrelevant to the issue of reliability and admissibility of firearms identification evidence, does not identify any new evidence undermining the core premises upon which ballistics analysis is based." The court was not asked to make a ruling on the confidence-level that the expert could testify to.

Ballistics: Testimony to a reasonable degree of ballistics certainty is allowed even though the court cites and quotes the DOJ limitations: *United States v. Hunt,* 2020 WL 2842844 (W.D.Okla): The court found that ballistics expert testimony was admissible, even though it was subjective. It found a sufficiently low rate of error, sufficient testing, and general acceptance. The defendants argued that the court should impose limits on potential overstatement of the ballistics expert's conclusions. On the question of overstatement, the court had this to say:

> In his penultimate argument, Defendant asks the Court to place limitations on the Government's firearm toolmark experts because the jury will be unduly swayed by the experts if not made aware of the limitations on their methodology. The Government responds that no limitation is necessary because Department of Justice guidance sufficiently limits a firearm examiner's testimony.
>
> Some federal courts have imposed limitations on firearm and toolmark expert testimony. See, e.g., *Ashburn*, 88 F. Supp. 3d at 249. However, many courts have continued to allow unfettered testimony. See, e.g., *Romero-Lobato*, 379 F. Supp. 3d at 1117.
>
> The general consensus is that firearm examiners should not testify that their conclusions are infallible or not subject to any rate of error, nor should they arbitrarily give a statistical probability for the accuracy of their conclusions. Several courts have also prohibited a firearm examiner from asserting that a particular bullet or shell casing could only have been discharged from a particular gun to the exclusion of all other guns in the world.
>
> In accordance with recent guidance from the Department of Justice, the Government's firearm experts have already agreed to refrain from expressing their findings in terms of absolute certainty, and they will not state or imply that a particular bullet or shell casing could only have been discharged from a particular firearm to the exclusion of all other firearms in the world. The Government has also made clear that it will not elicit a statement that its experts' conclusions are held to a reasonable degree of scientific certainty.
>
> The Court finds that the limitations mentioned above and prescribed by the Department of Justice are reasonable, and that the Government's experts should abide by those limitations. To that end, the Governments experts:

> [S]hall not [1] assert that two toolmarks originated from the same source to the exclusion of all other sources.... [2] assert that examinations conducted in the forensic firearms/toolmarks discipline are infallible or have a zero error rate.... [3] provide a conclusion that includes a statistic or numerical degree of probability except when based on relevant and appropriate data.... [4] cite the number of examinations conducted in the forensic firearms/toolmarks discipline performed in his or her career as a direct measure for the accuracy of a proffered conclusion..... [5] use the expressions 'reasonable degree of scientific certainty,' 'reasonable scientific certainty,' or similar assertions of reasonable certainty in either reports or testimony unless required to do so by [the Court] or applicable law.

As to the fifth limitation described above, ***the Court will permit the Government's experts to testify that their conclusions were reached to a reasonable degree of ballistic certainty, a reasonable degree of certainty in the field of firearm toolmark identification, or any other version of that standard.***

Note: The court allows the expert to testify to a reasonable degree of certainty even though it is not permitted under the DOJ guidelines. The DOJ guidelines have an exception for when the expert is *required* to so testify. But that exception should not apply here --- the court permitted the expert to testify to a reasonable degree of certainty, but certainly did not require it. But in *Ashburn, supra,* the Department took the position that it was ordered to testify to a reasonable degree of certainty when the court "limited" the expert to that standard. That wasn't an order to so testify, though. It appears that the "ordered to testify" exception to the DOJ standards is being expansively applied by the Department.

I have not been able to determine whether the expert in this case actually intends to testify in violation of the DOJ guidelines. But the fact that the court permitted such testimony in violation of the guidelines surely raises some question about the efficacy of the DOJ guidelines in controlling overstatement.

Ballistics: Not reliable under *Daubert* and therefore *no testimony of comparison allowed*: *United States v. Adams*, 2020 U.S. Dist. LEXIS 45125 (D. Ore.): The defendant was charged with felon gun possession. Mr. Gover, the expert for the government, proposed to testify that shell casings found at the crime scene "had been fired by" the gun found at the defendant's residence. Gover employed the AFTE methodology to make the identification. The court found that the AFTE methodology was essentially subjective, and lacked "any scientific standard that would explain to an examiner like Mr. Gover how to interpret the data he sees in any kind of objective way." As Judge Garaufis found in *Shipp, supra*, the court stated that the AFTE "sufficient agreement" standard "is a tautology that doesn't mean anything." The court asserted that "[n]ot only is the AFTE method not replicable for an outsider to the method, but it is not replicable between trained members of AFTE who are using the same means of testing." The court therefore concluded that ***no testimony*** about a comparison could be admitted --- unlike other cases *supra* in which courts allowed some testimony about comparison but limited overstatement.

The court analyzed rate of error in the AFTE methodology as follows:

> The Government initially asserted that the error rate for toolmark comparison testing is between .9 and 1.5 percent. But testing shows a range of outcomes, sometimes with an error rate as high as 2.2 percent. *United States v. Shipp*, 2019 WL 6329658 (E.D.N.Y.). If these all sound like low rates of error, whose differences could not possibly be material, it is helpful to consider them in terms of wrongful convictions, which is the correct framework for an error rate that measures only false-positives—i.e. incorrectly identified matches. A .9 percent error rate would lead to about 1 in 111 wrongful convictions. A 1.5 percent error rate would mean that 1 in 67 convictions were wrong. And 2.2 percent would mean that 1 in 46 convictions were wrong. These are dramatically different rates of error when put into context.
>
> What's more, the higher error rates tend to arise from the studies that most closely resemble the real-world conditions of toolmark testing. The lowest rates arise from the "closed-set" tests, which require the examinee to perform a matching exercise between two sets of bullets or shell casings. An examinee can "perform perfectly" if he simply matches each bullet to the standard that is closest. each match narrows the field for further matches. The next highest error rates—about 2.1 percent—arise from partly closed sets. These tests also give the examinee a closed set of matches, but it also includes two bullets or shells that do not have a match in the set. The error rate from these tests is nearly 100-fold higher than from the closed-set tests. Finally, the "black box" studies yield the highest error rates, about 2.2. percent. (citing PCAST Report at 110-11). These tests presented each examinee with an unknown shell casing or bullet and three test fires from the same known firearm, which may or may not have been the source of the unknown casing or bullet. These tests most closely resemble real-world analysis—i.e. what Mr. Gover testified that he did in this case.
>
> * * *
>
> The incentive structure for the testing process is also concerning. It appears to be the case that the only way to do poorly on a test of the AFTE method is to record a false positive. There seems to be no real negative consequence for reaching an answer of inconclusive. Since the test takers know this, and know they are being tested, it at least incentivizes a rate of false positives that is lower than real world results. This may mean the error rate is lower from testing than in real world examinations.
>
> It is hard to know exactly what to make of these results. It is possible that the error rate for toolmark testing is very low, but it is more likely that it is not. Assuming false positive test results lead to wrongful convictions, a wrongful conviction rate of 1 in 46 is far too high. The best test results would favor the government, but it is unlikely those tests reflect real-world error rates. The worst results favor Defendant. At most, then, this factor of the *Daubert* test is neutral as to both parties. In my opinion, it cuts somewhat in favor of Defendant.

———

The court also determined that the AFTE methodology has not been subject to peer review. This is because the methodology was published in the AFTE Journal, "a trade publication meant

only for industry insiders, not the scientific community […] whose purpose is not to review the methodology for flaws but to review studies for their adherence to the methodology." Nor did the court find that the AFTE methodology generally accepted in the broader scientific community --- the fact that it is accepted by toolmark examiners was found essentially irrelevant, because of the inherent bias of those in the field.

The court concluded that the AFTE methodology failed "to yield reproducible results or a precisely defined process." As a result of these deficiencies, the court granted in part and denied in part the defendant's motion to exclude the government's expert testimony. It set forth its limitations in this conclusion:

> I want to be clear that my ruling, as expressed in the foregoing opinion, is limited by the testimony before me during the hearings held in this case. It is not an indictment of forensic evidence or toolmark comparison analysis writ large. It is clear that Mr. Gover and his colleagues are on to something. Even at its worst, comparison analysis has a very low rate of error and yields results that cannot be random. But it is not clear that those results are the product of a scientific inquiry. Nothing in Mr. Gover's testimony explains how or why he reached his conclusion in any quantifiable, replicable way. It is possible that the AFTE method could be expressed in scientific terms, but I have not seen it done in this case, nor elsewhere.
>
> Therefore, for the reasons discussed above, Mr. Gover's expert testimony is limited to the following observational evidence: (1) the Taurus pistol recovered in the crawlspace of Mr. Adams's home is a 40 caliber, semi-automatic pistol with a hemispheric-tipped firing pin, barrel with six lands/grooves and right twist; (2) that the casings test fired from the Taurus showed 40 caliber, hemispheric firing pin impression; (3) the casings seized from outside the shooting scene were 40 caliber, with hemispheric firing pin impressions; and (4) the bullet recovered from gold Oldsmobile at the scene of the shooting were 40/10mm caliber, with six lands/groves and a right twist.
>
> No evidence relating to Mr. Gover's methodology or conclusions relating to whether the shell casings matched the Taurus will be admitted at trial.

Ballistics --- Overstatement --- 100% Certainty: *United States v. Casey*, 928 F. Supp. 2d 397 (D.P.R. 2013): The defendant requested that the court limit the testimony of the government's firearm expert, relying on several district court opinions restricting ballistics evidence based upon the NAS report. The court denied the motion. The expert was prepared to testify that he was 100% certain of a match. The government presented a sworn statement from the Chair of the group that prepared the NAS report, stating that its purpose "was not to pass judgment on the admissibility of ballistics evidence in legal proceedings, but, rather, to assess the feasibility of creating a ballistics data base." The court concluded that it would remain "faithful to the long-standing tradition of allowing the unfettered testimony of qualified ballistics experts."

> **Comment: If it has been established by scientists that there is no such thing as an error-free methodology, how is it permissible for an expert to say they are 100%**

certain? There was also a long-standing tradition of "unfettered" testimony on bite-marks and probably on leeches before that. That doesn't make it reliable.

Ballistics: Overstatement --- Reasonable degree of ballistics certainty: *United States v. Simmons,* 2018 U.S. Dist. LEXIS 18606 (E.D.Va.): The court held that ballistics was not a science because the process of identification was based on subjective judgment. But the court also held that ballistics identification, when independently verified, satisfied the standards of Rule 702 as reliable technical testimony. The defendant argued that the expert was contaminated by confirmation bias---because she was told that numerous cases were connected, was congratulated by the prosecution for her work in other cases, had numerous detailed conversations with prosecutors and law enforcement agents about the status of the investigation, the nature of the crimes, and the need to link the various items of evidence to each other. But the court held that the bias of a witness was classically a question for the jury.

On the question of the meaning of an identification, the government proffered two possible conclusions:

> The Government has suggested as appropriate such statements of certainty as "given her training, experience, and knowledge of the field, combined with the requirement that all identifications be verified by a second examiner, her opinion is that the likelihood that another tool could have produced an identified toolmark is so low as to be a practical, but not absolute, impossibility." Alternatively, the Government suggests that if asked, Ms. Moynihan would qualify the certainty of her conclusions with a phrase similar to "a reasonable degree of certainty in the ballistics field."

The court rejected the "almost impossible to be wrong" standard on the ground that "there is no meaningful distinction between a firearms examiner saying that 'the likelihood of another firearm having fired these cartridges is so remote as to be considered a practical impossibility' and saying that his identification is 'an absolute certainty.'" But the court found that the reasonable degree of certainty standard was just fine --- relying on precedent. The court summed up with an ode to precedent:

> Defendants concede, as they must, that no court has ever ***totally*** rejected firearms and toolmark examination testimony. [Though this is no longer true, see *Adams, supra*] * * * This Court's survey of federal courts in our sister circuits indicates that firearms and toolmark examination has and continues to be routinely accepted by courts pursuant to Fed. R. Evid. 702, *Daubert*, and its progeny, albeit with some limitations regarding statements of certainty and the requirement that certain prerequisites be satisfied. *See e.g., United States v. Casey*, 928 F. Supp. 2d 397 (D.P.R. 2013) (declining to follow sister courts who have limited expert testimony based on the 2008 and 2009 NAS reports and finding that the Committee(s) who authored such reports specifically stated that the purpose of the reports was not to weigh in on admissibility of firearm toolmark vidence) and encouraging a return to the previous tradition of unfettered admissibility of a firearm examiner's expert testimony without qualification of the expert's degree of certainty); *United States v. Taylor*, 663 F. Supp. 2d 1170 (D.N.M. 2009) (holding that expert could testify, in his

opinion, using pattern-based methodology, if such methodology was subject to peer review, that the bullet came from suspect rifle to within "reasonable degree of certainty in the firearms examination field"); *United States v. Glynn*, 578 F. Supp. 2d 567 (S.D.N.Y. 2008) (determining that although firearm toolmark examination is not a science, it is a field that is ripe for expert testimony because it is "technical" or "specialized" and the level of certainty could be expressed as "more likely than not" but nothing more); *United States v. Diaz*, 2007 U.S. Dist. LEXIS 13152, 2007 WL 485967 (N.D. Cal. 2007) (permitting the firearms examiner to testify, but could only testify that a particular bullet or cartridge case was fired from a firearm to a "reasonable degree of certainty in the ballistics field"); *United States v. Monteiro*, 407 F.Supp.2d 351 (D. Mass. 2006) (stating that the appropriate standard is "reasonable degree of ballistic certainty"). For reasons detailed herein, the Court declines Defendants' invitation to depart from this long-standing tradition favoring admissibility

> **Comment:** In dealing with the defendant's arguments about confirmation bias, the court relied on some of the many cases holding that the bias of a witness is a credibility question for the jury. But there is a difference between impeachment-bias and confirmation bias. Impeachment bias is that the witness has a motive to falsify testimony at trial. Confirmation bias is that the expert has information in advance of the testing so that she knows what the outcome of a test ought to be before doing it. That bias goes to application of the method, and should be considered an admissibility question.
>
> Finally, this is another court that thought it did a good job of protecting the defendant from overstated conclusions. But the solution was allowing the expert to testify to a reasonable degree of ballistics certainty --- and that is a standard that has been flatly rejected by scientists, as being both meaningless and misleading.
>
> Also note that this is a 2018 case and presumably the DOJ standards should have kept the expert from proffering an opinion based on a practical impossibility or a reasonable degree of certainty. And yet the expert was prepared to offer such an opinion.

Ballistics*:* Overstatement --- testimony of a match: *United States v. Wrensford*, 2014 WL 3715036 (D.V.I. July 28, 2014): The court allowed a ballistics expert to testify, noting that "although the comparison methodology and the sufficient agreement standard inherently involves the subjectivity of the examiner's judgment as to matching toolmarks, the AFTE theory is testable on the basis of achieving consistent and accurate results." The court relied heavily on precedent. It found that the method of comparison was peer reviewed by validation studies published in the journal of the Association of Firearm and Toolmark Examiners. The court found the method was generally accepted --- in the field of firearm and toolmark experts. It also relied on the fact that results must be confirmed by a second firearm examiner. The court also concluded, on the basis of the expert's assertion, that the rate of error was "close to zero." Finally the court rejected the

argument that the subjectivity inherent in the process was sufficient grounds for excluding an expert's opinion:

> Despite the subjectivity inherent in the AFTE standards, courts have nevertheless uniformly accepted the methodology as reliable, albeit sometimes with limitations. [Citing *Glynn]*. Although the AFTE identification theory involves subjectivity, its underlying foundation confirms that it does not involve the kind of subjective belief or unsupported speculation that runs afoul of *Daubert*. In line with the weight of the case law, the Court finds that the subjectivity inherent in firearms examination is not a bar to its admissibility.

Ballistics --- limits on overstatement: *United States v. Davis*, 2019 WL 4306971 (W.D. Va.): In a gang prosecution, the government proposed three toolmark and firearms identification experts. The defendants challenged the admissibility of these experts' testimony and the court conducted a *Daubert* hearing. The defendants argued that toolmark identification is subjective and has been bought into doubt by the NSF and PCAST reports.

The court shared the defendants' skepticism after hearing two of the government's toolmark experts testify about the highly subjective comparative step of toolmark analysis and accounting for a supplemental 2017 PCAST report noting that experience and judgment alone can never establish reliability in the way that empirical testing can. The court held that the experts' testimony had to be limited "given the subjectivity of the field and the lack of any established methodology, error rate, or statistical foundation for firearm identification experts' conclusions[.]" In determining how to limit the testimony, the court sought guidance from Judge Grimm's opinion in *United States v. Medley*, 312 F. Supp. 3d 493 (D. Md. 2018). Judge Grimm noted the difficulty in balancing the subjective nature of the analysis with the helpfulness of the analysis to the jury. Judge Grimm's compromise was to allow the expert testimony with the limitation that the expert may not opine that a cartridge was an exact match or express any level of confidence in his opinion. Here, the court agreed with Judge Grimm and held that the experts could not testify that the marks indicate a "match" or that the cartridges have "signature toolmarks" that identify a single firearm. Further, the court precluded the experts from testifying to any degree of confidence given the lack of an empirical rate of error.

Bite mark (mis)identification: *Starks v. City of Waukegan*, 123 F. Supp. 3d 1036 (N.D. Ill. 2015): The plaintiff was convicted of rape and assault. At his trial two bite mark experts testified that it was the defendant who bit the victim. He was eventually exonerated and brought a civil rights action against the dentists. The court granted summary judgment for the dentists. On the question of bite mark evidence, the court discussed the NAS report and other articles, and concluded that it is "doubtful that 'expert' bite mark analysis would pass muster under Federal Rule of Evidence 702 in a case tried in federal court." But the court noted that nonetheless "state courts have regularly accepted bite mark evidence—including in all three States in the Seventh Circuit." So the question was not whether bite mark evidence is now found to be unreliable, but whether it was, at the time of the criminal trial, so outrageous as to amount to a malicious use of unreliable evidence. The plaintiff argued that the dentist's opinions in this case were so far outside the norms of bite mark matching, such as they were in 1986, that their testimony violated due

process. But the court determined that while the experts overstated their conclusions and made analytical errors, nothing they did rose to the level of a due process violation.

Blood spatter: *Camm v. Faith*, 2018 WL 587197 (S.D. Ind. Jan. 29, 2018): This was a civil action seeking damages after the plaintiff was tried and acquitted of murdering his spouse and two children. Among other things, the plaintiff challenged the reliability of high velocity impact blood spatter evidence on the plaintiff's shirt, confirming that the plaintiff was close to the victims when they were murdered. The court granted summary judgment for the defendants, noting that "while [the plaintiff] contends that the field of blood spatter analysis is fraudulent, Indiana courts have consistently found blood spatter analysis to be an acceptable science."

Cell-Site Location --- court-imposed limitation on overstatement: *United States v. Medley,* 312 F.Supp.3d 493 (D.Md. 2018) (Grimm, J.): The court held that historical cell site location information is sufficiently reliable to be admissible under *Daubert.* But the court recognized that there was a danger in expert testimony that would ascribe a level of precision to CSLI that is not actually supported by the methodology. Thus the court limited the expert's testimony to the opinion that the "general location" of the defendant's phone was "consistent with" the location of the crime. And the court held that this opinion could only be given after the expert has "fully explained during direct examination the inherent limitations of the accuracy of the location evidence --- namely, the phone can only be placed in the general area of the cell tower sector that it connected to near the time of the carjacking, and the it cannot be placed any more specifically within the sector."

Cell-Site Location --- admissible because the government accepted a limitation on overstatement: *United States v. Brown*, 2019 WL 3543253 (E.D. Mich.): The court held that the methodology of cell site location is reliable, but relied on *United States v. Hill,* 818 F.3d 289 (7th Cir. 2017), for the proposition that the court cannot "give the Government a blank check when it comes to the admission of historical cell-site analysis." Specifically, an expert could not be allowed to testify that cell site location is more precise than the actual methodology could support. It concluded as follows:

> Although the science and methods upon which historical cell-site analysis is based are understood and well-documented, they are only reliable to show that a cell phone was in a general area. The Government acknowledges this relative imprecision in its response to Brown's motion. Thus, assuming that the Government lays a proper foundation and accurately represents historical cell-site analysis's limits at trial, its expert testimony is reliable.

Cell-Site Location --- admissible because the government accepted a limitation on overstatement: *United States v. Frazier,* 2020 U.S. Dist. LEXIS 35417 (M.D. Tenn.): In a prosecution on charges of kidnaping and murder, the defendants moved to exclude expert testimony concerning cellphone location. The expert was an FBI Special Agent assigned to the Cellular Analysis Survey Team. He reviewed the cell phone data reports of the cellphones allegedly utilized by the defendants during the time frame when the victim was kidnapped,

murdered, and buried. The court held that because historical cell-site analysis is only reliable to show that a cellphone was located within a general area, a *Daubert* hearing is not necessary and the expert testimony is reliable *so long as* the "[g]overnment lays a proper foundation and accurately represents historical cell-site analysis's limits at trial." The defendants raised "no unique arguments to the methodology employed" and instead claimed that the expert's report "places certain cell phones in proximity to a cell tower without providing information about the cell tower's range; fails to indicate the level of precision of location, and says nothing about the range of potential error." The court concluded that the asserted flaws would go to the weight and not the admissibility of the evidence.

Even though the court denied the defendants' motion to exclude the cell-site testimony, it deferred ruling on the admissibility of a slideshow put together by the cell-site expert that purported "to show the approximate location of cellphones based upon their cellular communications with towers at or around the time in question." The court observed that the slide show contained "testimonial statements, inferences, and conclusions" and concluded that "[j]ust as the Government cannot oversell the methodology through testimony, it cannot oversell the methodology through the introduction of evidence."

Chemical traces --- limits on overstatement: *United States v. Zajac*, 749 F. Supp. 2d 1299 (D. Utah 2010): The defendant was charged with bombing a library, and he moved to exclude expert testimony regarding trace evidence --- the consistency between the adhesives on the bomb and those found at the defendant's residence. The court noted that the 2009 NAS Report found problems with current forensic science standards in many areas, including paint examination. "While this case pertains to adhesives rather than paints, both are polymers that require microscopic examination, instrumental techniques and methods, and scientific knowledge for proper identification. Thus, the NAS Study is instructive here and lends support to the efficacy of [the expert's] tests." The court stated that *Daubert* did not require the expert to "conduct every conceivable test to determine consistency with absolute certainty. Instead, her tests had to be reliable rather than merely subjective and speculative." The expert in this case used four different instruments to determine consistency, and while that did not go to the level of confidence specified that the defendant desired, "*Daubert* does not require a validation study on every single compound tested through these instruments." The court noted that the instruments were designed to analyze many compounds and "there is no evidence before the court that Michaud misapplied techniques or methods when she conducted her analysis." Ultimately the court concluded that the tests were sufficient for the expert to be able to opine on the visual, chemical, and elemental consistency between the adhesives on the bomb and those found at the defendant's residence. *However, the court held that the expert could not testify to a conclusion that the adhesives came from the same source, as that would be overstating the results.*

Chromatography: *United States v. Tuzman,* 2017 WL 6527261 (S.D.N.Y.): In a securities fraud prosecution, the defendant sought to call a forensic chemist to testify that certain entries in a notebook were made after the fact --- in 2015 rather than between 2008-12. The expert performed (1) a physical examination of the notebook entries; (2) a Thin Layer Chromatography test of the ink used to make the entries, which is designed to determine

whether the same ink was used to make the entries; and (3) a Solvent Loss Ratio Method ("SLRM") analysis using Gas Chromatography/Mass Spectrometry ("GC/MS") testing, which is designed to date the use of the ink. The government objected to the SLRM process used by the expert. The government conceded that the process could be used to date ink, but argued that the expert failed to reliably apply the method. The court agreed with the government:

> The Court concludes that Dr. Lyter's failure to use basic quality control protocols—including those required in the two papers he purportedly relies on—demonstrates that he lacks "good grounds" for his conclusions. *Amorgianos*, 303 F.3d at 267-69 (upholding trial court's determination that proposed expert testimony was unreliable because expert witness "failed to apply his own methodology reliably"). * * *
>
> Here, Dr. Lyter did not use a GC/MS machine dedicated exclusively to ink analysis, despite the clear instruction in one of the two articles on which he relies "that accurate quantitative results can only be obtained if the GC-MS system is devoted for ink analysis only." He also did not test paper blanks, even though both papers on which he relies underscore the importance of performing tests on paper blanks to rule out contamination. These departures from the methodology on which Dr. Lyter purportedly relies demonstrate that his analysis is not "reliable at every step." *Amorgianos*, 303 F.3d at 267; *Brown v. Burlington N. Santa Fe Ry. Co*., 765 F.3d 765, 773 (7th Cir. 2014) ("[A]n expert must do more than just state that he is applying a respected methodology; he must follow through with it.").
>
> Dr. Lyter has not provided any justification for these substantial deviations from the methodology he claims to have followed, other than his subjective belief that these quality control protocols are unnecessary. Precedent makes clear, however, that an expert is not free to deviate—without justification—from the requirements of a methodology he claims to have followed.

Comment: This is an excellent example of proper application of Rule 702(d). Reliable application is treated as a Rule 104(a) question. The court notes what should be the obvious point that unreliable application of reliable methodology leads to an unreliable conclusion.

DNA identification, mixed samples: *United States v. Ha*yes, 2014 WL 5470496 (N.D. Cal.): The court rejected a challenge to PCR/STR DNA identification, as applied to mixed samples. The court stated that "the use of PCR/STR technology to analyze a mixed-source forensic sample is neither a new or novel technique or methodology. Hayes has not cited any legal or scientific authority to the contrary."

> **Comment:** The PCAST report constitutes "scientific authority to the contrary" regarding the subjectivity that is part of the process of extracting DNA from a mixed source. (Though it was published after this case.)

DNA – Mixtures, test found unreliable: *United States v. Williams*, 382 F.Supp.3d 928 (N.D. Cal. 2019): The court addressed the probabilistic genotype program Bullet, used by the Serological Research Institute (SERI) to analyze multiple source DNA mixtures that include up to four possible sources. The government expert, Hopper, analyzed the DNA under a four-person validation, despite a past analyst finding that the sample contained five possible sources. The expert proposed to testify that there is "very strong support" for the proposition that the defendant contributed DNA to the sample. The defendant moved to exclude the Bullet analysis on the ground that the program was not validated for five-source samples.

Judge Orrick provided this helpful background for the challenges to DNA identification of mixed samples:

> DNA analysis for single-source and simple mixtures—those with DNA from just one or two individuals—is objective and reproducible in part because it requires the exercise of little if any human judgment. Katherine Kwong, *The Algorithm Says You Did It: The Use of Black Box Algorithms to Analyze Complex DNA Evidence*, 31 Harv. J.L. & Tech. 275, 277 (2017)) By contrast, human judgment is required to analyze complex mixtures with three or more DNA profiles because "all of the individual DNA profiles [are] superimposed atop one another." Id. at 278. An analyst must decide between "different interpretations that might be equally or similarly valid – and those decisions may have significant impacts on the ultimate results of the analysis." Id.
>
> It is frequently impossible to tell how many individuals' DNA is present within a complex mixture; a greater number of contributors only increases the rate of error, which usually comes in the form of an underestimate. For example, a 2005 study found that analysts mischaracterized known four-person mixtures as three-person mixtures at a rate of 70%. These errors likely occur because of allele sharing:
>
> > Some alleles at some loci are relatively common and therefore likely to overlap between contributors to a mixture. Thus, the more individuals present in a mixture, the more likely it is the mixture will hide identifications of subsequent individuals, as the relative proportion of present versus absent alleles at each locus increases with each new contributor. * * * [A] five-person sample can present very similarly to the way four-person mixtures do.
>
> Advancements in amplification technology have improved analysts' ability to accurately determine the number of contributors because they amplify the alleles at more loci. For example, SERI previously relied on the Identifiler Plus kit, which amplifies the alleles at 15 loci. The newer GlobalFiler kit, which SERI validated in December 2016, amplifies the alleles present at 21 loci, and some of the additional loci are polymorphic. * * * GlobalFiler has improved the reliability of the conclusions regarding the number of contributors for known three-person mixtures. But known five-person mixtures were mischaracterized as originating from four or fewer individuals in approximately 61-75% of samples. When SERI validated GlobalFiler, it tested two-, three-, four-, and five-person mixtures. It experienced the same difficulties. In fact, it underestimated all of the known five-person mixtures tested:

> In each five-person mixture tested, the electropherograms showed no indication of more than four contributors. This was not due to a shortcoming of GlobalFiler or the testing process, but rather because, by coincidence, the contributors used to create the test mixture shared alleles. Given the genotypes of the contributors, no more than eight alleles could appear at any one locus.
>
> * * * SERI often uses DNA profiles of employees and friends during validation studies. A 2018 study found that analysts underestimated 64% of known five-person mixtures and 100% of known six-person mixtures—and characterized all of the mixtures as containing DNA from four individuals.
>
> Even with the improvement in amplification technology, other factors present challenges to accurately identifying the number of contributors. The challenge of allele sharing is "frequently exacerbated by samples that have degraded or which originally contained only a small amount of DNA." Kwong at 278. * * * [D]egradation occurs when DNA breaks off between the bases, which usually happens to larger pieces first. This process occurs naturally over time, although freezing DNA can slow it down. Amplification kits are unable to copy DNA past the point where the breakage has occurred.

The court excluded the Bullet analysis by Hopper because Hopper could not reliably conclude that only four, and not five, individuals contributed to the DNA mixture. The court noted the following issues: (1) the error rate for mistaking five-person mixtures for four-person mixtures was "troubling" (and research showed that the error rate only increased with the number of sources present in the mixture – 64% of 5-person mixtures and 100% of 6-person mixtures were underestimated); (2) SERI itself was unable to distinguish between four and five-person mixtures in a study by GlobalFiler where it failed to make a correct five-person identification even once; (3) Hopper used less than the recommended amount of DNA to test; (4) more than six years elapsed between the first test detecting a 5-person mixture and the second test by Hopper showing a 4-person mixture; and (5) "there are two loci with seven alleles—and one of those loci has a below-threshold peak that could represent an eighth allele. If that is the case, the sample can be a four-person mixture *only if* no two contributors share alleles at that locus, no contributor is a homozygote at that locus, and no additional alleles have dropped out at that locus."

The government argued that any flaws in the methodology and application to the DNA mixture could be raised on cross-examination. But the court disagreed, explaining as follows:

> The government argues that exclusion of the testimony is not appropriate; instead, Elmore can challenge Hopper's analysis and conclusions during cross-examination. But the number of contributors is a foundational part of every calculation Bullet performs. If that input is in doubt, the reliability of the entire analysis is necessarily in doubt. To corroborate Hopper's conclusion about the number of contributors, the government put forth the results he obtained after running Bullet with a five-person mixture input. But Bullet was not validated to test five-person mixtures, and I will not rely on that result for any purpose.

DNA evidence can have a powerful effect on a jury's evaluation of a criminal case. See John W. Strong, *Language and Logic in Expert Testimony: Limiting Expert Testimony by Restrictions of Function, Reliability and Form*, 71 Or. L. Rev. 349, 367 n.81 (1992) ("There is virtual unanimity among courts and commentators that evidence perceived by jurors to be 'scientific' in nature will have particularly persuasive effect.") (citing cases). If SERI could accurately identify five-person mixtures and if it had validated Bullet to analyze them, then it might have a reliable understanding of how underestimating a five-person mixture impacts the likelihood ratio. That understanding could improve the reliability of Hopper's conclusion on the number of contributors or make it appropriate to allow the government to present two likelihood ratios: one based on four contributors and a second based on five. Then the other problems identified in this Order, such as Harmor's changed testimony, the small testing sample, and the signs of degradation, would be ripe for cross-examination. But there are simply too many reasons to question the reliability of Hopper's conclusion on this foundational issue, which brings the entire analysis outside the parameters of Bullet's validation at SERI. This testimony is not reliable, and it is not admissible.

DNA Identification --- Low Copy Number: ***United States v. Sleugh***, 2015 WL 3866270 (N.D. Cal. 2015): The court rejected the defendant's motion to exclude an expert who would testify to a match based on Low Copy Number DNA sample. The court reasoned as follows:

The defendant argues that, as a matter of law, low copy number DNA samples produce inherently unreliable comparison results and, therefore, must be excluded from evidence or, in the alternative, warrant a *Daubert* hearing in all circumstances to determine whether the resulting findings were reliable. The defendant has not provided any binding authority—or, indeed, any legal authority—finding as a matter of law that a small sample size results in data that is inherently unreliable. At most, the defendant's authority suggests there may be a correlation between sample size and the frequency of stochastic effects—randomized errors resulting from contamination that could potentially render a comparison unreliable. See *McCluskey*, 954 F.Supp.2d at 1277 ("LCN testing carries a greater potential for error due to difficulties in analysis and interpretation caused by four stochastic effects: allele drop-in, allele drop-out, stutter, and heterozygote peak height imbalance."); see also *United States v. Morgan*, 53 F.Supp.3d 732, 743 (S.D.N.Y.2014) ("Although the presence of stochastic effects tends to correlate with DNA quantity, it is possible that a 14–pg sample may exhibit fewer stochastic effects than a 25–pg sample and therefore provide better results."). However, as the defendant's own authority explains, the critical inquiry remains whether there is evidence of unreliability (e.g., stochastic effects) in a particular case; there is no per se rule regarding sample size as called for by the defendant.

To rebut the defendant's reliability challenge on this basis, the government offered assurances that its serologist had not observed any stochastic effects. The defendant has had access to the serologist's report and hundreds of pages of underlying data for some time, and has not put forth a contrary proffer or evidence of unreliability in this specific case. Under such circumstances, and in light of the limited scope of the challenge and the

general admissibility of DNA comparison testing, the Court finds no need to hold a *Daubert* hearing on this question on the present record.

DNA--- Low Copy Number and Combined Probability Index: *United States v. Williams*, 2017 WL 3498694 (N.D. Cal. 2017) (Orrick, J.): The court rejected the defendant's motion to exclude DNA identification from mixed samples, derived from a Low Copy Number DNA sample. The court reasoned as follows:

> Gordon urges me to apply the rationale of *United States v. McCluskey*, 954 F.Supp.2d 1224 (D.N.M. 2013), in which the court excluded DNA testing results derived from a low copy number (LCN) DNA sample. The *McCluskey* court excluded the LCN test results based on several factors, including the lab's lack of certification and validation of its LCN testing. See also *United States v. Morgan*, 53 F.Supp.3d 732, 736 n.2 (S.D.N.Y. 2014) (discussing *McCluskey's* reasoning in excluding the LCN data, and ultimately ruling LCN DNA test results admissible). * * * In deciding to exclude the LCN evidence, the court was careful to articulate its basis for exclusion—not merely the use of an LCN DNA sample, but rather, the lab's methodology in interpreting that sample. * * * [T]he critical inquiry is whether the lab utilized reliable testing methods.
>
> Gordon cannot point to any evidence that Kim failed to abide by established protocol. Instead, he challenges the assumptions underlying her interpretation of the data. Gordon has all the information he needs regarding Kim's analysis to cross-examine her at trial. It would be improper to exclude such evidence from the purview of the jury when the lab utilized reliable methods that meet the standards under *Daubert*."

But the court excluded other lab results using enhanced methods for DNA identification, where the lab used a Combined Probability Index (CPI) statistical model to enhance and interpret the samples. The court found three problems with this methodology:

> First, [the] testing generated results below the stochastic threshold, which indicates the possibility of allelic dropout. * * * [T]he mere presence of results below the stochastic threshold indicates that some degree of randomness, and therefore questionable reliability, exists. Second, [the analyst] used two enhanced detection methods to account for the small amount of DNA available for testing. He testified that the lab protocol recommended using one or the other, but he chose to do both because he was "starting with low-template copy DNA." The enhanced detection methods were individually validated, but he "[didn't] recall" whether they were validated for use at the same time. * * * Third, SERI applied the CPI statistical model on complex mixed samples in an unreliable and untestable manner. Added to the other issues, this is an insurmountable problem. * * * SERI analysts failed to adhere to their own lab protocol or take any notes documenting their decision-making process. And they cannot point to any objective criteria guiding their methodology. [The analyst] repeatedly testified that his decisions were "very subjective" and based on his training and experience. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." *Joiner.*

The court explicitly rejected the government's arguments that the flaw, if any, was one of application and not methodology and so raised a question of weight and not admissibility:

> I fail to see the practical distinction the government seeks to draw between a methodology and the application of that methodology when it comes to my role as gatekeeper. Rule 702 explicitly directs courts to consider whether "the expert has reliably *applied* the principles and methods to the facts of the case." Fed. R. Evid. 702(d)(emphasis added). Proper application of the methods is a necessary component of ensuring the reliability of the opinion testimony. If SERI improperly employed accepted methodology then the results would lack a sound basis. That inquiry is appropriately included within the scope of a *Daubert* analysis. See *Daubert v. Merrell Dow Pharmaceuticals, Inc. ("Daubert II")*, 43 F.3d 1311, 1316 (9th Cir. 1995)("Our task, then, is to analyze not what the experts say, but what basis they have for saying it."). The basis for an expert's opinion must necessarily entail how he employed his methodology; that consideration is critical to a determination of whether the opinion "rests on a reliable foundation." See Daubert, 509 U.S. at 597.

Comment: **Low copy number DNA testing was purportedly a way of finding a match from infinitesimally small samples of DNA. It was a test developed and used in only one lab in the world --- the New York City Medical Examiner's lab. It was supposedly supported by a validating test, but that test was never disclosed by the Medical Examiner. A lawsuit brought by a forensic examiner alleged that the test was never conducted and the Medical Examiner lied about it. That suit was settled for $1,000,000. The Medical Examiner, in 2017, decided to abandon the Low Copy Number procedure. But courts have consistently admitted LCN results. See https://www.nytimes.com/2019/04/23/nyregion/dna-testing-nyc-medical-examiner.html?emc=edit_ur_20190424&nl=new-york-today&nlid=63305318201904 24&te=1**

DNA identification --- PCR/STR: ***Floyd v. Bondi***, 2018 WL 3422072 (S.D. Fla.): In a habeas challenge to convictions for kidnapping and sexual battery, the petitioner alleged ineffective assistance of counsel for failing to subject the government's DNA evidence to meaningful adversarial testing. The court rejected this argument and denied the petition for writ of habeas corpus, concluding that PCR/STR DNA testing is generally accepted in the scientific community. It stated as follows:

> The State's expert testified that she did autosomal STR, PCR testing. She further testified that this testing technique is used worldwide, has been subject to peer review, and is generally accepted in the scientific community. She also said that it was used and accepted by laboratories everywhere and is supported by scientific literature. She sent the material to another lab for Y-STR testing, by which only the DNA on the male chromosome would be analyzed. She said that Y-STR testing is PCR testing. Y-STR testing eliminates the female DNA, is equally effective when it is only a mixture of two people, and can use a smaller amount of DNA. . . . DNA evidence is not new or novel and both are generally accepted in Florida so long as the testing procedures are properly conducted. * * * As a

result, had counsel objected to the DNA expert, it is unlikely that the trial court would have sustained the objection.

DNA identification: *United States v. Jackson*, 2018 WL 3387461 (N.D. Ga.): In a robbery prosecution, the defendant moved to exclude DNA evidence implicating him. The DNA sample obtained from the defendant matched the DNA obtained from a black ski mask found at the scene of the robbery. The defendant argued that this evidence was not admissible because the government failed to show that the collection methods were proper or reasonably based on scientific principles. The court denied the defendant's motion, and exercised its discretion to forego a *Daubert* hearing. The court stated that the defendant's objections went to the weight of the evidence, not the "well-established reliability of the DNA testing methodology and process." The court elaborated as follows:

> Defendant has offered no reason to suspect that the mask was contaminated. * * * Defense counsel will have further opportunity to cast doubt on the evidence and testimony through cross-examination at trial. Though a court's decision of whether to conduct a *Daubert* Hearing is discretionary, the Court does not view it necessary on this issue, as the reliability of the [Georgia Bureau of Investigation's ("GBI")] DNA testing methods are "properly taken for granted." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S 137, 152 (1999). Here, the GBI forensic biologist's specialized knowledge will help the trier of fact understand the evidence by explaining the DNA testing process; the testimony is based on the sufficient facts and data; the testimony is based on widely accepted DNA testing methods; and the lab report makes clear that the forensic biologist reliably applied the aforementioned accepted methods to specific facts here, that is the comparison of the mask and the cheek swabs. Under Rule 702, the Government's forensic biologist may present expert testimony as to the DNA evidence.
>
> **Comment:** The court talks about questions of weight but here it is pretty clearly in a Rule 104(a) sense. The court makes specific findings that the expert had sufficient facts and reliably applied the methodology. And the methodology and "process" are found so sound that no *Daubert* hearing need be held. All this looks like an application of Rule 104(a).

DNA Identification --- probability testimony, avoiding overstatement: *McCollum v. United States*, 2020 WL 5363302 (M.D. Ga. Sept. 8, 2020): The defendant in a bank robbery prosecution argued that his defense counsel should have moved to exclude the testimony of an FBI forensic examiner in a bank robbery trial. The expert testified that there was "moderately strong support" that McCollum was a contributor of the DNA on "item 2" from a Camaro that was used in the bank robbery that was at issue in the trial; it was 170 times more likely that this DNA came from Petitioner as opposed to a random person. The court held as follows:

> If counsel had filed a motion to challenge the DNA expert's opinion that a likelihood ratio of 170 provides moderately strong support that Petitioner contributed the DNA on item 2, a hearing on that motion would have revealed something that the DNA expert stated in his report: based on the "standards published by the Association of Forensic Science

Providers," a likelihood ratio between 100 and 990 provides "moderately strong support" for inclusion. Since there is evidence that the relevant scientific community considers a likelihood ratio of 170 to be "moderately strong support" for inclusion, the evidence would not have been excluded under Rule 702.

DNA Identification: *United States v. Williams*, 2013 WL 4518215 (D. HI.): A forensic examiner's report found the victim's DNA on certain items in the defendant's house. He moved to exclude the testimony on the ground that source attribution methodologies are unreliable and therefore run afoul of *Daubert*. The court denied the motion, relying on precedent.

> The court agrees with those other decisions finding that the source attribution determination is based on methods of science that can be adequately explained, and that the jury should decide what weight to give this evidence based on these dueling expert opinions. See, e.g., *United States v. McCluskey*, —— F.Supp.2d ——, 2013 WL 3766686, at *44 (D. N.M. June 20, 2013) (determining that this 'battle of experts' regarding source attribution is for the jury to resolve); *United States v. Davis*, 602 F.Supp.2d 658, 683–84 (D.Md.2009) (determining that expert may opine that defendant was the source of the samples where the RMP calculation was sufficiently low to be considered unique) . . . . The court therefore rejects that *Daubert* prevents the government from providing testimony that to a reasonable degree of scientific certainty, several samples collected from Defendant's residence are from Talia.

DNA --- STR Mix Program: *United States v. Christensen*, 2019 WL 651500 (C.D. Ill. Feb. 15, 2019): In a kidnapping prosecution, the defendant moved to exclude DNA test results and requested a *Daubert* hearing on the reliability of the methods used. With regard to the DNA tests, law enforcement used the STRmix program to compare DNA samples taken from the defendant to samples from the alleged victim. The defendant challenged the reliability of the STRmix program, arguing that its use of allele length rather than more detailed sequencing analysis makes it unreliable. The court denied the defendant's motion, finding STRmix test to be a reliable methodology:

> Defendant moved to exclude the DNA test results on the grounds that STRmix is unreliable. At the evidentiary hearing, the United States called Ms. Jerrilyn Conway, a forensic examiner for the FBI, who testified that STRmix has been validated internally by the FBI and also by numerous studies conducted by employees of the company that produced it. She noted that STRmix is used by at least 43 laboratories in the United States, including the U.S. Army. Defendant argues that the STRmix program, which utilizes a probabilistic genotyping algorithm based on allele length, is not as reliable as next-generation sequencing analyses. Ms. Conway agreed at the hearing that next-generation sequencing could be more precise. However, she testified that STRmix is nonetheless reliable, partly because it compares allele length at not just one locus (where sequencing would prevent false matches among alleles with identical lengths but different contents), but at 21 regions of the sample. She testified that the probability of two different individuals

having matching allele lengths at one locus would be approximately 1 in 50, but that the probabilities STRmix generates are in the quintillions to octillions, due to the numerous loci compared. The evidence shows that STRmix has been repeatedly tested and widely accepted by the scientific community. Although there may be more precise tests available, such tests do not affect STRmix's reliability. Accordingly, Defendant's Motion to exclude the DNA evidence based on the alleged unreliability of STRmix is denied.

DNA Identification: ***Anderson v. City of Chicago,*** 2020 WL 3250679 (N.D.Ill.): Anderson was convicted of murder and rape, was eventually exonerated, and then sued the City of Chicago and certain law enforcement officials. The defendants moved to exclude DNA experts who would testify that Anderson's DNA could not be found on the murder weapon, and would also provide other exculpatory DNA results. The defendants argued that because these DNA tests were done decades after the crime, the risk of contamination over that time rendered the results unreliable. The defendants also argued that the DNA had degraded; that the experts relied on Low Copy Number methodology; and that the experts had not properly considered stochastic effects. As to all these arguments, the court essentially held that they went to weight and not admissibility. Here are some excerpts from the court's opinion:

> Defendants will be permitted to thoroughly cross-examine the experts about the potential for contamination and degradation and the possible impact on the results, as well as the fact that the source of the DNA is unknown. Defendants will have ample opportunity to argue to the jurors that the DNA on the evidence in 2014 does not reflect the DNA that may have been on the evidence in 1980, and that the jurors should therefore give little weight to the DNA testing results. [citations omitted] Cross-examination, rather than exclusion, is the appropriate course.
>
> * * *
>
> In their argument that it was improper to interpret the low-level DNA samples here, Defendants point generally to the proposition that low-level DNA can be "challenging to interpret" and that the "forensic DNA community needs to be vigilant" in interpreting such samples. But their arguments and the bases for them do not persuade the Court that such samples can *never* be reliably interpreted or that analysts should never attempt to do so.
>
> Specifically, Defendants point to the fact that only partial DNA profiles were derived from the samples, including the sample taken from Trunko's bra which was used to develop her profile for comparison purposes. Andersen, on the other hand, points to the 2017 Interpretation Guidelines published by the Scientific Working Group on DNA Analysis Methods ("SWGDAM"), which is "a group of scientists representing federal, state, and local forensic DNA laboratories in the United States and Canada." These guidelines support the reliability of the methods used by the experts. As explained in the 2017 SWGDAM guidelines, "DNA typing results may not be obtained at all loci for a given evidentiary sample (e.g., due to DNA degradation, inhibition of amplification and/or low-template quantity); a partial profile thus results." Yet the guidelines still anticipate that laboratories will analyze such partial profiles. * * * [E]very forensic DNA laboratory

constantly encounters and then interprets, partial profiles and * * * the wholesale dismissal of a partial profile because it is a partial profile is not part of forensic practice, is not warranted on analytical grounds, and would infer that autosomal STR loci are not genetically and analytically independent (which of course they are). Cellmark's SOPs allowed for interpretation of partial profiles and allowed for exclusions to be made based off of partial profiles. All of this points to the reliability of the methodology used here.

Defendants also point repeatedly to evidence of stochastic effects present in the testing results here, arguing that when present, such effects make interpretation and analysis unreliable. The 2017 SWGDAM guidelines define stochastic effects as "the observation of intra-locus peak imbalance and/or allele drop-out resulting from random, disproportionate amplification of alleles in low-quantity template samples." Yet, again, the 2017 SWGDAM guidelines anticipate that results may still be interpreted where stochastic effects are present. Cellmark SOPs provide that for low-level DNA, the possibility of stochastic effects must be considered, and the data must be interpreted with caution, and [the plaintiff's expert] testified that when interpreting the samples, she followed this guidance.

Defendants additionally point to the fact that at least some of the evidence samples reflected "low copy number" ("LCN") DNA, which again, they say, cannot be reliably interpreted. * * * Other district courts have concluded that interpreting LCN data is a generally accepted and reliable methodology. [citing cases]

In sum, the Court determines that it is a reliable science and generally accepted practice to interpret low-level and degraded DNA samples, as the experts did here. And, as evidenced in the reports and through testimony, the conclusions that the experts reached in their interpretations are supported by the profiles obtained from the DNA samples. In seeking to discount these conclusions, Defendants appear to forget that the Court's gatekeeping function is to determine whether the methods used by an expert in reaching a conclusion are sound, not to judge whether the conclusion is correct.

DNA Identification: ***United States v. Davis,*** 602 F. Supp. 2d 658 (D. Md. 2009): The defendant moved to exclude DNA test results and requested a *Daubert* hearing. He contended that the expert used a method called low copy number (LCN) testing, and argued that identification from an LCN sample is not a validated scientific methodology. The court made a factual finding that the expert did not use LCN testing, but rather used the generally accepted PCR/STR analysis. So no *Daubert* hearing was necessary.

DNA --- statistical evidence: ***United States v. Tucker***, 2019 WL 861215 (E.D. Mich): Following his conviction for armed bank robbery, the defendant moved to vacate his sentence, arguing that his trial counsel erred in failing to object to the DNA evidence that was offered against him. The court denied the defendant's motion, finding that the Sixth Circuit has repeatedly upheld the reliability of statistical evidence related to DNA testing:

Defendant's objection regarding the DNA evidence fails because the Sixth Circuit has consistently held that statistical evidence related to DNA testing is admissible. *See United States v. Beverly*, 369 F.3d 516, 528 (6th Cir. 2004) ("The use of nuclear DNA analysis as a forensic tool has been found to be scientifically reliable by the scientific community for more than a decade."); *United States v. Bonds*, 12 F.3d 540, 568 (6th Cir. 1993) ("Thus, because the theory, methodology, and reasoning used by the FBI lab to declare matches of DNA samples and to estimate statistical probabilities are scientifically valid and helpful to the trier of fact, we affirm the district court's conclusion that they are admissible under Rule 702."). Accordingly, counsel was not deficient for failing to raise a meritless objection to the statistical DNA evidence presented.

DNA Analysis --- mixed sample --- expert opinion excluded where the sample identified was a minor contributor to the mix: *United States v. Gissantaner*, 2019 WL 5205464 (W.D. Mich.): In a felon-firearm prosecution, the major piece of evidence was a small amount of DNA found on the firearm during a search of defendant's house. The gun was found in a chest belonging to another convicted felon, Patton. The DNA analysis was based on STRmix probabilistic genotyping software. The report from this analysis concluded that the defendant was a 7% minor contributor of the DNA and that it was at least 49 million times more likely that the DNA was that of the defendant and two unrelated, unknown individuals than that the DNA was from three unrelated, unknown contributors. The defendant challenged the use of the software under the circumstances of this case, in which his alleged DNA was a minor contributor to the mixed sample. He argued that many of the factors entered into the STRmix program are matters of judgment and thus are variable and affect the rate of error. One of these inputs is the number of contributors to a DNA mixture, which is determined by the analyst, but, empirically, is increasingly difficult to determine as the number of contributors increases.

The court noted there are no standards in the U.S. for the development and use of probabilistic genotyping software in forensic DNA analysis. There are guidelines, but those are not standards against which laboratories can be audited. The court relied on the PCAST report stating that while single-source DNA analysis is an objective method with precisely defined protocol complex mixtures with three or more contributors rely primarily on the interpretation of the DNA profile rather than on the laboratory processing --- and therefore are subject to error. The PCAST report specifically stated that STRmix methods "appear to be reliable for three-person mixtures in which the minor contributor constitutes at least 20 percent of the intact DNA in the mixture and in which the DNA amount exceeds the minimum level required for the method."

The court concluded that the government had not established adequate testing and validation of the STRmix under the conditions of DNA evidence in this case. Specifically, the court found that there were too many open and unanswered questions in the field about the testing and validation of STRmix in circumstances with low quantity, low level complex mixtures where the suspect's DNA could only at most constitute 7% of the sample. It noted that many published recommendations advise "extreme caution" using probabilistic genotype software on low-template DNA samples. The court observed that while STRmix has been the subject of many peer-reviewed articles, nothing in those articles supported its application in cases involving complex mixtures of low-quantity, low level DNA. The court also noted that no rate of error has been established for the application of STRmix in cases like the instant one.

The court ultimately held that the STRmix DNA report in this case did not meet *Daubert* reliability standards for admissibility. The court emphasized that it was not criticizing the use of STRmix or probabilistic genotyping evidence in cases where the contributor's percentage of the mix is higher.

DNA identification: *United States v. Williams*, 2010 WL 188233 (E.D. Mich.): The defendants moved to exclude the government expert's proposed blood identification DNA testimony. The defendants argued that the expert employed a valid procedure to reach an unfounded conclusion. The court held that the testimony was admissible, because it is "well-settled that the principles and methodology underlying DNA testing are scientifically valid" and "DNA expert testimony has been widely approved by the courts as a valid procedure for making identification of blood samples." The court held that the defendants' attack on the expert's conclusion did not raise a *Daubert* question, because *Daubert* held that the gatekeeper's focus must be on the methodology and not the conclusion. In this case, "[e]ven if matching two out of thirteen loci does not provide conclusive evidence that the bloodstain at the house was that of the victim, it would seem to provide at least some evidence. The procedures from which this conclusion was drawn are scientifically sound; if Defendants want to challenge Hutchison's conclusion, they are free to do so by cross-examining Hutchison or offering their own expert."

> ***Comment:*** It is true that the *Daubert* Court stated that the focus of the gatekeeper should be on methodology and not conclusion. But then in *Joiner,* the Court recognized that the gatekeeper must look at the conclusion as well --- and exclude if there is an "analytical gap" between methodology and conclusion. And Rule 702 (after 2000) *definitely* requires the court to scrutinize the expert's conclusion --- in order to determine that a reliable methodology was *reliably applied.*
>
> The court seems to treat the question of application (two out of thirteen loci) as a question of weight under Rule 104(b). How is the jury supposed to understand that?

DNA extraction --- STRmix: *United States v. Lewis*, 2020 U.S. Dist. LEXIS 36480 (D. Minn.): In a firearm prosecution, a forensic laboratory "analyzed three DNA swabs from the gun using a probabilistic genotyping software program called STRmix." The lab determined that the DNA on the gun was a mixture from four persons and that "the DNA mixture in each of the three swabs is greater than one billion times more likely if it originated from [the defendant] and three unknown unrelated individuals than if it originated from four unknown unrelated individuals." In addition, the STRmix results excluded as contributors to the DNA mixture the landlord and the police officers involved in the scuffling. The court granted in part and denied in part the defendant's motion to suppress the DNA evidence.

As to the validity of STRmix for extraction and identification, the defendant, relying on the PCAST report, argued that the range of reliability for STRmix does not extend to DNA mixtures of more than three contributors in which the minor contributor constitutes less than 20%. (The DNA mixtures in the case involved four contributors with the minor contributor constituting 6%). But the court noted that in response to the PCAST Report, a study was conducted and

published by a STRmix co-developer that "show[s] persuasively that STRmix is capable of producing accurate results with extremely low error rates: STRmix not only works, it seems to work extremely well, at least when used in the manner it was used in these studies."

The defendant argued that STRmix is unreliable because it does not have a known error rate, but the court concluded that the "error rate for false inclusion is known and is acceptably small." The court admitted that the rate of error could not be numerically quantified, but stated that "*Daubert* does not require that an error rate be numerically identified for scientific evidence to be found sufficiently reliable. Rather, the known or potential error rate is one of several non-exclusive factors that courts consider when assessing the scientific validity of a theory or technique."

While admitting the identification evidence, the court disallowed the "[DNA] evidence as to the exclusion of the relevant police officers and the landlord" for failing to meet the *Daubert* threshold of admissibility. The court concluded that while STRmix had been validated for extracting from DNA mixtures for *inclusion,* it has not been validated for extracting from DNA mixtures for *exclusion*.

DNA Extraction --- STRmix Admitted --- *United States v. Washington,* 2020 WL 3265142 (D. Neb. June 16, 2020): Law enforcement collected swabs for DNA testing from various objects to investigate a bank robbery. STRmix, a probabilistic genotyping software program, was used to test the swabs and ultimately linked the defendant's DNA to the DNA collected from the handlebars, the bike seat, the helmet, and the handle of a bag based on a likelihood ratio. The defendant argued that "STRmix relies on subjective information and results can vary to an impermissible degree depending on the lab and the analyst involved." Specifically, the defendant relied on the PCAST report, which concluded that the STRmix method "appear[s] to be reliable for three-person mixtures in which the minor contributor constitutes at least 20 percent of the intact DNA in the mixture." But the court based its decision on a study conducted and published by a STRmix co-developer at the New Zealand's Institute of Environmental Science and Research, which established that "when the [DNA] mixtures were compared with the DNA profiles of thousands of known contributors from non-contributors, STRmix was able to distinguish the contributors from non-contributors with a high level of accuracy [… and] extremely low error rates." The court observed that "[t]hese studies, including the PCAST itself, suggest that questions about STRmix's reliability arise only when samples contain several different contributors and only a low-level contribution from the minor contributor. Recent studies demonstrate that STRmix has become increasingly reliable, even with DNA samples with more than three contributors." Furthermore, the court emphasized that "STRmix is used in several federal laboratories, in more than forty states, and in at least thirteen other countries." The court stated that only one federal court ruled that STRmix failed to satisfy Rule 702, and it was a case in which "the DNA mixture at issue was composed of three contributors, with only a seven-percent contribution associated with the defendant." Because here the likelihood ratios linking the defendant to various items connected to the crime scene were "well above the 20% threshold at which the PCAST Report raised concern […] any questions regarding STRmix's reliability in this case go to the weight that should be given to STRmix statistics, not their admissibility."

DNA Identification, including Low Copy Number testing: *United States v. McCluskey*, 954 F. Supp. 2d 1224 (D.N.M. 2013): The defendant moved to exclude DNA test results, challenging the reliability of PCR/STR and LCN (low copy number) testing. The motion was denied in part and granted in part. The court found that the PCR/STR method of DNA typing is reliable under Rule 702, but the government had not carried its burden of demonstrating the reliability of LCN testing.

As to PCR/STR Methodology, the court noted that this was the only forensic method found to be scientific in the NAS report. The court stated that "it is clear that the PCR/STR method can be and has been extensively tested, it has been subjected to peer review and publication, there is a low error rate according to NRC (2009), and there are controls and standards in place." And it was also generally accepted.

As to low copy number (LCN) Testing --- which is a way of testing DNA that has become degraded or is only a small sample --- the court observed that "PCR/STR analysis of low-level DNA has been tested, and has been found to exhibit stochastic effects rendering the DNA profiles unreliable." Moreover peer review and publications "have raised serious questions about the reliability of testing low amounts of DNA and accounting for stochastic effects." And the reliability of LCN testing is not generally accepted in the relevant scientific community.

DNA --- Mixed sample: ***United States v. Tucker***, 2020 WL 93951 (E.D.N.Y.): In an armed robbery case, the government offered a DNA identification from a mixed sample. The court noted that although there are gaps in understanding the full reliability of probabilistic genotyping, such as STRmix, issues generally arise only where the analysis involves multiple contributors and only a low-level contribution from the minor contributor. This case involved two DNA samples that were each two-person mixtures and in one sample, the "Male Donor," alleged to be the defendant, was a 97 percent contributor. The PCAST report that criticizes STRmix did not challenge the reliability of STRmix in this context. The court found that STRmix is used in over forty states and has been peer-reviewed in over 90 articles. Further, its use is generally accepted in the relevant community and courts have "overwhelmingly admitted expert testimony based on STRmix results."

DNA Identification ---- LCN testing: *United States v. Morgan*, 53 F. Supp. 3d 732 (S.D.N.Y. 2014): The defendant was charged with felon-firearm possession. He moved to exclude any evidence of low copy number ("LCN") DNA test results of samples taken from the gun at issue. The court denied the motion, concluding that the methods of LCN DNA testing that the New York City Office of the Chief Medical Examiner ("OCME") employed are sufficiently reliable to satisfy *Daubert*. The court stated that "[a]though the Court in *United States v. McCluskey* ruled LCN testing evidence from a New Mexico lab to be inadmissible, its finding rested, at least partially, on that lab's lack of certification and validation of its LCN testing." [In fact that was only a very small part of the *McCluskey* court's reasoning.] The court held that the government "has clearly established that [the] validation studies are scientifically valid and bear a sufficient

analytical relationship to their protocols. Thus, Morgan's objections go to the weight to be accorded to the evidence, not to its admissibility. * * * Although OCME could have conducted more validation studies with degraded or crime-stain mixture samples, under *Daubert*, scientific techniques need not be tested so extensively as to create an absolute certainty in their reliability. Thus, additional validation studies using crime-stain or degraded mixture samples might have bolstered the strength of OCME's conclusions, but are not prerequisites to a finding of reliability sufficient to satisfy the *Daubert* test."

> **Comment:** It should be noted that there are allegations that the LCN process was never properly validated by the Office of the Chief Medical Examiner. The process was been abandoned by OCME. See *DNA Under the Scope, and a Forensic Tool Under a Cloud, New York Times,* 2/27/16.

DNA --- Low Copy Number: *United States v. Wilbern*, 2019 WL 5204829 (W.D.N.Y.): The government sought to introduce forensic DNA evidence from swabs taken from an umbrella left by the perpetrators at the scene of the crime. Of the four swabs taken, only two, Swabs 8.2 and 8.4, contained DNA profiles able to be developed. The swabs were sent to OCME, which used Low Copy Number ("LCN") testing. Upon testing, OCME determined that Swab 8.2 was a DNA mixture from at least two people, but that Swab 8.4 was a single-source sample from one person. OCME then determined that the source of Swab 8.4 was consistent with the major contributing source of Swab 8.2. OCME determined that Swab 8.2's major contributor was the defendant, with a probability of finding the same DNA profile at 1 in 6.8 trillion people. OCME determine that Swab 8.4's source was consistent with the defendant's profile, with the probability of finding the same match at 1 in 138 million people. Swab 8.4 was lower quantity than 8.2.

Relying mostly on *Morgan, supra,* the court held that results obtained from LCN DNA testing "do not amount to 'junk science,' to which the courtroom should remain closed. Rather, in this case, vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of testing what the Court finds to be admissible evidence."

DNA Identification --- Admissibility of "Bluestar" method of identifying latent blood stains for DNA testing: *United States v. Frazier*, 2020 U.S. Dist. LEXIS 35417 (M.D. Tenn. Mar. 2, 2020): In a murder and kidnaping prosecution involving DNA evidence, the defendants sought to exclude the testimony of Esperança, a French forensic specialist in the morpho analysis of blood tracing and the use of Bluestar Forensic --- a reagent, according to the expert, that "can be used to identify latent bloodstains without altering the DNA, in order to allow subsequent DNA typing." The government sought to admit this testimony to provide context for the DNA and blood testing they carried out to confirm the presence of the victim's blood. Although Esperança has been qualified as an expert by the French Supreme Court and the International Criminal Court in the areas of forensic science and criminology, the court stated that it did not know "what it takes to qualify as an expert in other countries." In addition, the court cast doubt on whether this testimony would be helpful to the jury as the methodology does not "conclusively identify blood,

but [aids] investigators by identifying areas to swab or collect for further testing to determine if blood is present." However, the court mentioned that the need for this testimony may become clear "if, for example, Defendants assert that the DNA or blood testing was somehow compromised by the use of Bluestar," assuming that the expert is deemed qualified to testify on the matter." For all these reasons, the court deferred ruling on the defendants' motion *in limine* as to Esperança's testimony.

DNA Identification: *United States v. Wrensford,* 2014 WL 1224657 (D.V.I. 2014): The court held that the PCR/STR method of DNA analysis is scientifically valid, and thus meets the standards of reliability established by *Daubert* and Rule 702.

Drug Identification --- Government had not established the reliability of the methodology: *United States v. Brown*, 2019 WL 3543253 (E.D. Mich.): The defendant challenged the testimony of a forensic expert on whether cocaine was found in a substance. The government argued that drug identification was basic and well established. It noted that the defendant provided no showing that the process of drug identification was unreliable. But the court stated that "it is the proponent of the testimony that must establish its admissibility by a preponderance of proof." It concluded as follows:

> The Government, as the proponent of Earles's testimony, has not offered any explanation on how Earles performed her test or about the reliability of her methods, other than to note that forensic scientists are frequently qualified as experts. Thus, the Government still needs to establish the reliability of Earles's methods.
>
> ***Comment:*** **The court is not at all saying that the methodology for drug identification is suspect. But it is absolutely right that if that methodology is challenged, the government must show its reliability by a preponderance of the evidence. That's the importance of the Rule 104(a) standard.**

Drug identification: *United States v. Reynoso*, 2019 WL 2868951 (D.N.M.): Testimony from lab analysts that substances obtained from the defendant contained methamphetamine was found to be admissible consistent with *Daubert.* The court stated:

> In regard to the forensic scientist and chemists, as the Government points out, "there are no novel scientific principles at play." Each of the proposed expert witnesses is employed in the field of forensic analysis and all are fully qualified to detect and analyze controlled substances. Thus, the Court rules that the proffered expert testimony of Mr. Chavez, Ms. Ponce, and Ms. Dewitt regarding the specific substances they personally analyzed have a reliable basis and will be admitted.

Fingerprints: ***United States v. Cerna***, 2010 WL 3448528 (N.D. Cal.): The court held that the ACE–V method of latent fingerprint identification, "if properly applied, is sufficiently reliable under *Daubert*." The court recognized that the NAS report "points out weaknesses in the ACE–V method" but stated that "these weaknesses do not automatically render the ACE–V theory unreliable under *Daubert*. Instead, the weaknesses highlighted by the NAS report—the lack of specificity of the ACE–V framework and its vulnerability to bias—speak more to an individual expert's application of the ACE–V method, rather than the universal reliability of the method."

Fingerprints: Overstatement --- testimony of a match --- *United States v. Love,* 2011 WL 2173644 (S.D. Cal.): The court denied a motion to exclude an expert's conclusion that the defendant's fingerprints "matched" fifteen latent prints. It recognized that "the NAS Report called for additional testing to determine the reliability of latent fingerprint analysis generally and of the ACE–V methodology in particular" and that the Report "questions the validity of the ACE–V method." But the court concluded that "*Daubert, Kumho,* and Rule 702 do not require absolute certainty." Instead, "they ask whether a methodology is testable and has been tested." The court concluded that "latent fingerprint analysis can be tested and has been subject to at least a modest amount of testing—some of which, like the study published in May 2011, was apparently undertaken in direct response to the NAS's concerns." The court also noted that "the ACE–V methodology results in very few false positives" and that "despite the subjectivity of examiners' conclusions, the FBI laboratory imposes numerous standards designed to ensure that those conclusions are sound." Concluding on the NAS report, the court stated that "[i]nstead of a full-fledged attack on friction ridge analysis, the report is essentially a call for better documentation, more standards, and more research."

> **Note: As DOJ points out, it was the court and not the witness who referred to the testimony as a match. As pointed out earlier, the fact that the court thinks that the testimony is matching testimony is a problem of its own.**

Fingerprints ---PCAST Report: ***United States v. Casaus*****,** 2017 WL 6729619 (D. Colo.): The defendant moved to exclude latent fingerprint identification evidence, challenging the reliability of the ACE-V method. The court denied the motion. (The opinion does not mention the level of certainty that the expert proposed to testify to.) The defendant relied heavily on the PCAST report, but the court relied on precedent:

> To support his contentions that the ACE-V method is per se unreliable, Defendant Casaus relies heavily on a 2016 report created by President Obama's Council of Advisors on Science and Technology, wherein the Council criticized latent fingerprint examinations. This Court, however, is bound by established Tenth Circuit precedent concluding otherwise—that fingerprint comparison is a reliable method of identifying persons and one that courts have consistently upheld against a *Daubert* challenge. * * * Although the Court understands that further research and intellectual scrutiny into the reliability of fingerprint evidence would be all to the good, the Court agrees with the conclusion of the Tenth Circuit

that to postpone present in-court utilization of this "bedrock forensic identifier" pending such research would be to make the best the enemy of the good.

Fingerprints: Overstatement --- testimony of a match --- *United States v. Shaw*, 2016 WL 5719303 (M.D. Fla.): In a felon-firearm possession prosecution, the government offered a fingerprint expert to analyze a latent fingerprint on a firearm, using the ACE-V method. The expert concluded that it matched the defendant's known fingerprint. The court found the expert's testimony to be admissible. The court relied on precedent:

> [F]ederal courts have routinely upheld the admissibility of fingerprint evidence under *Daubert*. In this case, Maurice's analysis followed ACE-V a formal and established fingerprint methodology that has been allowed by courts for over twenty years. Her work was reviewed by another crime scene/latent print analyst who verified Maurice's conclusions. Although there does not appear to be a scientifically determined error rate for ACE-V methodology, courts have found that the ACE-V method is reliable and it is generally accepted in the fingerprint analysis community.

Fingerprints: Overstatement --- testimony of a match --- *United States v. Campbell*, 2012 WL 2373037 (N.D. Ga.): The court denied a motion to exclude expert testimony that the defendant's fingerprint was a "match" to a latent print. The defendant cited the NAS critique on fingerprint methodology. The court relied on precedent:

> [C]ourts have rejected this precise argument [that latent fingerprint analysis is unreliable] and have concluded that while there may be a need for further research into fingerprint analysis, this need does not require courts to take the "drastic step" of excluding a "long-accepted form of expert evidence" and "bedrock forensic identifier.' *Stone,* 2012 WL 219435, at *3 (quoting *United States v. Crisp*, 324 F.3d 261, 268, 270 (4th Cir.2003)); see also *United States v. Cerna,* 2010 WL 3448528 (N.D.Cal.) (noting that the "NAS report may be used for cross-examination or may offer guidance for fact-specific challenges," and that the methodology "need not be perfect science to satisfy *Daubert* so long as it is sufficiently reliable"); *United States v. Rose*, 672 F.Supp.2d 723, 725–726 (D.Md.2009).
>
> **Note: DOJ says that the word "match" is supplied by the court, not by the witness. But the court used the term "match" after citing two government documents in support of the expert's testimony. So the term "match" actually comes from the government --- which is the problem that an overstatement amendment is intended to address.**

Fingerprints – Overstatement --- Testimony of a Match; PCAST and NAS Reports: *United States v. Kimble*, 2018 U.S. Dist. LEXIS 138988 (S.D. Ga.): In a prosecution for bank robbery, the defendant sought to exclude expert testimony that a latent fingerprint recovered from the getaway vehicle matched the defendant's right middle fingerprint. The court denied the defendant's request for a *Daubert* hearing. The defendant cited the PCAST and NAS Reports in

challenging the reliability of fingerprint analysis, but the court relied on precedent and on an addendum to the PCAST Report, which speaks favorably about recent developments in latent fingerprinting. The court concluded that critiques of fingerprint analysis go to the weight of the evidence, not its admissibility.

> The Government's fingerprint expert used the Analysis, Comparison, Evaluation, and Verification ('ACE-V') methodology in comparing Kimble's known fingerprints to the print lifted from the getaway vehicle. Numerous federal courts have held that that method of fingerprint comparison is widely recognized as reliable in both the scientific and judicial communities. *United States v. John*, 597 F.3d 263, 274-75 (5th Cir. 2010) (because fingerprint evidence is sufficiently reliable to satisfy Rule 702, a district court may dispense with a *Daubert* hearing); *United States v. Pena*, 586 F.3d 105, 111 (1st Cir. 2009) (district court did not err in declining to hold a *Daubert* hearing before admitting fingerprint evidence); *United States v. Crisp*, 324 F.3d 261 (4th Cir. 2003) (describing latent fingerprint methodology as a 'long-accepted form of expert evidence' and 'bedrock forensic identifier' relied upon by courts for the past century); *United States v. Abreu*, 406 F.3d 1304, 1307 (11th Cir. 2005); *United States v. Scott*, 403 F. App'x 392, 398 (11th Cir. 2010).
>
> Kimble is challenging the application of fingerprint analysis science to the specific examinations conducted in this case. * * * [T]he scientific validity and reliability of the ACE-V methodology is so well established that it is not necessary for a district court to conduct a *Daubert* hearing prior to the admission of such expert evidence at trial. [citing a bunch of case law] He can expose any weaknesses in the Government expert's application of ACE-V methodology on cross examination without the court having to expend its scarce judicial resources conducting a pretrial hearing.
>
> **Note: DOJ says that the term "match" comes from the court and that it is unknown what the witness actually testified to. But again, the point is that the court thinks that the testimony is "matching" testimony and admits it with that understanding --- how is a jury supposed to do a better job of distinguishing "match" from "identification"?**

Fingerprints --- after PCAST --- Overstatement --- testimony to a match: *United States v. Bonds*, 2017 WL 4511061 (N.D. Ill.): The court upheld the use of latent fingerprint identification under the ACE-V method. The expert was allowed to testify to a match. The defendant argued that ACE-V is not a reproducible and consistent means of determining whether two prints have a common source and that ACE-V's false positive rate is too high to justify reliance on it in a criminal trial. He relied on the PCAST report, which raises concerns about the subjective nature of fingerprint analysis and calls for efforts to validate the methodology through black box studies. But the court relied on precedent to reject the PCAST findings. It noted that the defendant's arguments have been rejected by the Seventh Circuit in *Herrera, supra*, which noted that the "methodology requires recognizing and categorizing scores of distinctive features in the prints, and it is the distinctiveness of these features, rather than the ACE-V method itself, that enables expert fingerprint examiners to match fingerprints with a high degree of confidence." The court

stated that "[a]lthough the PCAST Report focuses on scientific validity, the Court agrees with *Herrera's* broader reading of Rule 702's reliability requirement." The court also noted that the PCAST report was not completely negative on latent fingerprint analysis, as PCAST concluded that "latent fingerprint analysis is a foundationally valid subjective methodology—albeit with a false positive rate that is substantial and is likely to be higher than expected by many jurors based on longstanding claims about the infallibility of fingerprint analysis." The court concluded that "[a]lthough the PCAST Report suggested that accurate information about limitations on the reliability of the evidence be provided, this information concerning false positive rates, in addition to the other concerns raised in the PCAST Report * * * goes to the weight of the fingerprint evidence, not its admissibility. Bonds will have adequate opportunity to explore these issues on cross-examination."

Comment: Again, it is the court that uses the term "match" and we don't know what the witness actually testified to. But the fact that the court is not following the ambiguous distinction between "match" and "identification" is problematic.

Fingerprints—Overstatement --- testimony to a match: *United States v. Rose*, 672 F. Supp. 2d 723 (D. Md. 2009): In a carjacking prosecution, the defendant challenged the admissibility of fingerprint evidence identifying him as the source of two latent prints recovered from the victim's Mercedes and one latent print recovered from the murder scene. The court addressed the findings of the NAS report:

> The [2009 NAS] Report identified a need for additional published peer-reviewed studies and the setting of national standards in various forensic evidence disciplines, including fingerprint identification. While the Report quoted a paper by Haber and Haber, the defendant's proposed experts in this case, in which the Habers found no "available scientific evidence of the validity of the ACE-V method," the Report itself did not conclude that fingerprint evidence was unreliable such as to render it inadmissible under Fed. R. Evid. 702."[T]he Habers' criticism of fingerprint methodology from their perspective as human factors consultants does not outweigh the contrary conclusions from experts within the field as evidenced by caselaw and the amicus brief in this case."

Fingerprints: *United States v. Cruz-Mercedes*, 2019 WL 2124250 (D. Mass.): The court, during a *Daubert* hearing, compared the testimony of two experts who used the ACE-V method of fingerprint analysis. The government's expert testified to the procedure he followed, where he went through all four stages of ACE-V methodology and documented his procedures according to MSP protocol. However, he failed to follow standards for documentation set by the Scientific Working Group on Friction Ridge Analysis Study and Technology ("SWGFAST"). The defendant's expert did not find that the ACE-V method was unreliable, rather she found that none of the prints used by the government's expert were suitable for comparison or clear enough for positive identification. She also found that the government expert's failure to follow SWGFAST procedures opened the door to unconscious bias and prevented third party evaluation of his analysis. The court concluded as follows:

> Based on the testimony presented during the evidentiary hearing, I could not find that Sgt. Costa's methodology was so unreliable that it should be kept from the jury. To be sure, Dr. Wilcox's testimony highlighted the importance of documentation to the scientific process, and I did not accept the Government's suggestion that documentation is irrelevant to a determination of reliability. The documentation here was not full and complete, and that affects the credibility of Sgt. Costa's conclusion, even if he properly used the ACE-V procedures.
>
> While the SWGFAST standards for documentation represent the consensus view on what is appropriate, I was not convinced that Stg. Costa's failure to follow them renders his conclusions so unreliable that his opinion must be kept from the jury entirely. While that failure certainly raised concerns about confirmation bias and opens Stg. Costa's conclusions to robust challenge on cross-examination, the question whether to accept his comparison as accurate is properly left for the jury.

Comment: In finding the expert's testimony to be not so unreliable as to be excluded, it can be argued that the court flipped the burden of persuasion from that imposed by *Daubert* and Rule 104(a): the proponent has the burden of showing reliability by a preponderance of the evidence. The court is essentially saying that defects in reliability are regulated by cross-examination, which is contrary to the presumption of *Daubert.*

Fingerprints: *United States v. Stone*, 848 F. Supp. 2d 714 (E.D. Mich. 2012): The court admitted expert testimony regarding fingerprints. The defendant raised the NAS report, but the court was "unpersuaded that the NAS Report provides a sufficient basis to exclude Mr. Wintz's testimony." The court relied on case law prior to the NAS Report. It noted that "in *United States v. Crisp*, the Fourth Circuit acknowledged the need for further research into fingerprint analysis, 324 F.3d at 270, but concluded that the need for more research does not require courts to take the 'drastic step' of excluding a 'long-accepted form of expert evidence' and 'bedrock forensic identifier.'" The court stated that "[w]holesale objections to latent fingerprint identification evidence have been uniformly rejected by courts across the country."

Fingerprints: Overstatement --- error rate of 30 out of a zillion --- *United States v. Gutierrez-Castro*, 805 F. Supp. 2d 1218 (D.N.M. 2011): The government sought to introduce an expert's testimony about the methods and practices of inked fingerprint analysis. The expert compared several examples of fingerprints obtained from the defendant and would testify that all the fingerprints belong to the defendant. The court permitted the testimony, relying heavily on the Tenth Circuit's decision in *United States v. Baines,* 573 F.3d 979 (10th Cir. 2009) (supra). The court stated that fingerprint analysis is used throughout the country and that "there have been over a hundred years of empirical validation to support fingerprint analysis, although it has not been scientifically established that fingerprints are unique to each individual." The court acknowledged that the NAS Report calls into question ACE-V methodology, and concluded that its conclusions cut against admissibility under the *Daubert* peer review factor. The court found that the low rate of error weighed in favor of admissibility. The expert testified that error rates do exist, though it is hard to determine an error rate. He stated that there have been approximately thirty documented

misidentifications in the last thirty or forty years out of millions of fingerprints. Finally, the court concluded that the *Daubert* factor of standards and controls was met because there are "standards that guide and limit the analyst in the exercise of subjective judgments."

> **Comment:** The expert's testimony that the rate of error is 30/millions is wildly off, as shown in the PCAST report.

Fingerprints: ***United States v. Mercado-Gracia***, 2018 WL 5924390 (D.N.M. Nov. 13, 2018): In an armed drug trafficking prosecution, the defendant sought to exclude the testimony of the government's latent fingerprint expert, Lloyd. The court held a *Daubert* hearing on the reliability of the ACE-V method and denied the defendant's request, applying the *Daubert* factors as follows:

> 1. Whether the Theory Can be Tested
>
> Research on the persistence and uniqueness of fingerprints has occurred over hundreds of years. * * * Continued studies are ongoing in the fingerprint community. Numerous courts, including this one, have held that the ACE-V method can be tested. Given the record and authority, the first *Daubert* factor weighs in support of admissibility. * * *
>
> 2. Peer Review and Publication of the ACE-V Method
>
> The record contains information on studies concerning the reliability of latent fingerprint analysis but contains less on the extent of peer review of the studies or the ACE-V method. This factor is thus neutral.
>
> 3. Known or Potential Error Rate
>
> Defendant argues that fingerprint analysis is completely subjective and bias affects fingerprint analysis results, citing publications in support. Additionally, defense counsel highlighted at the hearing that Lloyd was unaware of population statistics regarding the uniqueness of fingerprints. Lloyd acknowledged that latent print examinations involve subjectivity, and human error can occur, notably in the comparison step of the ACE-V method.
>
> Nevertheless, the training and experience of latent print analysts is important in the field of fingerprint analysis. * * * In the Ulery study, 169 latent print examiners were given 100 prints, and the analysts made correct identifications 99.8% of the time. The Ulery study found a false negative rate of 7.5%. Numerous courts to have examined this issue have found that the error rate evidence in fingerprint identification weighs in favor of admissibility. * * * The recent bias studies cited by Defendant indicate that the error rate could be higher in real world settings where bias may be introduced; however, the very low error rate in the controlled Ulery study favors admissibility.

4. Existence and Maintenance of Standards

The Customs and Border Patrol ("CBP") laboratory is certified by an outside agency, the American Society of Crime Laboratory Directors/Laboratory Accreditation Board ("ASCLD"). ASCLD promulgates its own standards that the ASCLD-certified laboratories must follow. Independent examiners from ASCLD analyze cases from the laboratory to make sure all laboratory analysts are following the same guidelines and the laboratory internal procedures and that the analysts all have the same training. ASCLD and the fingerprint analysis community use the ACE-V process for latent print comparison.

CBP latent print examiners throughout the world, including Douglas Lloyd, are certified by the International Association for Identification ("IAI"). Latent print examiners must pass a test issued by the IAI. The IAI requires re-testing every five years and training within the five years to stay continually certified. Failure to pass the IAI's proficiency test will result in a six to twelve-month suspension, mandatory retraining, and re-testing.

Although the ACE-V system is a procedural standard relying on the subjective judgment of the examiner, there are accepted standards for following the ACE-V method, training on the system, and certification processes within the fingerprint examiner community to help ensure quality. This factor therefore weighs in favor of admissibility.

5. General Acceptance of Theory

The IAI, a worldwide standard, follows the ACE-V methodology. Despite the subjectivity inherent in the ACE-V method and some studies suggesting bias can affect results, federal courts of appeals have consistently concluded that ACE-V is an acceptable and reliable methodology. [citing a number of cases]. The general-acceptance-in-the-community factor favors admissibility.

The court concluded as follows:

Although not entirely scientific in nature, fingerprint analysis requires significant training and experience using a standard methodology. As *Kumho Tire* instructs, expert testimony on matters of a technical nature or related to specialized knowledge, albeit not scientific, can be admissible under Rule 702, so long as the testimony satisfies the Court's test of reliability and relevance. Fingerprint identification testimony is sufficiently reliable to be admitted into evidence at trial and Lloyd is qualified by his education, training, and experience to testify to matters in the field of fingerprint analysis and identification. The Court will therefore deny Defendant's motion to exclude Lloyd from testifying at trial.

Note: The government in this case provided notice that "Lloyd is expected to testify that he viewed the digital images photographed by Handley, compared them to Defendant's fingerprint images, and identified fingerprints of value 4A and 5A as the right thumb and right index finger of Defendant." So this is testimony of a match --- an overstatement, given that no testimony of a possible rate of error is contemplated. The testimony, however, is permitted under the DOJ protocol, where the word "identification" is interpreted as something other than a statement that there is a match.

Fingerprints – PCAST and NAS Reports --- prohibiting testimony of zero error rate but no discussion of an alternative : *United States v. Pitts*, 2018 WL 1116550 (E.D.N.Y. Feb. 26, 2018): In a prosecution for attempted bank robbery, the defendant moved to exclude expert testimony that latent fingerprints recovered from a withdrawal slip at the crime scene were a match to the defendant. The court denied the motion. With regard to latent fingerprint analysis, the court noted that the PCAST and NAS Reports raise a number of concerns:

> First, error rates are much higher than jurors anticipate. PCAST Report at 9-10 (noting that error rates can be as high as one in eighteen); Jonathan J. Koehler, *Intuitive Error Rate Estimates for the Forensic Sciences*, 57 Jurismetrics J. 153, 162 (2017) (noting that jurors estimate the error rate to be one in 5.5 million)). Second, the NAS Report concluded that the ACE-V method lacks scientific credibility, stating that: "We have reviewed available scientific evidence of the validity of the ACE-V method and found none." NAS Report at 143. Defendant also suggests that fingerprint analysts typically testify that the methodology has a zero or near zero error rate. *See* Mot. at 10 (citing *United States v. Mitchell*, 365 F.3d 215, 246 (3d Cir. 2004) ('[S]ome latent fingerprint examiners insist that there is no error rate associated with their activities.... This would be out-of-place under Rule 702.')). These analysts reason that errors are either human or methodological, and, in the absence of human error, the methodology of fingerprint analysis is 100% accurate. *See* Simon A. Cole, *More Than Zero: Accounting for Error in Latent Fingerprint Identification*, 95 J. Crim. L. & Criminology 985, 1034-49 (2005) ('More Than Zero'). Finally, Defendant contends that the critiques in the PCAST Report and NAS Report demonstrate that fingerprint analysis has not gained widespread acceptance among the relevant community.

As to these arguments the court first noted that the PCAST report eventually was more favorable to latent fingerprint analysis, given the empirical studies that have recently been done. The court stated that while the PCAST report "reinforced the need for empirical testing of fingerprint analysis and other forensic methods, noting that 'experience and judgment alone—no matter how great—can *never* establish the validity or degree of reliability of any particular method,' it also 'applaud[ed] the work of the friction-ridge discipline' for steps it had taken to confirm the validity and reliability of its methods."

Ultimately the court relied heavily on precedent:

> Fingerprint analysis has long been admitted at trial without a *Daubert* hearing. *United States v. Stevens*, 219 Fed.Appx. 108, 109 (2d Cir. 2007) * * *; *United States v. Salameh*, 152 F.3d 88, 128-129 (2d Cir. 1998) (affirming admission of fingerprint evidence); *See also United States v. Avitia-Guillen*, 680 F.3d 1253, 1260 (10th Cir. 2012) ('Fingerprint comparison is a well-established method of identifying persons, and one we have upheld against a *Daubert* challenge.').

The Court finds the government's citation to *United States v. Bonds*, 2017 WL 4511061 (N.D. Ill.) instructive. The court in *Bonds* reviewed the same arguments presented here: that the PCAST Report renders fingerprint analysis inadmissible.

Finally, the court addressed the possibility that the expert would overstate the meaning of the results. It noted that the government had averred that its fingerprint experts would not testify that fingerprint analysis has a zero or near zero error rate.

While the government concedes that experts at one time claimed that the error rate was zero, recent guidance instructs experts to have familiarity with error rates and the steps taken to reduce error rates, and "not [to] state that errors are inherently impossible or that a method inherently has a zero error rate." (Nat'l Institute of Standards and Tech., *Latent Print Examination and Human Factors: Improving the Practice through a Systems Approach* (2012), http://www.nist.gov/oles/upload/latent.pdf (last visited Feb. 26, 2017)). Thus, Defendant's critiques appear to be misplaced.

The court emphasized, in conclusion, that it was not holding that fingerprint analysis is *per se* admissible." It observed that the PCAST and NAS Reports "note a number of areas for improvement among the forensic sciences, and a number of courts have criticized forensic sciences as potentially lacking in the 'science' aspect." However, the defendant, by simply relying on these reports, had not made a sufficient showing "that his critiques go to the admissibility of fingerprint analysis, rather than its weight." [Which, given everything in the opinion, looks like an application of Rule 104(a).]

Comment: In discussing the question of overstatement, the court was happy that the experts were not going to testify to a zero rate of error. That is good, but there is no discussion in the opinion of what kind of confidence level and error rate the experts were going to testify to. If the expert just says it is a match --- or that the defendant's fingerprint has been "identified" --- with no indication of the meaning of that conclusion, it is arguably not much better than testimony about a zero rate of error. Arguably, this is the kind of case where an amendment to Rule 702 that prohibits overstatement of results might focus the court on what the expert should be allowed to say.

Fingerprints – Defendant's expert prohibited from testifying that experts exaggerate their results: *United States v. Pitts*, 2018 U.S. Dist. LEXIS 34552 (E.D.N.Y. Mar. 2, 2018): In a prosecution for attempted bank robbery, the government moved to exclude the testimony of the defendant's fingerprint expert, Dr. Cole. The court granted the government's motion, concluding that Dr. Cole's testimony would not assist the trier of fact, and that excluding his testimony would not deprive the defendant of the right to use the PCAST and NAS Reports to cross-examine the government's experts.

The Court is not convinced that Dr. Cole's testimony would be helpful to the trier of fact. The only opinion Defendant seeks to introduce is that fingerprint examiners "exaggerate" their results and exclude the possibility of error. However, the government has indicated that its experts will not testify to absolutely certain identification nor that the

identification was to the exclusion of all others. Thus, Defendant seeks to admit Dr. Cole's testimony for the sole purpose of rebutting testimony the government does not seek to elicit. Accordingly, Dr. Cole's testimony will not assist the trier of fact to understand the evidence or determine a fact in issue.

The court argued further that a defense expert was not necessary, because there was literature about error rates on which the defense could rely – most importantly, the PCAST report. The court stated that the defendant "identifies no additional information or expertise that Dr. Cole's testimony provides beyond what is in these articles and does not explain why cross-examination of the government's experts using these reports would be insufficient."

Comment: This result shows the importance of having an admissibility requirement that specifically prohibits overstatement of results. The court was essentially treating the possibility of overstatement as a question of weight that could be dealt with on cross-examination.

As stated above, the fact that the experts were not going to testify to a zero rate of error is insufficient to guard against the risk of overstatement. The court seems to think that the problem is solved by any language other than zero rate of error.

Next, it is difficult to accept the court's assumption that cross-examination with reports will be as effective as an expert witness for the defense. And it seems unfortunate that prosecution forensic experts are admitted and defense experts are excluded in the same case.

Fingerprints – Question of application of the method: *United States v. Lundi*, 2018 WL 3369665 (E.D.N.Y.): In a robbery prosecution, the defendant moved to exclude expert testimony that the defendant was the source of latent fingerprints recovered at the crime scene, and the government moved to preclude the defendant's fingerprint expert from testifying. The defendant, relying on the PCAST Report, did not argue that the ACE-V method itself is flawed, but instead argued that the government's expert failed to use the ACE-V method and therefore should be precluded from testifying. The court denied the defendant's motion, concluding that the government sufficiently established that the method was used, and therefore that the defendant's challenges go to the weight of the evidence, not admissibility.

The court --- the judge that issued the opinions in *Pitts, supra* --- evaluated the government's expert as follows:

Defendant argues that the government's expert testimony as to fingerprint analysis should be excluded in this case because the government has not shown that the multistep ACE-V method for analyzing fingerprints was used by its proposed expert, Detective Skelly. However, the government points to concrete indicators of how the ACE-V method actually was followed by Detective Skelly. Defendant does not argue that the method itself is flawed. Indeed, Defendant relies upon the addendum to the *Forensic Science in Criminal Courts: Ensuring Scientific Validity of Feature-Comparison Methods* (2016) report of the President's Council of Advisors on Science and Technology, which recognizes the ACE-V method as scientifically valid and reliable. * * * This Court is not persuaded that Defendant's challenges go to the admissibility of the government's fingerprint evidence,

rather than to the weight accorded to it. Moreover, as this Court noted in *Pitts*, fingerprint analysis has long been admitted at trial without a *Daubert* hearing. The Court sees no reason to preclude such evidence here.

The defendant's expert was the same witness that the court excluded in *Pitts, supra.* As in *Pitts,* the court found that the expert could not testify to overstatement, because, once again, the government witnesses were not going to testify to a zero rate of error. Unlike in *Pitts,* however, the defense expert in this case proposed to testify to the reliability of fingerprint examinations and the "best practices" to be followed when conducting such examinations. But once again the court found the PCAST and other reports to be sufficient fodder for cross-examination of the government's experts, and so concluded that the expert's testimony would not be helpful.

Comment: At least on the admissibility/weight question, the court seems correct. While questions of application go to admissibility, and the defendant argued that the expert did not apply the ACE-V method, the government countered with evidence that he actually did apply the method. Thus, any questions of proper application are in the nature of a swearing match, and so are matters of weight.

Again it seems problematic for the court to hold: 1) that a promise not to testify to zero rate of error completely solves the problem of overstatement; and 2) that an expert in the defendant's case is not helpful because the defendant can use reports cross-examine experts in the government's case.

Fingerprints: PCAST report; and some limit on overstatement: *United States v. Cantoni*, 2019 WL 1259630 (E.D.N.Y.): The defendant moved to exclude expert testimony by the NYPD Latent Print Section ("LPS"). The NYPD LPS uses the ACE-V approach for fingerprint analysis. The defendant relied on the PCAST report, which expressed doubts about the reliability of fingerprint identification and proposed a five-step process for to correct for bias. The PCAST recommendations are that latent print examiners (1) have undergone proficiency testing, (2) disclose whether they have analyzed the latent print before comparing it to the known print, (3) document their comparison of the prints' features, (4) disclose the existence of other facts that could have influenced their conclusion, and (5) verify that the latent print is comparable in quality to those prints used in certain foundational studies of latent print analysis. The defendant argued that aside from the NYPD experts undergoing proficiency testing, there was no evidence to suggest that they followed the remaining guidelines.

The court assumed, without deciding, that the defendant was correct that the NYPD experts had not satisfied the PCAST protocol. But the court concluded that "the analysis makes clear that LPS followed the ACE-V procedure, a procedure that the PCAST report deemed scientifically valid and reliable. Indeed, an addendum to the PCAST report concluded that 'there was clear empirical evidence' that 'latent fingerprint analysis [...] method[ology] met the threshold requirements of scientific validity and reliability under the Federal Rules of Evidence." (citations and internal quotations omitted). The court concluded as follows:

> Although NYPD's methods may have been imperfect and may not have delivered scientifically certain results, there is no indication that they were so fundamentally unreliable as to preclude the testimony of the experts. At best, Cantoni's submission shows certain ways in which cognitive bias may have affected the NYPD examiners' analysis but does not show that it actually did so or that any cognitive bias was so significant as to produce an erroneous conclusion. Defendant's concerns are fodder for cross-examination rather than grounds to exclude the latent print evidence entirely. This is the approach that has been adopted each time courts in this district have considered similar motions.

The defendant alternatively sought relief from possible overstatement in the expert's opinions. He moved to preclude the government experts from testifying that their conclusion is certain, that latent print analysis has a zero error rate, or that their analysis could exclude all other persons who might have left the print. In response, the government acknowledged that "the language and claims that are of concern to defense counsel are disfavored in the latent print discipline," and that "absolutely certain opinions" and identifications "to the exclusion of all others" are "not approved for latent print examination testimony." The court granted the defendant's motion to exclude such claims "without opposition." [Nonetheless, the experts were presumably allowed to testify to a source identification.]

Finally, the defendant sought to call an expert, Dr. Cole, who would testify to the rate of error in fingerprint identification, and challenges to its reliability. This was the same expert that the defendants proffered in *Pitts, supra.* Like the court in *Pitts,* the court here found that an expert would not be helpful, because the issues that would be addressed by the expert could be raised on cross-examination of the government experts.

Fingerprints: Overstatement --- testimony to a match--- *United States v. Myers*, 2012 WL 6152922 (N.D. Okla.): The court allowed an expert to testify to a fingerprint match, using the ACE-V method. The court relied heavily on *Baines, supra.* The court ticked off the *Daubert* factors:

> 1. *Testing:* "Gorges has undergone demanding training culminating in proficiency examinations, followed by further proficiency examinations at regular intervals during her career. Thus, Gorges' testing is commensurate with the training undergone by fingerprint analysts employed by the FBI and other law enforcement agencies all over the world, and is sufficient to weight the first *Daubert* factor in favor of admissibility."
>
> 2. *Peer Review and Publication:* The court cited a report of the Office of the Inspector General (OIG), which is an updated analysis of the FBI's fingerprint identification procedures. "Although the peer review contained in the report is not strictly scientific peer review of the ACE–V methodology contemplated by independent peer review of true science, it is sufficient to lend credibility to the methodology. Gorges also testified that, pursuant to TPD protocol, both positive and negative identifications are subject to verification. Again, although review by a secondary examiner is not the independent peer review of true science, it again lends credibility to the ACE–V methodology, especially where the review is sometimes blindly done."

3. *Error Rates*: "Gorges stated that a trained, competent examiner using the ACE–V method properly should not make a misidentification. Therefore, this factor also weighs slightly in favor of admissibility."

4. *Standards and Controls*: "As Gorges testified, several steps of the analysis require subjective judgments. Although subjectivity does not, in itself, preclude a finding of reliability, the reliance on subjective judgments may weigh against admissibility. However, Gorges also testified that the extensive training and testing that she undergoes makes the subjective analysis more exacting. When defendant asked whether two examiners might view the print differently or examine a print differently in the analysis step, Gorges stated that, while two examiners might notice different areas of the print, an examiner following the standard operating procedures, or the ACE–V method in the TPD, would not have a lot of leeway. Therefore, the fourth factor weighs both for and against admissibility."

5. *General Acceptance*: "Gorges testified that ACE–V is currently utilized by the FBI. She also stated that it is the most reliable standard or protocol. Because fingerprint analysis has achieved overwhelming acceptance by experts in Gorges' field, and because ACE–V is accepted as the most reliable methodology, this final factor weighs in favor of admissibility."

Comment: There are many challengeable assertions in the court's application of the *Daubert* factors. To take what is probably the most important: the *Daubert* Court's reference to testing goes to whether the *method* can be verified empirically. That methodology-based focus is different from whether the *expert* is trained.

Fingerprints: Overstatement --- testimony to a match: *United States v. Aman,* 748 F. Supp. 2d 531 (E.D. Va. 2010): In an arson prosecution, the defendant moved to exclude the expert's testimony that the latent fingerprints and palmprints from the crime scene matched the defendant's known prints. He attacked the validity of the expert's Analysis-Comparison-Evaluation-Verification ("ACE-V") method for fingerprint identification. The court rejected the motion. It provided a helpful analysis of the reliability concerns attendant to fingerprint identification methodology. But ultimately it found that these concerns, about subjectivity and the lack of validation with empirical evidence, were questions of weight and not admissibility:

> The ACE–V method is not without criticism. Although fingerprint examination has been conducted for a century, the process still involves a measure of art as well as science. . . . The NRC Report [Strengthening Forensic Science in the United States: A Path Forward (2009)] devotes significant attention to friction ridge analysis, noting the "subjective" and "interpret[ive]" nature of such examination. Additionally, the examiner does not know, *a priori*, which areas of the print will be most relevant to the given analysis, and small twists or smudges in prints can significantly alter the points of comparison. This unpredictability can make it difficult to establish a clear framework with objective criteria for fingerprint examiners. And unlike DNA analysis, which has been subjected to population studies to

demonstrate its precision, studies on friction ridge analysis to date have not yielded accurate population statistics. In other words, while some may assert that no two fingerprints are alike, the proposition is not easily susceptible to scientific validation.

Furthermore, while fingerprint experts sometimes use terms like "absolute" and "positive" to describe the confidence of their matches, the NRC has recognized that a zero-percent error rate is "not scientifically plausible."

The absence of a known error rate, the lack of population studies, and the involvement of examiner judgment all raise important questions about the rigorousness of friction ridge analysis. To be sure, further testing and study would likely enhance the precision and reviewability of fingerprint examiners' work, the issues defendant raises concerning the ACE–V method are appropriate topics for cross-examination, not grounds for exclusion. [T]he fact that ACE–V involves judgment does not render the method unreliable for *Daubert* purposes.

Fingerprints (Palmprints): Overstatement --- testimony to a match --- *United States v. Council*, 777 F. Supp. 2d 1006 (E.D. Va. 2011): The defendant moved to exclude an expert's testimony that known palm prints collected from the defendant matched a latent palmprint on a handgun. He relied on the NAS report that critiqued fingerprint methodology as subjective and lacking a scientific basis. The court rejected the defendant's arguments, concluding the "friction ridge analysis has gained [acceptance] from numerous forensic experts and law enforcement officials across the country. See *Crisp*, 324 F.3d at 269 (holding a district court was 'within its discretion in accepting at face value the consensus of expert and judicial communities that the fingerprint identification technique is reliable')." The court stated that the NAS report has "usefully pointed out areas in which standards governing friction ridge analysis should continue to develop" but that its critique was "insufficiently penetrating to warrant the exclusion of Dwyer's testimony."

Comment: It is hard to believe that dispositive weight should be given to general acceptance by members of the field, and law enforcement officials. That is like voting for yourself in an election, and you get the dispositive vote.

Fingerprints—PCAST report --- defense rebuttal expert rejected: *United States v. Hendrix*, 2020 WL 30342 (W.D. Wash.): The expert testified to a fingerprint identification, having used the ACE-V methodology. On cross-examination, she could not recall the error rates from the studies she relied on. At the *Daubert* hearing, the defendant offered testimony from Professor Cole, who is not a fingerprint examiner, to testify mainly on rates of error for fingerprint analysis based on the PCAST report. The court denied the defendant's motion to exclude the fingerprint identification, finding it to be relevant and reliable. The defendant sought at trial call Professor Cole as a rebuttal witness to testify to the following: (1) scientific probability; (2) error rates in specific fingerprinting studies; and (3) whether the government's expert's testimony was "scientifically acceptable."

First, the court found that Professor Cole's broad-sweeping conclusions about probability, that "all evidence and all science is probabilistic in nature" was outside his expertise and not relevant to this case. Next, the court concluded that Professor Cole could not offer opinions on error rate in fingerprint analysis because he is a social scientist and not a fingerprint examiner. It reasoned that Cole's testimony would serve, not as expertise, but as a conduit for hearsay contained in the PCAST report and other studies. Finally, the court found that Professor Cole could not testify as to what was "accepted within the latent print discipline" because he is not a member of that discipline. Thus, the court excluded the entirety of Professor Cole's proposed testimony.

Footprint identification: *United States v. Pugh,* 2009 WL 2928757 (S.D. Miss.): The court rejected a challenge to footprint analysis, relying mainly on precedent:

> Footprint analysis is not a new concept and expert testimony on footwear comparisons has been admitted in courts in the United States. [The footprint expert] established that the theory and technique of footwear comparisons have been tested; that the techniques for shoe-print identification are generally accepted in the forensic community, and that the science of footwear analysis has by now been generally accepted. The expert shoe print testimony was based on specialized knowledge and would aid the jury in making comparisons between the soles of shoes found on or with the Defendant and the imprints of soles found on surfaces at the crime scene.

Gunshot residue: *United States v. North*, 2017 WL 5508138 (N.D. Ga.): The defendant moved to exclude expert testimony on gunshot residue. The court denied the motion. The court noted that the defendant "does not cite any authorities or other information that the GSR analysis is unreliable, non-scientific, or that it does not have broad acceptance in the forensic community." The defendant cited the NAS and PCAST reports but the court observed that nothing in any of those reports cast doubt on the largely mechanical process of determining gunshot residue. The court also relied on the fact that other courts "have admitted expert testimony regarding GSR testing similar to that which it intends to be offered at this trial in this case." The court concluded that to the extent the defendant sought to attack the credibility and accuracy of the results of the GSR analysis, "these matters can be the subject of vigorous cross examination, presentation of contrary evidence, and careful instructions on the burden of proof."

Gunshot residue: *Sanford v. Russell*, 2019 WL 2169911 (E.D. Mich.): This was a section 1983 action alleging that the defendants prosecuted the plaintiff after coercing his confession and generating false forensic evidence. The defendants challenged the plaintiff's expert testimony that the presence of primer residue on the plaintiff's pants did not mean that he had recently fired a gun. The defendants argued that the expert's opinions about the primer gunshot residue test were fatally uninformed because he admitted that he never even performed such a test. But the court was persuaded by the expert's explanation that he never performed the test *because it was deemed unreliable and too likely to produce misleading results*. Here is the expert's explanation:

> During my twenty years at the Michigan State Police Northville Forensic Laboratory, I never performed primer residue testing. To my knowledge, the Michigan State Police has never performed this type of test because the test can generate the false and misleading impression that someone has recently fired a gun when, in fact, it establishes nothing of the kind. In fact, there is no test today, nor has there ever been, that definitively determines whether a person did or did not fire a weapon.

The court stated that "the fact that an expert witness refuses to employ a method that is regarded in his field as unreliable certainly does not justify *excluding* his testimony; in fact, it suggests that his opinions are *more* reliable rather than less."

> **Comment: *Sanford* is a topsy-turvy case because it is essentially law enforcement challenging a (former) criminal defendant's expert testimony that a gunshot residue test is unreliable. It's interesting that the court agrees with the expert that the test is unreliable, given the fact that there is a good deal of precedent (cited in the *North* case, immediately above) that finds gunshot residue tests to be reliable.**

Handwriting: *United States v. Yass,* 2008 WL 5377827 (D. Kan.): The defendant argued that handwriting analysis must be excluded under Rule 702 because it is not based on a reliable methodology reliably applied. The court found the evidence admissible, relying almost exclusively on precedent:

> Federal appellate courts have been unanimous in approving expert testimony in the field of handwriting analysis. Rather than to exclude handwriting analysis as "junk science," as urged by defendant, the Court finds the process of handwriting analysis sufficiently reliable to satisfy *Daubert* and the Federal Rules of Evidence and declines to depart from the clear majority of courts weighing in on the issue. Moreover, despite the uneven treatment of handwriting experts by district courts, every appellate court to have considered the issue of handwriting testimony has held that the expert's ultimate opinion was admissible.

Handwriting: *Boomj.com v. Pursglove*, 2011 WL 2174966 (D. Nev.): The court rejected a challenge to testimony of a handwriting expert that certain handwriting was not the defendant's. It relied heavily on the fact that "[t]he Ninth Circuit and six other circuits have already addressed the admissibility of handwriting expert testimony and determined that handwriting expert testimony can satisfy the reliability threshold." It concluded that "handwriting analysis is a tested theory, it has been subject to peer review and publication, there is a known potential rate of error and there are standards controlling the technique's operation, and it enjoys general acceptance within the relevant scientific community."

> **Comment:** That conclusion appears to be an overstatement in several respects. Handwriting analysis is not even close to being scientific, so it can't really enjoy general acceptance within a relevant scientific community; the data on rate of error on handwriting is that it is that experts are not much more accurate than laypeople; and there are no

consistent standards and controls in the field. Nor is there an empirical basis for the premise that each person's handwriting is unique.

Handwriting: Overstatement – testimony to a match --- *United States v. Brooks,* 2010 WL 291769 (E.D.N.Y.): The court rejected a *Daubert* challenge to handwriting identification, relying exclusively on precedent:

> Even though the district court in *United States v. Oskowitz*, 294 F.Supp.2d 379, 383–384 (E.D.N.Y.2003) partially limited a handwriting expert's testimony, the Second Circuit has "never held that a handwriting expert may not offer an opinion on the ultimate question of authorship." *A.V. by Versace, Inc.,* 2006 U.S. Dist. LEXIS 62193 at *269 fn. 14. In fact, no Second Circuit district court has wholly excluded "the testimony of a handwriting expert based on a finding that forensic document examination does not pass the *Daubert* standard." Id. And, the Second Circuit itself has routinely alluded to expert handwriting analysis without expressing any discomfort as to its admissibility. *See, e.g., United States v. Tin Yat Chin*, 371 F.3d 31, 39 (2d Cir.2004) (referring to defendant's proffer of a handwriting expert); *United States v. Badmus*, 325 F.3d 133, 138 (2d Cir.2003) (discussing government's use of expert testimony to identify defendant's handwriting on series of documents).

Handwriting --- excluded: *Almeciga v. Center for Investigative Reporting,* 2016 WL 2621131 (S.D.N.Y.): Judge Rakoff rejected the opinion of a handwriting expert that a signature on a release was forged. His analysis is extensive. He noted that while courts were originally skeptical of allowing handwriting experts to testify, the practice became prevalent after the Lindbergh case. But he also noted that in the last few years some courts have become more skeptical, because "even if handwriting expertise were always admitted in the past (which it was not), it was not until *Daubert* that the scientific validity of such expertise was subject to any serious scrutiny." Judge Rakoff observed that in the Second Circuit, "the issue of the admissibility and reliability of handwriting analysis is an open one. See *United States v. Adeyi*, 165 Fed.Appx. 944, 945 (2d Cir.2006) ("Our circuit has not authoritatively decided whether a handwriting expert may offer his opinion as to the authorship of a handwriting sample, based on a comparison with a known sample.") As such, the Court is free to consider how well handwriting analysis fares under *Daubert* and whether Carlson's testimony is admissible, either as 'science' or otherwise."

Judge Rakoff found that the ACE-V process of handwriting identification was not even close to being a scientific methodology. He applied the *Daubert* factors:

> *Testing:* To this Court's knowledge, no studies have evaluated the reliability or relevance of the specific techniques, methods, and markers used by forensic document examiners to determine authorship * * * . For example, there are no studies that have evaluated the extent to which the angle at which one writes or the curvature of one's loops distinguish one person's handwriting from the next. Precisely what degree of variation falls within or outside an expected range of natural variation in one's handwriting—such that an

examiner could distinguish in an objective way between variations that indicate different authorship and variations that do not—appears to be completely unknown and untested. Ditto the extent to which such a range is affected by the use of different writing instruments or the intentional disguise of one's natural hand or the passage of time. Such things could be tested and studied, but they have not been; and this by itself renders the field unscientific in nature. * * * Until the forensic document examination community refines its methodology, it is virtually untestable, rendering it an unscientific endeavor.

Peer Review and Publication: Of course, the key question here is what constitutes a "peer," because, just as astrologers will attest to the reliability of astrology, defining "peer" in terms of those who make their living through handwriting analysis would render this *Daubert* factor a charade. While some journals exist to serve the community of those who make their living through forensic document examination, numerous courts have found that the field of handwriting comparison suffers from a lack of meaningful peer review by anyone remotely disinterested.

Rate of Error: There is little known about the error rates of forensic document examiners. * * * Certain studies conducted by Dr. Moshe Kam, a computer scientist commissioned by the FBI to research handwriting expertise, have suggested that forensic document examiners are moderately better at handwriting identification than laypeople. For example, in one such study, the forensic document examiners correctly identified forgeries as forgeries 96% of the time and only incorrectly identified forgeries as genuine .5% of the time, while laypeople correctly identified forgeries as forgeries 92% of the time and incorrectly identified forgeries as genuine 6.5% of the time. * * * Although such studies may seem to suggest that trained forensic document examiners in the aggregate do have an advantage over laypeople in performing particular tasks, not all of these results appear to be statistically significant and the methodology of the Kam studies has been the subject of significant criticism. * * * [I]n a 2001 study in which forensic document examiners were asked to compare (among other things) the "known" signature of an individual in his natural hand to the "questioned" signature of the same individual in a disguised hand, examiners were only able to identify the association 30% of the time. Twenty-four percent of the time they were wrong, and 46% of the time they were unable to reach a result.

Standards and Controls: The field of handwriting comparison appears to be entirely lacking in controlling standards, as is well illustrated by Carlson's own amorphous, subjective approach to conducting her analysis here. At her deposition, for example, when asked "what amount of difference in curvature is enough to identify different authorship," Carlson vaguely responded, "[y]ou know, that's just a part of all of the features to take into context, so I wouldn't rely on a specific stroke to determine authorship." Similarly, when asked at the *Daubert* hearing how many exemplars she requires to conduct a handwriting comparison, Carlson testified:

> You know, that's really—that has been up for debate for a long time. I know that a lot of document examiners, myself included, I would prefer—I ask for a half a dozen to a dozen. That at least gives me a decent sampling. Others request 25 or

more. I feel like if you get too many signatures you have got so much information it is overwhelming and you tend to get lost in it.

Nor is there any agreement as to how many similarities it takes to declare a match. * * * And because there are no recognized standards, it is impossible to compare the opinion reached by an examiner with a standard protocol subject to validity testing. Furthermore, there is no standardization of training enforced either by any licensing agency or by professional tradition, nor a single accepted professional certifying body of forensic document examiners. Rather, training is by apprenticeship, which in Carlson's case, took the form of a two-year, part-time internet course, involving about five to ten hours of work per week under the tutelage of a mentor she met with personally when they were "able to connect."

General Acceptance: [H]andwriting experts certainly find general acceptance within their own community, but this community is devoid of financially disinterested parties. * * * A more objective measure of acceptance is the National Academy of Sciences' 2009 Report, which struck a cautious note, finding that while "there may be some value in handwriting analysis," "[t]he scientific basis for handwriting comparisons needs to be strengthened." The Report also noted that "there may be a scientific basis for handwriting comparison, at least in the absence of intentional obfuscation or forgery"—a highly relevant caveat for present purposes [because the contention in this case was that the defendant was *trying* to make a signature look forged]. This is far from general acceptance.

Judge Rakoff concluded that "[f]or decades, the forensic document examiner community has essentially said to courts, 'Trust us.' And many courts have. But that does not make what the examiners do science."

Judge Rakoff then considered whether the testimony could be qualified as "technical knowledge" that would assist the jury under *Kumho.* But he found that "the subjectivity and vagueness that characterizes Carlson's analysis severely diminishes the reliability of Carlson's methodology." He concluded as follows:

Several courts that have found themselves dubious of the reliability of forensic document examination have adopted a compromise approach of admitting a handwriting expert's testimony as to similarities and differences between writings, while precluding any opinion as to authorship. See, e.g., *Rutherford*, 104 F.Supp.2d at 1192–94. That Solomonic solution might be justified in some circumstances, but it cannot be here where the Court finds the proffered expert's methodology fundamentally unreliable and critically flawed in so many respects. * * * It would be an abdication of this Court's gatekeeping role under Rule 702 to admit Carlson's testimony in light of its deficiencies and unreliability. Accordingly, Carlson's testimony must be excluded in its entirety.

Handwriting – PCAST and NAS Reports --- Overstatement---- testimony to a match: ***United States v. Pitts*****,** 2018 WL 1116550 (E.D.N.Y. Feb. 26, 2018): In a prosecution for attempted

bank robbery, the defendant moved to exclude expert testimony that handwriting on a withdrawal slip at the crime scene was a match to the defendant's. The court denied the motion. The defendant relied heavily on Judge Rakoff's decision in *Almeciga*, *supra,* but the court relied on other precedent and determined that *Almeciga* was factually distinguishable. The court noted that *Almeciga* involved analysis of a forgery, "which is a more difficult handwriting analysis with a higher error rate." The court also noted that the expert in *Almeciga* "performed her initial analysis without any independent knowledge of whether the 'known' handwriting samples used for comparison belonged to the plaintiff." Third, "the expert conflictingly claimed that her analysis was based on her 'experience' as a handwriting analyst, but then claimed in her expert report that her conclusions were based on her 'scientific examination' of the handwriting samples." Given these differences, the court found *Almeciga* "inapposite and unpersuasive."

The court then went to other precedent in which the ACE-V method of latent fingerprint analysis had been admitted:

> The Second Circuit Court of Appeals has not addressed directly the admissibility of handwriting analysis. * * * Courts in this district, however, routinely admit handwriting evidence. *See, e.g.*, *United States v. Tarantino*, 2011 WL 1113504, at *7-8 (E.D.N.Y. Mar. 23, 2011) ('Subject to *voir dire* of the analyst's expert qualifications, the Court will permit the analyst to describe for the jury the similarities and differences between the Defendant's exemplar and the handwritten notes.'); *United States v. Brooks*, 2010 WL 291769, at *3 (E.D.N.Y. Jan. 11, 2010) ('[H]andwriting analysis is sufficiently reliable under *Daubert* and [Rule 702].'); *United States v. Jabali*, 2003 WL 22170595, at *2 (E.D.N.Y. Sept. 12, 2003) (citation omitted) ('Blanket exclusion [of handwriting analysis] is not favored, as any questions concerning reliability should be directed to weight given to testimony, not its admissibility.').

The court noted that the defendant had not demonstrated any flaws in the government expert's analysis. Rather, the defendant's push was for wholesale exclusion, which the court found not viable given all the precedent:

> As the Second Circuit has recognized, handwriting analysis is one area in which a juror, in some, but not all cases, may be as adept as an expert at comparing handwriting samples. *See United States v. Tarricone*, 21 F.3d 474, 476 (2d Cir. 1993) ("[The] jury could, on its own, recognize that the handwriting on the throughput agreement was not Barberio's."). Therefore, there is little reason to be concerned that a jury will place undue weight on the expert's ultimate opinion without carefully scrutinizing the basis for his conclusion. Given the liberal standard under *Daubert* and Rule 702 and the numerous cases in this district and circuit admitting expert opinion testimony regarding handwriting analysis, preclusion is neither appropriate nor warranted.
>
> **Comment:** It is notable that in its argument for admissibility, the government relied in its brief on the citation to a handwriting case in the Committee Note to the 2000 amendment to Rule 702. According to the government, the Committee Note provides that "experience is a basis for qualifying an expert" --- which it surely does so provide --- and "specifically reference[s] handwriting

experts as an example of experts qualified based on experience." The court did not rely on this citation specifically, but did note it in its opinion. It can be argued that the government made too much of a single citation, written 9 years before the NAS report and 15 years before the PCAST report.

Handwriting: ***DRFP L.L.C. v. Republica Bouvariana De Venezuela*****,** 2016 WL 3996719 (S.D. Ohio 2016): In a suit on promissory notes, with an allegation of forgery, the defendants offered the testimony of a handwriting expert, testifying to a match. The court rejected the plaintiff's motion to exclude the expert.

> Skye argues that Browne's methodology is inherently subjective and empirically unreliable. Skye points to Browne's own testimony that handwriting analysis is not scientific, it is not capable of empirical testing, all persons vary their signatures from one time to the next, no data can establish the frequency with which stylistic details recur in a person's signature, and it is impossible for Browne to determine his own error rate. Each of these critiques focuses on handwriting evidence in general, rather than on Browne's credentials or his specific methodology. The Sixth Circuit, however, has squarely ruled that handwriting analysis falls into the 'technical, or other specialized knowledge' component of Federal Rule of Evidence 702. *U.S. v. Jones*, 107 F.3d 1147, 1157-59 (6th Cir. 1997).
>
> As in *Jones*, Browne's specific testimony in this case outlined the procedure that he uses when comparing a questioned signature with a known one. He then focused on enlargements of the signatures at issue in this case and described to the finder of fact, in some detail, how he reached his ultimate conclusions. His testimony enabled the factfinder to observe firsthand the parts of the various signatures on which he focused. As a result, the Court credits Browne's expert testimony as well as his conclusions that: there is definite evidence that Puigbó's signatures on the Notes are forgeries; there is a strong probability that the Fontana' signatures on the Notes are forgeries; and it is probable that Cordero's signatures on the Notes are forgeries.

Handwriting --- handprinting, excluded: ***United States v. Johnsted,*** 30 F. Supp. 3d 814 (W.D. Wis. 2013): The defendant moved to exclude the report and expert testimony of the government's handwriting analyst, who would opine that the hand printing on the communications at issue belonged to the defendant. The court granted the motion (!) ruling that "the science or art underlying handwriting analysis falls well short of a reliability threshold when applied to hand printing analysis." The court concluded that the government's showing "indicates only that current standards of analysis are the same for handwriting and hand printing, not that they should be. The absence of such evidence might be less important if a consensus existed that hand printing and handwriting can reliably be analyzed in the same way, but that is not the case." It stated that "the limited testing that exists is inconclusive as to the reliability of hand printing analysis. Thus, while the government appears to be technically correct that standards exist controlling the technique's

operations * * * that fact does not tend to establish reliability without some evidence that those standards are actually appropriate in the hand printing context." The court also noted that peer review and publication regarding hand printing was limited. The court concluded as follows:

> The proffered expert testimony here . . . does not even qualify as the 'shaky but admissible' variety. It is testimony based on two fundamental principles, one of which has not been tested or proven, and neither of which have been proven sufficiently reliable to assist a lay jury beyond its own ability to assess the similarity and differences in the hand printing in this case.

Comment: While the court's exclusion was specific to hand *printing*, it was no fan of handwriting comparison either. The court argued that there are two fundamental premises of handwriting identification that have not been validated. The court explained as follows:

> The government cites to a number of studies as demonstrating that handwriting is unique, including some showing that twins's writings were individualistic and others demonstrating computer software's ability to measure selected handwriting features. Defendant contends that these studies are problematic, and that even one of the government's own studies states that "the individuality of writing in handwritten notes and documents has not been established with scientific rigor." * * *
>
> Even accepting that studies have adequately tested the first principle—that all handwriting is unique—the government does not dispute the troubling lack of evidence testing or supporting the second fundamental premise of handwriting analysis. Even more troubling is an apparent lack of double blind studies demonstrating the ability of certified experts to distinguish between individual's handwriting or identify forgeries to any reliable degree of certainty. This lack of testing has serious repercussions on a practical level: because the entire premise of interpersonal individuality and intrapersonal variations of handwriting remains untested in reliable, double blind studies, the task of distinguishing a minor intrapersonal variation from a significant interpersonal difference—which is necessary for making an identification or exclusion—cannot be said to rest on scientifically valid principles. The lack of testing also calls into question the reliability of analysts's highly discretionary decisions as to whether some aspect of a questioned writing constitutes a difference or merely a variation; without any proof indicating that the distinction between the two is valid, those decisions do not appear based on a reliable methodology. With its underlying principles at best half-tested, handwriting analysis itself would appear to rest on a shaky foundation. See *Deputy v. Lehman Bros., Inc.,* 345 F.3d 494, 509 (7th Cir.2003) (noting that among courts, "there appears to be some divergence of opinion as to the soundness of handwriting analysis").

Paint Identification: ***United States v. Pugh*****, 2009 WL 2928757 (S.D. Miss.):** The court rejected a challenge to an expert's forensic paint analysis. It stated: "The Standard Guide for Forensic Paint Analysis and Comparison of the American Society for Testing and Materials [ASTM], which [the paint expert] relied on in her testing, is widely accepted by engineers and other professionals in the field of materials testing. [Her] testimony is sufficiently reliable and relevant and may assist the trier of fact in understanding the evidence or determining a fact in issue, as required by Rule 702."

Serology tests: ***United States v. Christensen***, 2019 WL 651500 (C.D. Ill.): In a kidnapping prosecution, the defendant moved to exclude serology test results and requested a *Daubert* hearing on the reliability of the methods used. The defendant challenged the reliability of the Takayama hemochromogen test used to confirm the presence of blood. The court denied the defendant's motion, finding the Takayama test to be reliable:

> Defendant moves for a *Daubert* hearing on the reliability of the Takayama hemochromogen test and the methods of the law enforcement official who performed that test. The United States responds that such a hearing is unnecessary because the test has been the standard confirmatory test for blood for over 100 years, and the law enforcement official's application of this reliable method is a subject appropriate for cross-examination at trial, not a pre-trial hearing. The Court held an evidentiary hearing on this matter on February 11, 2019, effectively granting this aspect of Defendant's Motion.
>
> At that hearing, Ms. Conway testified that the Takayama hemochromogen test is the prevailing confirmatory blood test in the field. She stated that multiple studies have confirmed that the Takayama test does not react to substances other than blood, and that the FBI has control testing protocols to avoid errors. Ms. Conway further testified that standard procedure in conducting the Takayama hemochromogen test does not involve photographic or descriptive records other than documenting whether the analyst determined that it was positive or negative. According to Ms. Conway, a second examiner always checks positive results to ensure accuracy. The Court finds that the Takayama test is well-known, widely used, not prone to errors, subject to peer review, and applied reliably in this case. Thus, Defendant's Motion to exclude the test results on reliability grounds is denied.

Shooting reconstruction: ***Merritt v. Arizona***, 2019 WL 2549696 (D. Ariz.) (Campbell, J.): This action was a product of the I-10 freeway shootings in Phoenix, AZ. The plaintiff brought section 1983 claims relating to his prosecution for the shootings. The Arizona Department of Public Safety identified plaintiff's weapon, a 9mm handgun, as the source for four freeway shootings. The plaintiff contended that he pawned the gun more than four hours before the shooting of a tire occurred. He proffered experts in shooting reconstruction to testify about the timing of the shooting. The State of Arizona offered rebuttal experts Noedel and Grant to testify about the possibility that the tire in question was shot before the gun was pawned, but retained air pressure

for a time after the gun was pawned. The plaintiff moved to exclude these experts under Rule 702 and *Daubert*.

Noedel, an expert in reconstructing shooting incidents, would testify on the question whether the tire at issue could hold air pressure after being struck by a ricocheted bullet. The purpose of his opinion was to attack the plaintiff's experts' testimony that the tire must have lost pressure immediately after being shot, which would make it impossible for the shooting to be caused by the defendant's pawned gun. Noedel concluded that "there are several unknown variables that make it impossible to say, based on analysis of the tire alone, where and when [the] tire was struck, and whether it retained air after being struck. Among the possibilities, none of which can be determined with any degree of certainty, is that the tire retained air after being shot." The court found that Noedel could testify to flaws in the plaintiff's experts' opinions and the variables that make it difficult to replicate the exact damage to the tire. However, the court found no basis for Noedel to go past rebuttal and offer testimony suggesting affirmatively that the tire could have retained pressure after the shooting. Noedel only conducted one test, and in that test the tire lost air immediately. Nothing else he relied on supported his opinion that the tire could retain air after being shot with a ricocheted bullet. The court stated that "when an expert's testimony is not based on independent research or publications, he must present some "other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'" Here, the court found too great of an analytical gap between the data and the opinion.

Grant was offered as an expert in forensic tire analysis. He offered four conclusions: (1) based on the small size of the puncture, the angle of the puncture, and the loose flaps of rubber inside the puncture, the tire may only have lost minimal air at the time it was shot; (2) it is well known in the tire industry that small punctures do no always leak immediately; (3) it is impossible to determine when the tire was shot to any degree of engineering certainty because of the sporadic air loss the tire experienced while driving; and (4) plaintiff's expert (who tested the BMW tire in question after the shooting, after it had been driven, and after chemical analysis) had inaccurate results because he did not test the tire at the time it was shot. The Court found this expert's testimony to be reliable because of Grant's extensive experience with tires and shooting reconstruction. The court found that Grant's opinion on scientific principles of tires air pressure was necessary for rebuttal because the plaintiff's experts' testimony is "the kind of testimony whose reliability depends heavily on the knowledge and the experience of the expert, rather than the methodology or theory behind it."

> **Comment: This is a good example of expert opinion that avoided overstatement. If anything, it was the plaintiffs' experts who might have overstated their conclusions, and the defendant's reconstruction expert was basically explaining the overstatement.**

Toolmarks --- Expert unqualified: *United States v. Smallwood,* 2010 WL 4168823 (W.D. Ky.): The defendant moved to exclude the government's expert testimony that the knife found by law enforcement was the knife that slashed the tires of a vandalized vehicle. The court granted the motion, finding that the witness was unqualified --- the witness was a firearms expert, not a toolmarks expert. The court provided some helpful background:

> According to The Association of Firearm and Tool Mark Examiners ('AFTE'), a match is determined if a "specific set of [tool marks] demonstrates sufficient agreement in the pattern of two sets of marks." See National Research Council of the National Academies, Strengthening Forensic Science in the United States: A Path Forward (2009) (hereinafter "Strengthening"). AFTE standards acknowledge that these decisions involve subjective qualitative judgments and that the accuracy of examiners' assessments is "highly dependent on their skill and training." * * * Even with new technology, "the decision of the [tool mark] examiner remains a subjective decision based on unarticulated standards."
>
> By AFTE's own standard, there is no reliability in the instant case. While Gerber is most likely an expert in firearm identification, that expertise cannot be transferred to other marks. * * * Given the subjective nature of firearm and tool mark identification, the relative frequency of firearm cases compared to tool mark cases—and knife cases in particular—necessarily makes a tool mark identification less reliable than a firearm identification. This goes directly to the "skill and experience an examiner is expected to draw on." Strengthening, pg. 155.
>
> Similar to polygraphs, it is important for this Court to thoroughly examine the underlying reliability of a tool mark identification before allowing expert testimony at trial. * * * A thorough examination of the facts and science present in this case must lead to a finding of unreliability and exclusion.

Toolmarks: Court Order Limiting Overstatement Consistently with DOJ Uniform Standards: *United States v. Haig*, 2019 WL 3683584 (D. Nev.): Haig was charged in connection with the October 2017 Las Vegas music festival mass shooting. Boxes of ammunition were found in the shooter's room addressed from the defendant. Haig admitted that he sold the shooter ammunition, but claimed that he did not manufacture the ammunition. He claimed the ammunition from the Las Vegas crime scene would not have the toolmarks of his manufactured ammunition. The government's toolmark expert intended to testify on the process of reloading ammunition, identifying ammunition, identifying toolmarks, and his conclusions in this case. The court rejected the defendant's argument that the methodology of toolmark identification was unreliable, stating that the Ninth Circuit "has consistently affirmed the admission of toolmark identification evidence and expert testimony of that evidence. See, e.g., United States v. Cazares, 788 F.3d 956, 988 (9th Cir. 2015); see also, e.g., United States v. Felix, 727 Fed. App'x 921, 924–925 (9th Cir. 2018). Smith's anticipated testimony falls well-within the type of evidence which the Ninth Circuit has previously considered. Thus, Smith's methods are reliable and his testimony is admissible."

The court noted, however, that "scientific certainty" is an improper characterization of expert conclusions based on toolmark identification methods --- because the conclusions are based on subjective judgment and have not been validated as science. But the court also emphasized that "[t]he government concedes this point and represents that Smith will not provide such testimony as it would violate the Depart of Justice's uniform standards for testimonies and reports."

While recognizing the importance of the DOJ standards, the court stated:

> Nevertheless, the court will exercise caution and exclude Smith from testifying that he reached his conclusions with scientific certainty or other similar standards of reasonable certainty.

Voice identification: ***United States v. Felix***, 2019 WL 2744621 (S.D. Ohio): The defendant was indicted for armed bank robbery and sought to introduce expert testimony to rebut the voice identification procedures conducted by the government. The expert would opine that (1) the earwitness procedure used for voice identification was untested and unreliable, (2) Felix's voice did not have any anomalies that would draw attention to his voice, (3) memory research is relevant to police investigators' results, and (4) the audio from the recorded traffic stop was poor quality, the signal was enhanced for analysis, and the hearing of listeners could be a factor.

The government did not dispute the expert's qualifications, but the court conducted an independent analysis of the expert's qualifications anyway. The court noted that the expert had a Ph.D. in Psychoacoustics, was a Professor of Speech and Hearing Sciences, and published and presented extensively on speech and voice analysis. The court concluded that the expert could opine on the science of voice analysis and audiology as well as how people recognize vocal patterns, but he could not testify as to whether police practices of voice identification were appropriate or the credibility of victims' voice identifications.

To analyze reliability, the court cited to the *Daubert* factors (testability, peer-reviewed, rate of error, standards and controls, general acceptance). The government argued that the expert's opinion was based on decades-old research and that voice identification or "earwitness" research is less developed and is usually not accepted by courts. The government also cited to Rule 901's advisory notes that state "voice identification is not a subject of expert testimony." However, the court mentions that the advisory notes were from 1972 and relied on cases from 1935-1952, also decades old, as the government claimed of the expert's research. However, the defense provided an updated supplemental research list relied upon by the expert which were significantly more recent. The court found that based on the updated research *and* the expert's background, education, and experience in the relevant areas, there was a sufficiently reliable foundation to support his area of expertise, but once again, not enough to reliably support his opinions on law enforcement procedures or victim credibility.

TAB 2C

THIS PAGE INTENTIONALLY BLANK

95 Notre Dame L. Rev. 2039

Notre Dame Law Review
May, 2020

Federal Courts, Practice and Procedure

Thomas D. Schroeder [a1]

TOWARD A MORE APPARENT APPROACH TO CONSIDERING THE ADMISSION OF EXPERT TESTIMONY

INTRODUCTION

Over a quarter century ago, *Daubert v. Merrell Dow Pharmaceuticals, Inc*. reaffirmed the trial court's role as "gatekeeper" for the admission of scientific expert evidence, to screen it not only for relevance, but for reliability. [1] To discharge this gatekeeper role, a trial court must make a preliminary determination whether the expert's opinion evidence meets the admissibility standards of Federal Rule of Evidence 702, which in turn requires application of Federal Rule of Evidence 104(a)'s preponderance test. Trial judges are cautioned not to unduly assess the validity or strength of an expert's scientific conclusions, and the Supreme Court has said that "shaky but admissible evidence" [2] should be left for a jury's consideration where it can be tested by cross-examination and contrary evidence. But application of these principles can be difficult, and appellate review can be frustrated, even under a deferential abuse of discretion standard, where trial courts are not clear about what standard they are applying. Worse, some trial and appellate courts misstate and muddle the *admissibility* standard, suggesting that questions of the sufficiency of the expert's basis and the reliability of the application of the expert's method raise questions of weight that should be resolved by a jury, where they can be subject to cross-examination and competing evidence. ***2040** The state of affairs has prompted the United States Judicial Conference's Advisory Committee on the Federal Rules of Evidence to consider possible amendment to Rule 702 to reiterate the need for proper application of Rule 104(a)'s threshold to each requirement of Rule 702.

This Article highlights lingering confusion in the caselaw as to the proper standard for the trial court's discharge of its gatekeeping role for the admission of expert testimony. The Article urges correction of the faulty application of *Daubert*'s admonition as to "shaky but admissible" evidence as a substitute for proper discharge of the trial court's gatekeeper function under Rule 104(a). The Article concludes with several suggestions for trial and appellate courts to consider for better decisionmaking in discharging their duty to apply Rule 104(a)'s preponderance standard to the elements of Rule 702.

I. THE DAUBERT STANDARD IN APPLICATION

In 1993, the Supreme Court decided *Daubert*, a personal injury case involving an antinausea drug, and revolutionized how trial courts are to consider the admission of scientific and technical expert evidence. In eschewing the *Frye* [3] "general acceptance" test as inconsistent with the "liberal thrust" of the subsequent Federal Rules of Evidence, [4] the Court simultaneously expanded and restricted the availability of expert testimony. It liberalized the availability of evidence because the *Frye* test became, under the language of Rule 702, but one of several factors for a court to consider when determining whether the proffered evidence is valid and reliable: whether the theory or technique can be (or has been) tested; whether it has been subjected to peer review and publication; its known or potential rate of error; the existence and maintenance of standards controlling its operation; and whether it has attracted "widespread acceptance within a relevant scientific community." [5] At the same time, the Court tightened the admissibility threshold by charging trial judges to act as "gatekeepers" against the admission of unreliable expert opinion. [6]

In doing so, the Court reminded trial judges that, as with other questions of preliminary admissibility, a court "[f]aced with a proffer of expert scientific testimony ... must determine at the outset ... whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." [7] In a footnote, the Court noted that "[t]hese matters should be established by a preponderance of proof," pursuant to Rule 104(a). [8]

***2041** Rule 702 was amended in 2000. [9] In addition to requiring that the expert be qualified to testify about scientific knowledge that will assist the trier of fact, the Rule added further foundational requirements, now found in sections (b), (c), and (d), that the testimony be based on sufficient facts or data, the testimony be the product of reliable principles and methods, and the expert have reliably applied the principles and methods to the facts of the case, respectively. [10] In light of *Daubert*'s reference to Rule 104(a), the Advisory Committee expressly stated that the trial judge determine these elements by a preponderance before allowing such testimony into evidence. [11] The extensive Advisory Committee note further explained the limits of the preponderance standard in this context. For example, competing and contradictory expert testimony can meet the standard, as proponents "do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*," but only that "their opinions are reliable"--a lesser standard. [12] Moreover, the standard can be met even where competing experts rely on competing versions of the facts, as it is not the trial judge's role to believe one version of the facts over another.

After *Daubert*, the Court has clarified that this gatekeeper function applies to all expert testimony, not just that based on science. [13] Over the years, courts have supplemented the various *Daubert* factors for determining reliability. They include whether the opinions are litigation driven, or naturally flow from independent scientific research; whether the expert has accounted for obvious alternative explanations; whether the expert has employed the same level of rigor as required in the relevant field; and whether the field of expertise is known to reach reliable results. [14]

Ever since *Daubert*, the Court has expressed conflicting views on the ease with which trial judges will be able to discharge their gatekeeper role. [15] For ***2042** example, in *General Electric Co. v. Joiner*, [16] the Court retrenched from its previous admonition against judging the strength of an expert's conclusions by recognizing that on occasion an expert may "unjustifiably extrapolate[ ] from an accepted premise to an unfounded conclusion" [17] such that the trial judge may find that there is "simply too great an analytical gap between the data and the opinion proffered" to rely on the expert's *ipse dixit* to make the connection. [18] Justice Breyer, after acknowledging that *Daubert* "ask[s] judges to make subtle and sophisticated determinations" about scientific methodology and its relation to the conclusions offered by an expert witness, nevertheless predicted that given the "offer of cooperative effort" from the scientific community (there, the *New England Journal of Medicine*) and the "various Rules-authorized methods for facilitating the [trial] courts' task" (such as appointing a Rule 706 [19] advisory expert), implementing *Daubert*'s gatekeeping task "will not prove inordinately difficult." [20] Justice Stevens, in contrast, noted that "*Daubert* quite clearly forbids trial judges to assess the validity or strength of an expert's scientific conclusions, which is a matter for the jury." [21] Justice Stevens saw a distinct difference between methodology and conclusions, relying on *Daubert*'s statement that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." [22]

Not only is it "not always a straightforward exercise to disaggregate method and conclusion," [23] it is also not always easy to assess when the Rule's foundational requirements--namely, sufficiency of the basis of a proposed opinion and whether the opinion resulted from reliable application of valid principles and methods--falls short of the preponderance standard for threshold admissibility. While courts no doubt acknowledge and grapple with the issue before determining admissibility, some courts have defaulted to invoking the Supreme Court's caution that Rule 702 is not meant to prohibit "shaky but admissible" evidence and have relegated the issue to the jury's consideration on the grounds it can be subject to cross-examination and contrary proof. In doing so, some of these courts have inadvertently ***2043** applied Rule 104(b)'s standard for admissibility, in contravention of *Daubert*. [24] Some courts merely find that there is sufficient evidence, *if believed*, for a reasonable juror to find that the expert has a sufficient basis for his opinion or that he reliably applied the principles and methods he claims. Other courts conclude that the application of a valid methodology should be deemed unreliable only if it skews the methodology itself. Rule

104(a) and the *Daubert* line of cases require, however, that the trial judge *actually determine* whether it is more likely than not that the expert has met these threshold requirements of Rule 702.

In this respect, therefore, some courts appear to be abdicating their charge under the Federal Rules of Evidence and *Daubert* and its progeny to make the hard call on admissibility. The end result in such cases is to relegate to the jury the very decisions Rule 702 contemplates to be beyond jury consideration. In other cases, however, it is more difficult to tell what the courts are actually doing, as they do not articulate their reasoning in a way that demonstrates how they are applying the preponderance standard to the required elements of the Rule.

II. COURTS THAT SEEMINGLY MISSTATE AND/OR MISAPPLY THE RULE 104(a) STANDARD

Numerous cases have stated that questions as to sufficiency of basis or reliability of application raise questions of weight that are necessarily for a jury, and not questions of admissibility for the court. Some of these courts may very well have actually applied Rule 104(a)'s standard; or, they may have applied Rule 104(b)'s standard. It is simply difficult to tell, and the courts' misstatement of the legal standard confounds a clear determination.

Since *Joiner*, it has been settled that an appellate court reviews the trial judge's Rule 702 admissibility determination for an abuse of discretion--the same standard that governs most trial court evidentiary decisions. Thus, an admissibility ruling as to evidence will not be reversed unless "manifestly erroneous."[25] Inherent in this highly deferential standard is a certain "play in the joints" that permits divergent results on the same evidence, depending on the judge's explanation for the exercise of discretion. Consequently, as the *Joiner* Court observed, "[a] court of appeals applying 'abuse-of-discretion' ***2044** review to such rulings may not categorically distinguish between rulings allowing expert testimony and rulings disallowing it."[26] This is yet another reason trial and appellate courts would be best served to be as clear as possible in their reasoning and to avoid generalized misstatements that questions as to sufficiency of basis and reliable application of method go to weight and not admissibility.

What follows is a sampling of illustrative cases that have been identified to the Advisory Committee as evidence that courts are abdicating their gatekeeper role.[27] This selection is by no means intended to be complete, nor is it meant to suggest (except perhaps for the Ninth Circuit) a consistent circuit-wide problem. What it tends to show is that in many instances the extent of the problem is murky. A closer look at the facts of these cases suggests that some courts may be hewing closer to the Rule 702 standard than the decisions suggest.

A. First Circuit

Milward v. Acuity Specialty Products Group, Inc.,[28] has been cited as a prime example of the problem. The question in that case was the admissibility of testimony by Dr. Martyn Smith, a toxicologist, as to general causation--that exposure to benzene can cause acute promyelocytic leukemia, which the plaintiff had contracted.[29] After a four-day evidentiary hearing, the district court concluded that the expert's testimony lacked sufficient demonstrated scientific reliability under Rule 702.[30] The First Circuit reversed.[31] After citing the requirements of Rule 702 and *Joiner*'s acknowledgment that "conclusions and methodology are not entirely distinct from one another," the court engaged in a lengthy analysis of Dr. Smith's "weight of the evidence" methodology for arriving at his opinion.[32] This methodology was drawn from the work of Sir Austin Bradford Hill, who concluded that an association between a disease and a feature of the environment should not be deemed causal without a proper weighing of several factors, including the strength, frequency, consistency, and specificity of the association; the temporal relationship; the dose-response curve; biological plausibility; coherence of the explanation with generally known factors of the disease; experimental data; ***2045** and analogous causal relationships.[33] The weight of the evidence approach involves the drawing of an "inference to the best explanation."[34]

The First Circuit found that the district court had abused its discretion in rejecting the sufficiency of some of the Hill criteria on which Dr. Smith relied, [35] stating that the alleged flaws "go to the weight of Dr. Smith's opinion, not its admissibility." [36] The court noted that "[t]here is an important difference between what is unreliable support and what a trier of fact may conclude is insufficient support for an expert's conclusion." [37] Finding that the district court exceeded its gatekeeper role, the court stated that "[t]he soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact." [38] So, when the factual underpinning is "weak," it is a matter "affecting the weight and credibility of the testimony," which is for a jury's determination. [39] It was sufficient for the court of appeals that Dr. Smith opined that, in his opinion, he weighed these flaws in his weight of the evidence methodology and nevertheless concluded there was general causation.

Putting aside any criticism of the "weight of the evidence" approach, [40] the problem with the court's analysis is that it appears to require a preponderance standard for application of Rule 702(c) (reliable method) but not for Rule 702(b) (sufficiency of basis). This, even though the trial judge had found that the expert's assumptions were "plausible" but not "based on sufficient facts and data to be accepted as a reliable scientific conclusion"--a Rule 104(a) determination. [41] The court of appeals's error may have resulted in part from the fact that it cited cases decided before the 2000 amendment to Rule 702, a problem not unique to this case. [42]

2046** ***B. Eighth Circuit

United States v. Gipson [43] involved the use of DNA evidence to link a baseball cap left at the scene of a bank robbery to the defendant. Part of the government's case rested on a forensic expert's use of AmpF/STR Profiler Plus and AmpF/STR Cofiler multiplex kits to apply the Sort Tandem Repeat (STR) profiling methodology to the DNA found on the cap so she could create the relevant DNA profiles of the dominant DNA within the mixture found on the cap. [44] Before trial, the defendant moved to suppress the expert's testimony as unreliable based on the application of the kits; the defendant did not challenge the reliability of the STR DNA methodology itself. [45] The government argued that the reliability of the use of the kits went to the weight, not the admissibility, of the challenged evidence. [46] The trial court denied the motion, and the court of appeals affirmed. [47] While the appellate court cited to *Daubert*, it never cited the then-amended Rule 702. In citing to cases predating the 2000 revisions, the court stated that "this court has drawn a distinction between, on the one hand, challenges to a scientific methodology, and, on the other hand, challenges to the *application* of that scientific methodology." [48] So, "when the *application* of a scientific methodology is challenged as unreliable under *Daubert* and the methodology itself is otherwise sufficiently reliable," the court said, "outright exclusion of the evidence in question is warranted only if the methodology 'was so altered [by a deficient application] as to skew the methodology itself.'" [49] The problem is that this construction ignores Rule 702(d), which requires that the trial court find by a preponderance that the expert has reliably applied the methodology to the facts of the case, and effectively creates a rebuttable presumption in favor of admissibility. It may be that the court nevertheless found by a preponderance that the application of the kits to the methodology was reliable, but that is not clear from the opinion, and the statement of law is incorrect.

The difficulty of conducting a proper Rule 104(a) analysis under Rule 702 is illustrated by *Kuhn v. Wyeth, Inc.* [50] There, the parties disputed whether the use of the defendant's hormone replacement drug, Prempro, caused the breast cancers of two plaintiffs, both of whom used the drug for three years ***2047** or less. [51] The plaintiffs proffered Donald Austin, MD, who opined that this short-term use of the drug increased their cancer risk. [52] Wyeth challenged his opinions, and the court held a lengthy *Daubert* hearing, ultimately excluding his testimony because the expert failed to discredit a key Women's Health Initiative (WHI) study that found no risk from short-term drug use and because he failed to base his opinions on epidemiological studies that "reliably support[ed] his position." [53] The court of appeals reversed. [54] As to the WHI study, the court found, quite properly, that the trial court erroneously put the burden on the expert to exclude the study, when Rule 702 requires that the expert demonstrate he "arrived at his contrary opinion in a scientifically sound and methodological fashion." [55] Dr. Austin had provided his opinion that the WHI study did not preclude his opinion on short-term risk because it was designed to measure

heart disease, involved a study population at a much lower risk of cancer, and involved participants who had a larger gap time between menopause and beginning hormone therapy than women who began their hormone therapy on their own. [56] The study found women using hormone therapy for more than five years to have a statistically significantly increased risk of breast cancer, which Dr. Austin found supportive of his opinion on short-term risk. [57] As to this aspect of the case, the court of appeals properly applied Rule 104(a)'s preponderance standard to the methodology the expert used.

The court of appeals also reversed the district court on the sufficiency of basis as well. This aspect of the court's ruling is more suspect. The record revealed that the selection of studies Dr. Austin relied upon was made by plaintiffs' counsel, a fact that no doubt influenced the trial court. [58] And, according to the court, Dr. Austin had ignored "a wealth of studies showing no increased risk of breast cancer from short-term Prempro use," which led to an accusation he had "cherry picked" the handful of studies he relied upon. [59] Indeed, the record showed, the expert "had never really thought about the short-term use issue before Plaintiffs' counsel presented it to him shortly before the recent *Daubert* challenge." [60] Moreover, during the *Daubert* hearing, Dr. Austin conceded that two studies he had listed on his declaration as supportive of his opinion on causation were not and should not have been included. [61] Apart from the WHI study, this left the "Million Women Study," the "French Teachers Study," and an American Cancer Society ***2048** study--all observational studies--as the basis for his opinion that short-term use causes breast cancer, even though he conceded that observational studies were "not as good for demonstrating cause and effect." [62] The trial court had found too great an analytical gap between the underlying studies and Dr. Austin's opinion. [63] But the court of appeals found that Dr. Austin's studies provided "adequate foundation" [64] for his opinion, citing *Daubert*'s admonition that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." [65] Although the trial court found the American Cancer Society study (which found no risk below two years of use, but a significant increase at two and three years) [66] unreliable because it failed to account for prior use of hormone therapy, the appellate court was satisfied that the study purported to exclude women with unknown duration of use. As to the Million Women Study, an English study, the trial court considered it unreliable because it analyzed the use of Prempro for "five years or less" [67] without breaking out three years or less, involved other formulations of estrogen, and did not measure use after enrollment--a fact the judge found "irreconcilable with 'his position that when looking at short-term use, one must be quite precise.'" [68] But the court of appeals found the lack of material difference in the other formulations of estrogen and Dr. Austin's decision to add 1.2 years to those participants with less than one year of use to be adequate responses. [69] Finally, the trial court had found the French Teachers Study unreliable because it admittedly provided no analysis of Prempro at three years or less and did not separate Prempro use from other formulations. [70] Again, the court of appeals determined that the differences in formulations of estrogen failed to render the study unreliable. [71]

These conclusions by the court of appeals are hard to explain. To say that an underestimate of 1.2 years in the Million Women Study "do[es] not create so great an analytical gap between the data and the opinion as to render the opinion inadmissible" [72] when the issue in the case involves causation for use of three years or less seems to be an abdication of the gatekeeping function and an application of Rule 104(b). Moreover, the trial court ***2049** had found that, based on Dr. Austin's prior testimony, the studies failed to meet his own previously set criteria of accurate characterization of exposure to the drug, identification of the specific drug formulation, and analysis of Prempro separately. [73] For the court of appeals, this was merely a reason to "call his credibility into question." [74] The court even rejected the fairly obvious cherry picking that occurred, ostensibly at the behest of plaintiffs' counsel, with the statement that while "[t]here may be several studies supporting Wyeth's contrary position, ... it is not the province of the court to choose between the competing theories." [75] These were not theories, of course, but rather factual bases for the opinions. As the dissent suggested, it surely seemed that in the end the district court properly exercised its gatekeeping function by concluding that the proffered opinion simply lacked a sufficient, reliable basis. [76]

C. Fourth Circuit

Bresler v. Wilmington Trust Co. [77] was a breach of contract case involving life insurance held in a trust for tax purposes. Plaintiff beneficiaries contended that the defendants breached an agreement to lend money to maintain and fund certain investments related to the life insurance policies. [78] Defendants challenged the plaintiffs' accounting expert's damages calculations on the grounds they included certain cost-of-insurance values, used an "invalid interest spread," and improperly calculated the present value of the future net trust shortfall. [79] Defendants contended that the expert's calculations were "riddled with mistakes" and "wholly unreliable." [80] Acknowledging that these were challenges made under Rule 702 and *Daubert* to the factual sufficiency of the method used, the court affirmed the district court's refusal to exclude the opinion testimony. [81] According to the court, "'questions regarding the factual underpinnings of the [expert witness'] opinion affect the weight and credibility' of the witness' assessment, 'not its admissibility.'" [82] Without explanation, the court concluded that the defendants' challenge amounted to a "disagreement" with the values the expert chose for certain variables in his opinion and consequently "'affect[ed] the weight and ***2050** credibility' of [the expert's] assessment, not its admissibility." [83] As a general rule, the Fourth Circuit's statement effectively vitiated the application of Rule 104(a) to Rule 702(b). Here, too, it may be that the court was effectively saying that there *was* a showing by a preponderance that the expert's opinion had sufficient basis under Rule 702(b), but in light of the claim that the bases of the opinions were "riddled with mistakes" and "wholly unreliable," and without any analysis, one cannot know for sure. [84]

D. Ninth Circuit

Ninth Circuit caselaw appears to interpret *Daubert* as liberalizing the admission of expert testimony, which may explain decisions from that circuit that set it apart from most others. [85] *City of Pomona v. SQM North America Corp*. [86] is illustrative. The City of Pomona sued the importer of natural sodium nitrate from the Atacama Desert in Chile between 1927 and the 1950s, contending that perchlorate impurities in the nitrate, which had been used in fertilizer, contaminated its groundwater. [87] Central to the city's claim was Dr. Neil Sturchio, the city's causation expert, who opined that his fourstep "stable isotope analysis" led him to conclude that the perchlorate found in the city's water had the same distinctive isotopic composition as the perchlorate from the Atacama Desert. [88] Upon the defendant's motion in limine, the trial judge held a *Daubert* hearing and excluded the expert's opinions as unreliable on several grounds. [89] The Ninth Circuit reversed, citing the proposition that "[s]haky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." [90]

***2051** To be sure, the Ninth Circuit properly noted that a lack of general acceptance was not grounds alone to exclude an expert's methodology, especially if there is a "recognized minority of scientists in the[ ] field" who support it. [91] Likewise, that the expert did not retest his results himself was not a basis to reject his evidence, where other independent laboratories have tested the methodology. [92] But the court's blanket conclusion that challenges to the expert's deviation from the protocols merely raised questions as to the weight of the evidence and presented a question for the fact finder, not the trial court, appears facially wrong.

The Ninth Circuit properly recited the 2000 version of Rule 702 and its Advisory Committee note to the amendments, [93] but then it rested its key statements on *United States v. Chischilly*, [94] a 1994 opinion that predated *Daubert* and, more importantly, the 2000 changes to Rule 702, for the proposition that an argument as to "adherence to protocol ... typically is an issue for the jury." [95] The court specifically rejected *In re Paoli Railroad Yard PCB Litigation*, [96] which held that "any step that renders the analysis unreliable ... renders the expert's testimony inadmissible." [97] Instead, and again citing *Chischilly*, the court stated that in the Ninth Circuit expert evidence "is inadmissible where the analysis 'is the result of a faulty methodology or theory as opposed to imperfect execution of laboratory techniques whose theoretical foundation is sufficiently accepted in the scientific community to pass muster under *Daubert*.'" [98] According to the court, a "more measured approach" to an expert's adherence to methodological protocol is more "consistent with the spirit of *Daubert* and the Federal Rules of Evidence" because they place a "strong emphasis on the role of the fact finder in assessing and weighing the evidence." [99]

The Ninth Circuit appears to set its own standard for assessing admissibility of expert opinion apart from Rule 702. Notably, in rejecting *In re Paoli*, the Ninth Circuit disregarded the 2000 Advisory Committee note's favorable citation to the case for the proposition that under Rule 702(d) the methodology must be applied accurately to every step. [100] What confounds the analysis is that the Ninth Circuit ultimately may have been correct on the result, despite these apparent misstatements of the law, when one examines the court's statements as to the factual record. The court noted the district ***2052** court's lack of explanation as to why the expert's failure to adhere to protocols was significant enough to warrant exclusion, and the expert did testify that he followed the protocols. [101] In this light, if the failure to adhere to protocols was relatively minor and did not undermine the reliability of the method or its application, the result comports with current law. For questions of weight frequently arise, even under a proper Rule 104(a) analysis as to Rule 702. But such questions do not automatically render it a jury question. To suggest otherwise, as this case does, misreads Rule 702 and ignores the proper standard. The issue is whether the deviations from the proper method are enough to render the principles and methods not reliably applied--and that's a determination that Rule 702(d) requires the trial judge to make. [102]

E. Eleventh Circuit

Quiet Technology DC-8, Inc. v. Hurel-Dubois UK Ltd. [103] demonstrates the difficulty in asking courts of general jurisdiction to delve into sophisticated scientific questions that arise in cases dependent on technical experts. In this case, Quiet, which manufactured noise-reducing "hush kits" to retrofit DC-8 jet engines, contracted with Hurel to make a compatible thrust reverser, a necessary component for stopping upon landing. Quiet contended that the thrust reversers were defective because their linkages blocked the engine air flow and thereby significantly impaired the efficiency of performance. Hurel blamed the problem on the design of Quiet's hush kit. [104] The case focused on a battle of experts, whose analyses attempted to explain the phenomenon observed.

Hurel proffered Joel Frank, an expert in aerodynamics, to testify that using a commercial computer software to measure fluid dynamics (CFD)--the airflow around and through the jet engine--only 3.08% of the loss in performance was attributable to Hurel's reverser linkages. [105] Quiet did not challenge the reliability of CFD software generally, but it did challenge Frank's application of it under Rule 702. Quiet focused on the "boundary conditions" the expert had selected, which "define where the [computer] model begins and where it ends." [106] More specifically, in uniform flow profile cases (where a constant uniform pressure was applied at the leading edge ***2053** of the ejector, to serve as a baseline), the expert placed the inlet boundary more than a meter ahead of the leading edge of the ejector; while for inflight profile cases (using pressure measurements Quiet had taken during its in-flight testing), he placed the inlet boundary condition at the "highlight of the ejector's leading edge." [107] Relatedly, Quiet challenged the expert's use of the formula for calculating the intake pressures in his uniform profile cases. Quiet contended that the expert had "put the wrong information into the ... software" or, as the court of appeals characterized it, "garbage in, garbage out." [108] The trial court held a *Daubert* hearing and denied the motion. [109] A jury returned a verdict for Hurel, and the court of appeals affirmed. [110]

Surely animating the Eleventh Circuit's analysis, under an abuse of discretion standard, was the parties' extension of expert discovery up until close to trial, and the timing of the objection forced the court to conduct its *Daubert* hearing on the sixth day of trial. Moreover, the substance of the challenge was literally rocket science: Quiet contested the application of the expert's fan pressure ratio, using "$PT_{Intake} = FPR(P_{amb})$, where PT_{Intake} is the intake pressure, FPR is the fan pressure ratio, and P_{amb} is the ambient pressure." [111] As the Eleventh Circuit explained:

> Thus, the intake pressure equaled the fan pressure ratio multiplied by the standard ambient pressure for the particular altitude being tested. For example, for the 35,000 feet altitude calculation, the ambient pressure--which is a known, unchanging figure--was 23,842 pascals which, when multiplied by a power setting of 1.9 FPR, yields a PT_{Intake} of 45,300 pascals. To arrive at the FPR, Frank divided the total pressure at the intake (Pt2.5) by the ambient pressure. However, Quiet says that he should have derived the FPR by dividing the total intake pressure (Pt2.5) by the exit pressure (Pt2). Quiet avers that as a result of this error, the Pt_{Intake} derived by Frank was "substantially less than the actual varying intake pressures at the fan exit and substantially greater than the actual

> varying pressures at the ambient air intake gap .... [B]y using the wrong formula and the fictitious uniform flow, Frank did not even come close to duplicating the actual ejector intake pressures." [112]

It is not surprising, therefore, that the Eleventh Circuit affirmed the trial judge's decision. Before doing so, the court engaged in an extensive analysis of the technical testimony, eventually concluding that the ultimate issue was whether the expert's selection of variables for the formula was correct. Citing the Supreme Court's admonition that "[n]ormally, failure to include variables will affect the analysis' probativeness, not its admissibility," the court ***2054** rejected the challenges. [113] The court emphasized that Quiet had ample opportunity to cross-examine Frank as to his application of the methodology, noting that "[t]he identification of such flaws in generally reliable scientific evidence is precisely the role of cross-examination." [114] Thus, the court held that the trial judge did not abuse his discretion in allowing the testimony, and that ultimately it was for the jury to appropriately weigh the alleged defects, which "go to the weight, not the admissibility." [115]

Given the highly complex nature of the testimony, it is difficult to be too critical of the Eleventh Circuit. That said, there are two problems with the court's opinion. First, the court appears to have abdicated its role under Rule 702(d) to ensure, by a preponderance, that the methodology (which went largely unchallenged) was *applied* reliably. Instead, the court left that issue to a jury. As one can tell from the excerpt above, even an experienced trial judge would have difficulty working through the science. Could a jury? We do not know, but that is the point of Rule 702: to ensure that the methodology is not only reliable, but that it is reliably applied in the particular instance, with the underlying assumption that the jury is not able to handle these matters. However, it is entirely possible that the court of appeals did not mean to issue a categorical statement that arguments as to an expert's application of a recognized methodology go to the weight of such testimony. Rather, its statement that the alleged flaws "are of a character that impugn the accuracy of [Frank's] results, not the general scientific validity of his methods" [116] may have been a conclusion that Frank met Rule 104(a)'s threshold and that the criticisms were sufficiently minor so as to go to weight. [117] The opinion also reflects the high level of deference accorded a trial court under the abuse of discretion standard of review.

Second, it appears that the Eleventh Circuit was incorrect as a technical matter. [118] While it stated that Quiet "does not contest the [expert's] formulation that $PT_{Intake} = FPR(P_{amb})$," [119] the court's footnote one page earlier acknowledged that Quiet had in fact argued that Frank should have "derived the FPR by dividing the total intake pressure (Pt2.5) by the exit pressure (Pt2)" such that $PT_{Intake} = FPR(P_{exit})$. [120] This fundamental contradiction went unrecognized in the court's opinion. In this light, the court's citation to the ***2055** Supreme Court's statement that "[n]ormally, failure to include variables will affect the analysis' probativeness, not its admissibility" [121] seems misplaced, as the claim was use of the *wrong* variable. In the end, the case puts to the test Justice Breyer's prediction that implementing *Daubert*'s gatekeeping task "will not prove inordinately difficult." [122]

F. Sixth Circuit

McLean v. 988011 Ontario, Ltd. [123] was a wrongful death lawsuit involving the crash of a private airplane brought against a refurbisher and an inspector. The pilot had purchased the used Piper Cherokee the month before the crash and had the defendants paint it and replace horizontal stabilizer tips, dorsal fin fairings, and other miscellaneous items. At the time of the crash at 1:04 a.m., the pilot had only 110 flight hours of experience, was in instrument meteorological conditions even though he was only trained for visual flight rules, and had just received a traffic advisory from air traffic control. [124] Plaintiffs offered two expert witnesses who contradicted each other as to the cause of the crash, but both contended it was ultimately a result of "flutter"--a "destructive harmonic event that virtually destroys the integrity of the control" of an aircraft. [125] The trial court granted summary judgment to the defendants on the grounds that the experts contradicted each other, relied on circumstantial evidence whose factual basis was undermined on key points by the defendants, and provided an explanation no more plausible than the defendants' explanation of pilot error. [126] The Sixth Circuit reversed. [127] Acknowledging that an expert's opinion must

be supported by "'good grounds,' based on what is known," [128] the court nevertheless stated that "mere 'weaknesses in the factual basis of an expert witness' opinion ... bear on the weight of the evidence rather than on its admissibility."' [129]

The defects the defendants noted appear to be more than "mere weaknesses," however. For example, one expert, Rick Wilken, attributed the crash to a horizontal stabilizer that had been improperly balanced and separated in flight, a sloppy paint job, the lack of calibration, the use of replacement parts not from the manufacturer, and improper tensioning of the control ***2056** cables. [130] However, Wilken did not know whether the control cables had been adjusted, and defendants' paperwork did not indicate that anyone "had touched the cables," although one employee's testimony "appears to indicate that the cables were detached and reattached" as part of the stabilizer-rebalancing procedure. [131] Plaintiffs' other expert, Robert Donham, was a "flutter" expert. He blamed the crash on a loose balance weight on the top of the plane's rudder. However, he admitted he did not know specifically what the defendant did or did not do wrong in removing and reinstalling the weight, conceding, "I have no idea what happened to the unit." [132] Moreover, the National Transportation Safety Board report of the crash did not show the weight as being found upstream of the crash, as Donham's theory assumed. [133] The court of appeals found both expert theories "plausible" and "supported by what evidence is available." [134] In other words, the court appeared to accept that the dearth of available evidence hampered plaintiffs' ability to demonstrate causation with any more precision. Plausibility, however, is plainly lower than a preponderance.

It would have been far better had the Sixth Circuit described how the available evidence was a sufficient basis for the expert's opinion under Rules 702(b) and 104(a). In the absence of such explication and given the lack of factual support for the opinions of the experts, relegating the decision to a jury under the notion that obvious weaknesses go to the weight, not admissibility, of the alleged flutter theory as the cause of the crash appears to invite speculation. This is particularly so given the uncontested facts surrounding the accident and the pilot's inexperience and lack of training for instrument meteorological weather conditions.

G. District Courts

Several district court opinions also address the sufficiency/weight/admissibility question. The following are representative.

Bouchard v. American Home Products Corp. [135] was a personal injury action involving the diet drug Redux. The plaintiff contended that ingesting the drug caused cardiac, brain, and pulmonary injury. Among the pretrial motions were motions to exclude expert testimony of experts by both parties. In one motion, the plaintiff moved to exclude the defendant's vocational expert, a licensed psychologist, who proposed to testify that the plaintiff could still perform sedentary work and lost only twenty percent of her ability to perform household services. Plaintiff contended that the expert lacked a sufficient basis for his opinion because he failed to evaluate all available information before making his decision and relied in part on the plaintiff's ***2057** self-assessment of her lifting requirements at work. [136] Though the opinion does not explain the nature of the alleged deficiencies, the court agreed with the defendant that such challenges did not warrant exclusion, noting that "weaknesses in the factual basis of an expert witness' opinion ... bear on the weight of the evidence rather than on its admissibility." [137] According to the court, the failure to "examine sufficient evidence" was a subject "fit ... for cross-examination, not a grounds for wholesale rejection of the expert opinion." [138]

Facially, the court's opinion appears to have ignored Rule 702(b)'s requirement that there be a preponderance of evidence to support the basis for the expert's opinion. However, other aspects of the court's opinion suggest otherwise. For example, the court rejected the plaintiff's contention that an expert could not rely on the plaintiff's self-assessment of work obligations without independently verifying it, finding that a plaintiff's self-assessment is prima facie evidence sufficient for an expert's reliance. Moreover, the expert had reviewed four of the five years since plaintiff had been diagnosed, which the court may have found sufficient for admissibility under Rule 702(b). These facts may explain the court's practical recognition that had the plaintiff felt the alleged flaws would have required the expert "to substantially change his opinion," the plaintiff would have cross-examined him in his deposition. [139] In addition, although not expressly recognizing the Rule 104(a) requirement, the court provided a thorough and complete recitation of the legal standards for the admission of expert opinion and, in a careful analysis granting

the plaintiff's motion to exclude another witness (the defendant's economist), found that his testimony violated the rule that it "must be accompanied by a sufficient factual foundation before it can be submitted to the jury." [140]

In many ways, *United States v. McCluskey* [141] encapsulates the conflicting approaches to considering threshold sufficiency under Rule 702 reflected in the caselaw. The defendant moved to preclude the government's expert from testifying that polymerase chain reaction/short tandem repeat (PCR/STR) DNA analysis tied the defendant to a firearm used as a murder weapon. [142] The government argued that PCR/STR DNA analysis has been widely held to be a reliable methodology and that the defendant's challenges to its application went "primarily to the weight ... not [to] its admissibility." [143] The defendant contended that neither the methodology nor application ***2058** was reliable and that "no distinction should be made between methodology and application" in the court's analytical approach. [144] According to the defendant, the government must prove that "each step in the procedure and each item used in the procedure meet the *Daubert* test for scientific reliability." [145] The court independently determined that the PCR/STR methodology was reliable and admissible under Rule 702 and *Daubert* and concluded that the defendant's challenges to the application of that methodology "go primarily to the weight of the DNA evidence, not its admissibility." [146]

What is remarkable about the case is the trial court's extensive analysis. It contains an erudite discussion of the policy and principles underlying Rule 702 and *Daubert*. In painstaking detail, the court described all the proper applicable standards, even acknowledging that the government, as proponent, bore the burden under Rule 104(a) of proving admissibility under Rule 702 by a preponderance of the evidence. [147] The court also held an evidentiary hearing, accepted hundreds of pages of briefing, and admitted about 3500 pages of exhibits. [148] The opinion reviews scores of cases nationwide (many of which are described in this Article) to determine the proper standard for analyzing the application of the PCR/STR methodology to the defendant's facts. The court eventually sided with those courts that hold that unless the challenges to the application of the methodology raise a "major flaw which undermines the entire analysis," they constitute questions of weight for the jury. [149]

For all that the *McCluskey* court did right (and it is a lot), it failed to analyze and apply Rule 702(d), which requires that the court apply the Rule 104(a) standard to the question of reliable application of the methodology to the facts of the case. In adopting the rule that challenges to application should be left to the jury "unless the alleged 'error negates the basis for the reliability of the principle itself,'" the court relied upon cases predating the 2000 amendments to the Rules, particularly those in the Third and Eighth Circuits. [150] The court also interpreted Tenth Circuit cases to hold that *In re Paoli*'s admonition that "any step that renders the analysis unreliable ... renders the expert's testimony inadmissible" [151] was merely a reference to *Joiner*'s invitation to ensure there is not "too great an analytical gap" between the ***2059** methodology and result. [152] This conclusion seems to be a strained reading of *In re Paoli*, which went on to say that "[t]his is true whether the step completely changes a reliable methodology or merely misapplies that methodology." [153] The *McCluskey* court arrived at this conclusion by repeatedly characterizing *Daubert* as *liberalizing* the admissibility standard and citing the opinion's reference to the "liberal thrust" of the Federal Rules and their "general approach of relaxing the traditional barriers to 'opinion' testimony." [154] While the Supreme Court indeed said this, such statements do not override the express terms of the 2000 version of Rule 702(d).

III. SUGGESTIONS FOR FUTURE CASES

Based on decisions like those highlighted in this Article, the Advisory Committee on the Federal Rules of Evidence has spent the last two years debating whether Rule 702 should be amended to underscore the need to apply Rule 104(a) to ensure that the gatekeeper function contemplated by the Rules and *Daubert* and its progeny is performed. Central to the Committee's discussion is adding the preponderance requirement to the text of Rule 702. The argument in favor construes the cases as evidence that a significant number of courts are simply misapplying Rule 702 and misstating the law. [155] The argument against the amendment is that Rule 104(a) is a rule of general application and that Rule 702 should not be singled out for special treatment. Moreover, the Supreme Court has already made the point in *Daubert*, and the 2000 Advisory Committee note repeats it. Therefore, some say, the amendment would do no more than reinforce what has already been said. If courts are currently ignoring the Supreme Court and the 2000 amendments, is it likely they would follow a new amendment?

No doubt, in some cases the courts are misstating and misapplying Rule 702. Correction by the courts of appeals will go a long way to remedying the most obvious outliers. But it is unlikely that in the main courts are erring as egregiously as the proponents of a rule change suggest. [156] True, courts could be more careful in how they state that the challenges "go to weight, not admissibility." But as demonstrated above, in many cases the courts may very well be applying the proper Rule 104(a) standard; they are just not explicating it. Confounding any ultimate determination are the oftentimes complex and highly technical nature of the disputes, *Daubert*'s description of the Rule 702 inquiry as "a flexible one" [157] that accords the trial judge "considerable ***2060** leeway," [158] and the highly deferential abuse of discretion standard of review. Whether or not Rule 702 is amended, however, trial and appellate courts would be best served to adopt better practices in analyzing challenges to the admissibility of expert witnesses under Rule 702.

First, courts should cite the standard of admissibility they are employing. Specifically, citation to Rule 104(a) and its preponderance standard will educate the reader (and reviewing court) as to the threshold used and reinforce the proper admissibility framework. In virtually every other context, a judicial opinion always begins with a recitation of the proper standard of review. In the vast majority of cases under question, while Rule 702 and relevant cases are cited, there is no acknowledgment that the gatekeeper function requires application of Rule 104(a)'s preponderance test, much less for *each* of the elements of the Rule. Instead, courts tend to defer to statements from caselaw, even if it is outdated.

Second, a surprising number of cases start and end with *Daubert* and its progeny and fail to mention Rule 702. [159] Of course, Rule 702 was amended in 2000, and the elements of Rule 702, not the caselaw, are the starting point for the requirements for admissibility. [160] In this respect, labeling expert challenges "*Daubert*" motions is a misnomer. Moreover, statements as to the "liberal thrust" of Rule 702 and "flexible" standard trial judges should apply must be contextualized. Expansion of the gatekeeper inquiry beyond *Frye*'s general acceptance test is necessarily cabined by the elements of Rule 702. And the flexibility accorded trial judges relates to which *Daubert* factors, in the totality of circumstances, the court chooses to examine in applying Rule 702's required elements; the court cannot pick and choose among the Rule 702 elements. Such generalizations should not be used as a basis to evade the Rule. Rather, courts should cite the current Rule 702 and its elements for admissibility. Caselaw may be indispensable for interpreting those elements, but the foundation for the test is Rule 702.

Third, courts should read cases predating the 2000 amendments to Rule 702 with caution. Rule 702 has changed, and thus so have the admissibility requirements. *City of Pomona* illustrates this problem.

Fourth, courts should identify what evidence either meets or fails the preponderance standard for threshold admissibility, and why. In several cases, such as *Bouchard*, statements that the weaknesses of the evidence went to the weight and not admissibility may have merely reflected the court's conclusion ***2061** that there was a preponderance of evidence to support the opinion. One does not always know for sure, as it was never articulated. *Daubert*'s famous line about "shaky *but admissible* evidence" [161] should not be misused to avoid a proper analysis or, worse, relegate gatekeeper questions to a factfinder. The trial court must first find whether the opinion testimony is admissible.

Fifth, courts should require that challenges be raised timely, so that thoughtful analysis can be conducted. Trial courts are exceedingly busy, and *Daubert* motions tend to be very time consuming. [162] Many Rule 702 challenges involve highly technical questions, and the parties' disagreement often stems from the complexity. Planning should begin with the Rule 26(f) scheduling conference, allowing ample time for the court to understand and contemplate the issues. In this respect, criminal cases raise even more of a challenge. [163] For the seasoned trial judge, last-minute challenges may be resolved during trial for efficiency's sake, [164] but making appropriate findings on the record at this late stage may be more difficult.

Sixth, there will be challenges to the weight of an opinion's basis even under a proper Rule 104(a) analysis. This does not automatically render the question one for a jury, as some of the cases suggest. Rather, the trial judge, as gatekeeper, must determine whether such challenges are so significant that the factual basis for the opinion fails to reach the preponderance standard or, instead, whether the alleged defects are sufficiently minor, such that they do not undermine the remaining basis. In the latter instance, the alleged flaws do not impugn the reliability or validity of the method or results. For example, an expert

who allegedly failed to include a handful of patients in a study of over 100 patients, or an expert whose opinion is supported by a dozen studies but is contrary to a study that would not undermine her ultimate conclusion would likely pass the Rule 104(a) bar. [165] Of ***2062** course, where there is a legitimate question of fact on which the admissibility of the expert opinion turns, Rule 104(a) does not allow the trial court to make that call, and the jury must decide. [166]

In the end, just as the Supreme Court has reiterated that the nature of the task of gatekeeping is by design flexible, there will be no silver bullet to ensuring a proper application of Rule 702. But the leeway accorded trial courts in deciding *how* to determine reliability cannot serve as a substitute for the application of the proper threshold standards for determining admissibility. Hopefully, these suggestions will assist trial and appellate courts in making the best decisions possible.

CONCLUSION

As trial judges can attest, discharging their gatekeeper role under Rule 702 can frequently be exceedingly difficult, especially when it is case dispositive. While judges are accorded wide latitude in how they go about making that determination and are reviewed for an abuse of discretion, they are nevertheless bound by Rule 104(a)'s requirement that there be a preponderance of evidence supporting each of the requirements of Rule 702(a) through (d). Decisionmaking on the admissibility of expert testimony would be better served if trial judges acknowledged the Rule 104(a) standard and articulated how the expert's opinion fared under each element of Rule 702. This would also assist the appellate courts, which, in conducting their deferential review, should avoid blanket statements suggesting that any alleged flaws affect the weight of the evidence, not its admissibility.

Footnotes

a1 Chief United States District Judge for the Middle District of North Carolina. Member, United States Judicial Conference Advisory Committee on the Federal Rules of Evidence, and Chair of Subcommittee on Rule 702; Senior Lecturer, Duke University School of Law; Member, American Law Institute. The views expressed herein are mine only and do not represent the official views of the Advisory Committee on the Federal Rules of Evidence. I wish to thank Professor Daniel Capra, the Committee's Reporter, for use of his excellent memoranda on Rule 702, as well as materials from Timothy Lau, PhD, Senior Research Associate, of the Federal Judicial Center. The Advisory Committee memoranda are available at https://www.uscourts.gov/committees/evidence.

1 509 U.S. 579, 597 (1993).

2 *Id*. at 596.

3 Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

4 *Daubert*, 509 U.S. at 588 (citing Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 169 (1988)).

5 *Id*. at 580, 592-95.

6 *Id*. at 597.

7 *Id*. at 592.

8 *Id*. at 592 n.10 (citing Bourjaily v. United States, 483 U.S. 171, 175-76 (1987) (applying Rule 104(a)'s preponderance test to the threshold question of the existence of a conspiracy)). Rule 104(a) provides: “The court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible. In so deciding, the court is not bound by evidence rules, except those on privilege.” FED. R. EVID. 104(a).

9 FED. R. EVID. 702 advisory committee's note to 2000 amendment.

10 The full Rule provides: A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case. FED. R. EVID. 702.

11 FED. R. EVID. 702 advisory committee's note to 2000 amendment.

12 *Id*. (emphasis added) (quoting Brown v. Se. Pa. Transp. Auth. (*In re* Paoli R.R. Yard PCB Litig.), 35 F.3d 717, 744 (3d Cir. 1994)).

13 Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999).

14 *See* FED. R. EVID. 702 advisory committee's note to 2000 amendment.

15 *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 598-601 (1993) (Rehnquist, C.J., concurring in part and dissenting in part, joined by Stevens, J.).

16 522 U.S. 136 (1997).

17 FED. R. EVID. 702 advisory committee's note to 2000 amendment.

18 *Joiner*, 522 U.S. at 146.

19 FED. R. EVID. 706.

20 *Joiner*, 522 U.S. at 147, 150 (Breyer, J., concurring).

21 *Id*. at 154 (Stevens, J., concurring in part and dissenting in part).

22 *Id*. at 154 n.9 (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 596 (1993)). Some commentators have suggested that this mantra "simply begs the central question" of admissibility under Rule 702. KENNETH R. FOSTER & PETER W. HUBER, JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS 16 (1997); *see also id*. at 15 ("This language is usually cited by those favoring looser standards of admissibility.").

23 Norris v. Baxter Healthcare Corp., 397 F.3d 878, 886 (10th Cir. 2005) (quoting Bitler v. A.O. Smith Corp., 391 F.3d 1114, 1121 (10th Cir. 2004)) (but noting where the conclusion simply does not follow from the data, the district court is free to conclude that the analytical gap is impermissible).

24 Rule 104(b) provides: "When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist. The court may admit the proposed evidence on the condition that the proof be introduced later." FED. R. EVID. 104(b). In *Huddleston v. United States*, 485 U.S. 681, 690 (1988), the Court clarified that in determining whether a party has introduced sufficient evidence to meet Rule 104(b), "the trial court neither weighs credibility nor makes a finding that the [party] has proved the conditional fact by a preponderance of the evidence." Rather, "[t]he court simply examines all the evidence in the case and decides whether the jury could reasonably find the conditional fact ... by a preponderance of the evidence." *Id*.

25 *Joiner*, 522 U.S. at 142 (quoting Spring Co. v. Edgar, 99 U.S. 645, 658 (1879)). "[E]mbedded findings of fact are reviewed for clear error ...." Ungar v. Palestine Liberation Org., 599 F.3d 79, 83 (1st Cir. 2010).

26 *Joiner*, 522 U.S. at 142.

27 The Advisory Committee's investigation was prompted by an article by David E. Bernstein & Eric G. Lasker, *Defending* Daubert *: It's Time to Amend Federal Rule of Evidence 702*, 57 WM. & MARY L. REV. 1 (2015), which identified many

cases as evidencing erroneous application of Rule 702 and urged amendment of the Rule to underscore the need for the trial court to address each of the Rule's requirements.

28 639 F.3d 11 (1st Cir. 2011).

29 *Id*. at 13.

30 *Id*.

31 *Id*. at 14.

32 *Id*. at 15-16 (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)).

33 *Id*. at 17 (citing Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. ROYAL SOC'Y MED. 295, 295-99 (1965)).

34 *Id*. at 17 (quoting Bitler v. A.O. Smith Corp., 391 F.3d 1114, 1124 n.5 (10th Cir. 2004)).

35 For example, the district court had found that Dr. Smith's conclusions lacked general acceptance, there was insufficient evidence to support Dr. Smith's opinion that all subtypes of acute myeloid leukemia likely share a common etiology (finding the expert's broad extrapolation from acute myeloid leukemia to acute promyelocytic leukemia unsupported), existing knowledge of DNA did not support biological plausibility, insufficient evidence to support the expert's opinion on mechanism to cause chromosomal damage, the epidemiological evidence on which Dr. Smith relied was not statistically significant, and Dr. Smith had faulty calculations in his odds ratios. *See id*. at 21-23.

36 *Id*. at 22.

37 *Id*. (emphasis omitted).

38 *Id*. (quoting Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000)).

39 *Id*. (quoting United States v. Vargas, 471 F.3d 255, 264 (1st Cir. 2006)).

40 *See, e.g.*, Bernstein & Lasker, *supra* note 27, at 40-42 (arguing that the "weight of the evidence" methodology was rejected by *Joiner*).

41 *Milward*, 639 F.3d at 22 (quoting Milward v. Acuity Specialty Prods. Grp., Inc., 664 F. Supp. 2d 137, 146 (D. Mass. 2009)).

42 Other First Circuit caselaw demonstrates a proper application of Rule 104(a), *see, e.g.*, Pelletier v. Main St. Textiles, LP, 470 F.3d 48 (1st Cir. 2006), while other cases do not, *see, e.g.*, United States v. Shea, 211 F.3d 658, 668 (1st Cir. 2000) (noting that "any flaws in [an expert's] application of an otherwise reliable methodology went to weight and credibility and not to admissibility").

43 383 F.3d 689 (8th Cir. 2004).

44 *See id*. at 694.

45 *Id*.

46 *Id*. at 695.

47 *Id*. at 695, 670.

48 *Id*. at 696.

49 *Id*. at 697 (alteration in original) (quoting United States v. Beasley, 102 F.3d 1440, 1448 (8th Cir. 1996)).

50 686 F.3d 618 (8th Cir. 2012).

51 *Id*. at 620.

52 *Id*.

53 *Id*. at 624 (alteration in original) (quoting Kuhn v. Wyeth, Inc. (*In re* Prempro Prods. Liab. Litig.), 765 F. Supp. 2d 1113, 1126 (W.D. Ark. 2011)).

54 *Id*. at 633.

55 *Id*. at 626.

56 *Id*. at 627.

57 *See id*.

58 *See id*. at 628.

59 *Id*. at 633.

60 *Id*. (Loken, J., dissenting).

61 *Id*. at 624 (majority opinion).

62 *Id*. at 624, 627. He did contend that observational studies were "much better at estimating the size of the risk." *Id*. at 627.

63 *Id*. at 628.

64 *Id*.

65 *Id*. at 625 (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 596 (1993)) (citing amended Rule 702 as well).

66 *Id*. at 628.

67 *Id*. at 631 n.17.

68 *Id*. at 631 (quoting Kuhn v. Wyeth, Inc. (*In re* Prempro Prods. Liab. Litig.), 765 F. Supp. 2d 1113, 1123 (W.D. Ark. 2011)).

69 *See id*. at 629.

70 *Id*. at 631.

71 *Id*.

72 *Id*. at 632.

73 *Id*.

74 *Id*.

75 *Id*. at 633. Despite this statement, a review of the appellate briefs suggests that one plaintiff (Davidson) actually attempted to explain away the contrary data from the other studies cited by Wyeth. *See* Appellant's Brief at 42-45, Davidson v. Wyeth, 686 F.3d 618 (8th Cir. 2012) (No. 11-1815).

76 Kuhn v. Wyeth, Inc., 686 F.3d at 633-34 (Loken, J., dissenting).

77 855 F.3d 178 (4th Cir. 2017).

78 *Id*. at 203.

79 *Id*. at 195.

80 *Id*. at 188.

81 *Id*. at 195.

82 *Id*. (alteration in original) (quoting Structural Polymer Grp., Ltd. v. Zoltek Corp., 543 F.3d 987, 997-98 (8th Cir. 2008)).

83 *Id*. at 195-96 (quoting *Zoltek Corp.*, 543 F.3d at 997-98).

84 That this case may be an outlier is demonstrated by *Nease v. Ford Motor Co.*, 848 F.3d 219, 230-31 (4th Cir. 2017), where the court reversed the district court for concluding that criticisms of the expert's opinion testimony went to its weight and not its admissibility.

85 *See, e.g.*, *In re* Roundup Prods. Liab. Litig., 390 F. Supp. 3d 1102, 1112-13 (N.D. Cal. 2018) ("The Ninth Circuit has placed great emphasis on *Daubert*'s admonition that a district court should conduct this analysis 'with a "liberal thrust" favoring admission,"' which "has resulted in slightly more room for deference to experts in close cases than might be appropriate in some other Circuits." (quoting Messick v. Novartis Pharm. Corp., 747 F.3d 1193, 1196 (9th Cir. 2014))).

86 750 F.3d 1036 (9th Cir. 2014).

87 *Id*. at 1041.

88 *Id*. at 1042-43.

89 *Id*. at 1043.

90 *Id*. at 1044 (quoting Primiano v. Cook, 598 F.3d 558, 564 (9th Cir. 2010)). The court also cited its own standard, articulated in 2013, that "[t]he judge is 'supposed to screen the jury from unreliable nonsense opinions, but not exclude opinions merely because they are impeachable."' *Id*. (quoting Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc., 738 F.3d 960, 969 (9th Cir. 2013)). While true, this holding ignores the wide gap between the two standards where otherwise qualified experts rely on faulty data or misapply critical procedures.

91 *Id*. at 1045 (alternation in original) (quoting Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134, 1141 (9th Cir. 1997)).

92 *Id*. at 1046.

93 *Id*.

94 30 F.3d 1144 (9th Cir. 1994).

95 *City of Pomona*, 750 F.3d at 1047.

96 Brown v. Se. Pa. Transp. Auth. (*In re* Paoli R.R. Yard PCB Litig.), 35 F.3d 717 (3d Cir. 1994).

97 *City of Pomona*, 750 F.3d at 1047 (quoting *In re Paoli*, 35 F.3d at 745).

98 *Id*. at 1047-48 (quoting *Chischilly*, 30 F.3d at 1154).

99 *Id*. at 1048.

100 It is ironic that the court of appeals faulted the district court for "not apply[ing] the correct rule of law." *Id*. at 1048.

101 *Id*. Had the trial court articulated the reasons it determined the expert's failure to adhere to protocols rendered the expert's entire analysis unreliable, it is entirely possible that, under an abuse of discretion review, the decision to exclude the witness would have been affirmed.

102 *See, e.g.*, Dow Chem. Co. v. Seegott Holdings, Inc. (*In re* Urethane Antitrust Litig.), 768 F.3d 1245, 1261 (10th Cir. 2014) (finding that the district court reasonably concluded that the statistical expert's foundation was reliable because there was "no need to consider every measurable factor--just the 'major' ones").

103 326 F.3d 1333 (11th Cir. 2003).

104 *Id*. at 1336-37.

105 *Id*. at 1339.

106 *Id*. at 1338.

107 *Id*.

108 *Id*. at 1344.

109 *Id*. at 1352.

110 *Id*.

111 *Id*. at 1344 n.11.

112 *Id*.

113 *Id*. at 1346 (alteration in original) (quoting Bazemore v. Friday, 478 U.S. 385, 400 (1986) (Brennan, J., concurring in part)).

114 *Id*. at 1345.

115 *Id*.

116 *Id*.

117 For example, the court noted Hurel's contention that the criticism applied only in the calculations for the uniform profile cases, not the flight profile cases, and that even if Quiet was correct, Frank's analysis was "not completely invalid" but instead required (at most) a "re-matching" of data. *Id*. at 1344 n.12.

118 Dr. Timothy Lau is credited with this observation. Dr. Lau, a lawyer, also holds a doctorate in materials science and engineering from the Massachusetts Institute of Technology and serves as a Senior Research Associate at the Federal Judicial Center.

119 *Quiet Tech.*, 326 F.3d at 1345.

120 *Id*. at 1344 n.11.

121 *Id*. at 1346 (alteration in original) (quoting Bazemore v. Friday, 478 U.S. 385, 400 (1986) (Brennan, J., concurring in part)).

122 Gen. Elec. Co. v. Joiner, 522 U.S. 136, 150 (1997) (Breyer, J., concurring).

123 224 F.3d 797 (6th Cir. 2000).

124 *Id*. at 799.

125 *Id*. at 802. One expert blamed faulty repairs; the other cited a loose balance weight on the tail section. *Id*.

126 *Id*. at 799.

127 *Id*. at 800.

128 *Id*. at 801 (quoting Pomella v. Regency Coach Lines, Ltd., 899 F. Supp. 335, 342 (E.D. Mich. 1995)).

129 *Id*. (alteration in original) (quoting United States v. L.E. Cooke Co., 991 F.2d 336, 342 (6th Cir. 1993)).

130 *Id*. at 801-02.

131 *Id*. at 802.

132 *Id*. at 803-04.

133 *Id*. at 804.

134 *Id*. at 805.

135 No. 3:98CV7541, 2002 WL 32597992 (N.D. Ohio May 24, 2002).

136 *Id*. at *7.

137 *Id*. (citing *McLean*, 224 F.3d at 801).

138 *Id*.

139 *Id*.

140 *Id*. at *10 (quoting Elcock v. Kmart Corp., 233 F.3d 734, 754 (3d Cir. 2000)). The court ultimately rejected the testimony on a lack of "fit" with the evidence, because the expert had an "almost complete disregard for the ... facts of [the] case." *Id*.

141 954 F. Supp. 2d 1224 (D.N.M. 2013).

142 *Id*. at 1228.

143 *Id*. at 1244.

144 *Id*.

145 *Id*. Elsewhere, the court noted that the defendant argued that the methods employed must be "independently review[ed]" at "each major step" under *Daubert*. *Id*. (emphasis omitted).

146 *Id*.

147 *Id*. at 1233-36.

148 *Id*. at 1228-29.

149 *Id*. at 1248.

150 *Id*. at 1250 (quoting United States v. Martinez, 3 F.3d 1191, 1198 (8th Cir. 1993)).

151 *Id*. at 1245 (quoting Brown v. Se. Pa. Transp. Auth. (*In re* Paoli R.R. Yard PCB Litig.), 35 F.3d 717, 745 (3d Cir. 1994)). The "any step" requirement is specifically quoted in Rule 702's 2000 Advisory Committee note.

152 *Id*. (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)).

153 *In re Paoli*, 35 F.3d at 745 (emphasis omitted).

154 *McCluskey*, 954 F. Supp. 2d at 1238 (quoting Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 588 (1993)); *see also id*. at 1238, 1246, 1251, 1255.

155 *See* Bernstein & Lasker, *supra* note 27, at 19-25.

156 *See* 3 STEPHEN A. SALTZBURG, ET AL., FEDERAL RULES OF EVIDENCE MANUAL § 702.02[10], at 702-57 (12th ed. 2019) (concluding that the problem is "not ... as great" as intimated).

157 Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999) (quoting *Daubert*, 509 U.S. at 594).

158 *Id*. at 152.

159 This point was made by Bernstein & Lasker, *supra* note 27, at 8.

160 *See* Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 163 (1988) ("Because the Federal Rules of Evidence are a legislative enactment, we turn to the 'traditional tools of statutory construction' in order to construe their provisions. We begin with the language of the Rule itself." (quoting INS v. Cardonza-Fonseca, 480 U.S. 421, 446 (1987))); United States v. Parra, 402 F.3d 752, 758 (7th Cir. 2005) (acknowledging that "Rule 702 has superseded *Daubert*"); United States v. Mamah, 332 F.3d 475, 477 (7th Cir. 2003) ("We begin our analysis by looking at the actual text of Rule 702, which was amended in 2000 in response to *Daubert* and *Kumho Tire* ....").

161 *Daubert*, 509 U.S. at 596 (emphasis added).

162 *Symposium on Forensic Expert Testimony,* Daubert *, and Rule 702*, 86 FORDHAM L. REV. 1463, 1535 (2018) (U.S. District Judge Patti Saris noting necessity of reaching *Daubert* motions early in the litigation, "so that you can think about it more slowly" because it is "complicated" and "hard").

163 FED. R. CIV. P. 26(f); *see* Paul W. Grimm, *Challenges Facing Judges Regarding Expert Evidence in Criminal Cases*, 86 FORDHAM L. REV. 1601, 1611-13 (2018).

164 See, for example, *United States v. McCluskey*, 954 F. Supp. 2d 1224, 1234 (D.N.M. 2013) (citing United States v. Nichols, 169 F.3d 1255, 1264 (10th Cir. 1999)), for the proposition that, if the expert's testimony is admissible, the jury is entitled to hear the same criticisms raised during the *Daubert* challenge, and to avoid duplication it may be presented once before the jury.

165 How to deal with competing scientific studies is an area that continues to confound courts. Rule 702(b) requires that "the testimony [be] based on sufficient facts or data." FED. R. EVID. 702. The 2000 Advisory Committee note reminds that in determining reliability, a trial judge should consider "[w]hether the expert has adequately accounted for obvious alternative explanations." FED. R. EVID. 702 advisory committee's note to 2000 amendment. Here, too, the inquiry is one of degree. The Advisory Committee note provides some guidance in the context of causation: "[T]he possibility of some uneliminated causes presents a question of weight, so long as the most obvious causes have been considered and reasonably ruled out by the expert." *Id*. (citing Ambrosini v. Labarraque, 101 F.3d 129 (D.C. Cir. 1996)). Thus, where the studies relied upon provide sufficient basis for the expert's opinion, Rule 104(a) is met as long as the conflicting studies can be adequately explained or raise issues that are insufficient to undermine the Rule 104(a) preponderance requirement. In many cases, this may be what courts mean when they say that the criticisms "go to the weight, not the admissibility, of the evidence." Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1345 (11th Cir. 2003); *see also* Margaret A. Berger, *The Admissibility of Expert Testimony*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 11, 19 (3d ed. 2011) (discussing problems in experts' reliance on some, but not all, scientific studies in a field).

166 *See* FED. R. EVID. 702 advisory committee's note to 2000 amendment ("The emphasis in the amendment on 'sufficient facts or data' is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other."). To preserve the issue, the jury could be instructed that if they find the fact as proffered, they may consider the expert's opinion.

95 NTDLR 2039

End of Document

TAB 2D

THIS PAGE INTENTIONALLY BLANK

COMMENT
to the

ADVISORY COMMITTEE ON EVIDENCE RULES
and its
RULE 702 SUBCOMMITTEE

CLEARING UP THE CONFUSION: THE NEED FOR A RULE 702 AMENDMENT TO ADDRESS THE PROBLEMS OF INSUFFICIENT BASIS AND OVERSTATEMENT

September 6, 2019

Lawyers for Civil Justice ("LCJ")[1] respectfully submits this Comment to the Advisory Committee on Evidence Rules ("Committee") and its Rule 702 Subcommittee ("Subcommittee").

INTRODUCTION

The Committee's examination of expert evidence standards has revealed widespread inconsistency in the application of Rule 702. For example, the Committee's thorough evaluation of the cases cited in the William and Mary law review article[2] was summarized as follows:

> 1. Five circuit court opinions in which the court appeared to apply a Rule 104(b) standard to the questions of sufficiency of basis and reliable application;
> 2. Six circuit opinions in which the court used inappropriate Rule 104(b) language, but actually appeared to apply the Rule 104(a) standard to those questions;
> 3. Three district court opinions that wrongly applied the Rule 104(b) standard;
> 4. Four district court opinions that used Rule 104(b) language but actually appeared to review under Rule 104(a); and

[1] Lawyers for Civil Justice ("LCJ") is a national coalition of corporations, law firms, and defense trial lawyer organizations that promotes excellence and fairness in the civil justice system to secure the just, speedy, and inexpensive determination of civil cases. For over 30 years, LCJ has been closely engaged in reforming federal procedural rules in order to: (1) promote balance and fairness in the civil justice system; (2) reduce costs and burdens associated with litigation; and (3) advance predictability and efficiency in litigation.

[2] Eric Lasker and David Bernstein, *Defending Daubert: It's Time to Amend Federal Rule of Evidence 702*, 57William & Mary L. Rev. 1 (2015).

5. Three district court opinions in which Rule 104(b) language was used and there is not enough to determine from the opinion which standard was actually applied.[3]

Understanding the nuances among these decisions is very important—but so is the big picture: Rule 702 is not providing adequate direction to the courts, causing courts to misapply the rule's requirements and inviting policy judgments that are inconsistent with the rule's intent. That some courts nevertheless arrive at the correct result, after misapplying the rule, should be of little solace to the Committee.

An amendment to Rule 702 would remedy the widespread inconsistencies by clarifying that: (1) the proponent of the expert's testimony bears the burden of establishing its admissibility; (2) the proponent's burden requires demonstrating the sufficiency of the basis and reliability of the expert's methodology and its application; and (3) an expert shall not assert a degree of confidence in an opinion that is not itself derived from sufficient facts and reliable methods. Additionally, the Committee should clarify that the statement in the 2000 Note that "the rejection of expert testimony is the exception rather than the rule" was not meant to define or affect the standards for admissibility of expert opinion testimony.

I. FRE 702 SHOULD CLARIFY THAT THE PROPONENT HAS THE BURDEN TO ESTABLISH ADMISSIBILITY OF EXPERT TESTIMONY BECAUSE A MISUNDERSTANDING OF THAT BURDEN IS CAUSING COURTS TO MISAPPLY THE RULE.

The current absence of an explicit allocation of the burden for establishing admissibility has caused courts to rely upon their characterizations of the nature of Rule 702, rather than to apply the directives of the Rule itself. This drift away from the text of Rule 702 dilutes the consistency and thoroughness of judicial analysis and undermines the gatekeeper function that Rule 702 intends.

Specifically, a number of courts have invented a "presumption of admissibility" that puts a thumb on the scale when assessing whether an expert's testimony will pass muster under Rule 702.[4] No such presumption appears in the current language of the Rule. Rather, this phantom presumption seems to have arisen from a decision pre-dating the 2000 amendments to Rule 702, in which the Second Circuit asserted that "by loosening the strictures on scientific evidence set by *Frye* [*v. United States*, 293 F. 1013 (D.C.Cir.1923)], *Daubert* reinforces the idea that there

[3] Agenda Book, Spring 2019 at 118.

[4] *See*, *e.g.*, *Price v. General Motors, LLC*, No. CIV-17-156-R, 2018 WL 8333415, at *1 (W.D. Okla. Oct. 3, 2018)("there is a presumption under the Rules that expert testimony is admissible.")(quotation omitted); *Chen-Oster v. Goldman, Sachs & Co.*, 114 F. Supp.3d 110, 115 (S.D.N.Y. 2015)("There is a presumption that expert evidence is admissible"); *Powell v. Schindler Elevator Corp*., No. 3:14cv579 (WIG), 2015 WL 7720460, at *2 (D. Conn. Nov. 30, 2015)("The Second Circuit has made clear that *Daubert* contemplates liberal admissibility standards, and reinforces the idea that there should be a presumption of admissibility of evidence."); *Advanced Fiber Technologies (AFT) Trust v. J&L Fiber Services, Inc*., No. 1:07-CV-1191, 2015 WL 1472015, at *20 (N.D.N.Y. Mar. 31, 2015)("In assuming this [gatekeeper] role, the Court applies a presumption of admissibility."); *Bericochea-Cartagena v. Suzuki Motor Co.*, 7 F. Supp.2d 109, 112–13 (D.P.R. 1998)("this role is tempered by the liberal thrust of the Federal Rules of Evidence and the presumption of admissibility.")(quotation omitted).

should be a presumption of admissibility of evidence."[5] While the ancient *Frye* rule was certainly quite restrictive in some ways, its replacement provides no justification for creating a presumption in Rule 702 to negate the rule's intent that the proponent must demonstrate the admissibility of the expert's testimony.[6] In fact, the U.S. Supreme Court explicitly recognized that "while the Federal Rules of Evidence allow district courts to admit a somewhat broader range of scientific testimony than would have been admissible under *Frye*, they leave in place the 'gatekeeper' role of the trial judge in screening such evidence."[7]

In the absence of a clear textual statement of the proper burden of proof within Rule 702 itself, some other courts have incorporated the characterization of the rule as a "liberal standard" into the analysis of expert admissibility. Allowing such result-oriented viewpoints to influence a court's Rule 702 analysis produces a diluted assessment in which admission of the expert's testimony is a foregone conclusion.[8] A bias favoring expansive admissibility is pernicious because it can easily affect Rule 702 determinations that are otherwise subject only to a loose "abuse of discretion" appellate review.[9]

The rule's lack of clarity has also resulted in the formation of regional variations in the standard actually applied, contrary to the uniformity goal of the Federal Rules. Several circuits have adopted, as a matter of policy not simply interpretation, deliberately divergent views of the standard of expert admissibility. Courts in the Ninth Circuit recognize that they apply a standard

[5] *Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995), *cert denied*, 517 U.S. 1229 (1996). *See also Powell*, 2015 WL 7720460, at *2; (citing *Borawick* as the source of the referenced "presumption of admissibility"); *Milliman v. Mitsubishi Caterpillar Forklift Am., Inc.*, 594 F. Supp.2d 230, 238 (N.D.N.Y. 2009)(same); *UMG Recordings, Inc. v. Lindor*, 531 F. Supp.2d 453, 456 (E.D.N.Y. 2007) (same).

[6] The Rule 702 standard is widely recognized to place the burden of establishing admissibility on the proponent, rather than assuming the opinion testimony will be admitted unless demonstrated to be inadequate. *See*, *e.g.*, *Varlen Corp. v. Liberty Mut. Ins. Co.*, 924 F.3d 456, 459 (7th Cir. 2019)("An expert's proponent has the burden of establishing the admissibility of the opinions"); *In re Teltronics, Inc.*, 904 F.3d 1303, 1311 (11th Cir. 2018)("The proponent of the expert testimony bears the burden of establishing that each of these [Rule 792] criteria is satisfied."); *Sims v. Kia Motors of Am., Inc.*, 839 F.3d 393, 400 (5th Cir. 2016)("The proponent of expert testimony bears the burden of establishing the reliability of the expert's testimony."); *In re Pfizer Inc. Sec. Litig.*, 819 F.3d 642, 658 (2d Cir. 2016)(" The proponent of the expert testimony has the burden to establish these admissibility requirements[.]"); *United States v. McGill*, 815 F.3d 846, 903 (D.C. Cir. 2016)("The proponent of the expert testimony bears the burden to establish the admissibility of the testimony and the qualifications of the expert."); E.*E.O.C. v. Kaplan Higher Educ. Corp.*, 748 F.3d 749, 752 (6th Cir. 2014)("the proponent of expert testimony . . . bears the burden of proving its admissibility") (citing 2000 Advisory Committee notes); *United States v. Tetioukhine*, 725 F.3d 1, 6 (1st Cir. 2013) ("The proponent of the [Rule 702] evidence bears the burden of demonstrating its admissibility."); *Conroy v. Vilsack*, 707 F.3d 1163, 1168 (10th Cir. 2013) ("The proponent of expert testimony bears the burden of showing that the testimony is admissible."). *See* Fed. R. Evid. 702 Advisory Comm. Notes, 2000 Amendments ("the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence").

[7] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142, (1997).

[8] *See*, *e.g.*, *Bonita Properties, LLC v. C&C Marine Maintenance Co*., No. 2:12cv247, 2016 WL 10520137 (W.D. Pa. Aug. 16, 2016)("In performing this function, courts must be mindful that Rule 702 of the Federal Rules of Evidence has a liberal policy of admissibility. Indeed, the Third Circuit has observed that the standard for admissibility is not intended to be a high one.. . . . Perceived flaws in Dufour's methodology, standing alone, do not justify excluding his testimony.")(quotations omitted); *In re Zyprexa Prod. Liab. Litig.*, 489 F. Supp.2d 230, 282 (E.D.N.Y. 2007)("Since Rule 702 embodies a liberal standard ofadmissibility for expert opinions, the assumption the court starts with is that a well-qualified expert's testimony is admissible.").

[9] *Joiner*, 522 U.S. at 146, ("We hold . . . that abuse of discretion is the proper standard by which to review a district court's decision to admit or exclude scientific evidence.").

that is "more tolerant of borderline expert opinions than in other circuits."[10] Courts in the Second Circuit have determined that they will give "especially broad" reception to expert testimony, despite the directives of Rule 702.[11] The Eighth Circuit has taken a policy position that the burden of establishing reliability or a sufficient factual basis should not pose an obstacle to admitting expert testimony.[12]

The development of regional variations based on characterizations or policy preferences, rather than the standards set forth in Rule 702 itself, is increasingly problematic. MDL and pattern litigation concentrate key decisions into individual courts; MDL rulings on the admissibility of a particular expert's analysis are ordinarily given great weight by later courts addressing the admissibility of similar opinion testimony in remanded or companion cases in other districts. When courts from different circuits apply unique overlays or conceptions to the Rule 702 standard, the consistency expected from a uniform national rule vanishes, and forum shopping is encouraged.

Even more fundamentally, when courts assess expert opinions "presuming admissibility," or re-configuring the standard to exclude expert testimony only when it is "fundamentally unreliable," they effectively shift the burden of proof away from the proponent. The fact that these developments have taken place indicates that the current language of Rule 702 is failing to provide sufficient direction and needs amendment to re-align application of the Rule with its intent.[13] The intent can be restored by an amendment such as the following to insert the burden of proof into Rule 702:

[10] *In re Roundup Products Liability Litigation*, 358 F. Supp.2d 956, 959 (N.D. Cal. 2019). *See also id*. at 960 ("Of course, district judges must still exercise their discretion, but in doing so they must account for the fact that a wider range of expert opinions (arguably much wider) will be admissible in this circuit."); *Hannah v. United States*, No. 2:17-cv-01248-JAM-EFB, 2019 WL 316812, at *3 (E.D. Cal. Jan. 24, 2019)("The Ninth Circuit has not imposed such stringent requirements for medical experts."); *In re Roundup Products Liability Litigation*, No. 16-md-02741-VC, 2018 WL 3368534, at *5 (N.D. Cal. July 10, 2018) ("[The Ninth Circuit's] emphasis has resulted in slightly more room for deference to experts in close cases than might be appropriate in some other Circuits. This is a difference that could matter in close cases.")(citations omitted).

[11] *United States v. Raniere*, No. 18-CR-204-1 (NGG) (VMS), 2019 WL 2212639, at *6 (E.D.N.Y. May 22, 2019) ("The Second Circuit's standard for admissibility of expert testimony is especially broad.")(citations omitted).

[12] *See Nebraska Plastics, Inc. v. Holland Colors Americas, Inc.*, 408 F.3d 410, 416 (8th Cir. 2005)("As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination.")(quotation and citations omitted); *United States v. Ameren Missouri*, 2019 WL 1384580, at *3 (E.D. Mo. Mar. 27, 2019)("Additionally, in a borderline circumstance such as this, it is far better to allow the expert opinion, and if the court remains unconvinced, allow the jury to pass on the evidence.")(quotation and citations omitted); *Paul Beverage Co. v. American Bottling Co.*¸ No. 4:17CV2672 JCH, 2019 WL 1044057, at *2 (E.D. Mo. Mar. 5, 2019)("The expert's opinion thus should be excluded only when it is so fundamentally unreliable that it can offer no assistance to the jury.")(quotation and citations omitted).

[13] Even the circuits which incorporate presumptions, characterizations, and policy variations in the standard have acknowledged that Rule 702 intends to place the burden of establishing admissibility on the expert's proponent. See *Varlen Corp.*, 924 F.3d at 459 ("An expert's proponent has the burden of establishing the admissibility of the opinions"); *Pfizer Inc. Sec. Litig.*, 819 F.3d at 658 (" The proponent of the expert testimony has the burden to establish these admissibility requirements[.]"); *Conroy*, 707 F.3d at 1168 ("The proponent of expert testimony bears the burden of showing that the testimony is admissible."); *United States v. 87.98 Acres of Land More or Less in the Cty. of Merced*, 530 F.3d 899, 904 (9th Cir. 2008)(" As the proponent of . . . expert testimony, [it] also has the burden to establish its admissibility."); *Menz v. New Holland N. Am., Inc.*, 507 F.3d 1107, 1114 (8th Cir. 2007)("The proponent of the expert testimony bears the burden to prove its admissibility.").

> The proponent of the opinion testimony bears the burden of establishing the expert's qualification, helpfulness, and reliability for each opinion to be expressed.[14]

Placing this language within the Rule will remedy the inconsistencies the Committee has noted by focusing the attention of courts assessing challenged expert testimony on what is required to meet the standard.

II. THE 2000 COMMITTEE NOTE SHOULD BE CORRECTED BECAUSE A COMMON MISINTERPRETATION IS CAUSING COURTS TO PRESUME ADMISSIBILITY OF EXPERT TESTIMONY.

The Advisory Committee's 2000 Note mentioning that exclusion of expert testimony is the "exception" is also causing inconsistency, by drawing courts' attention away from the substance of Rule 702's requirements. Taken in context,[15] this Note makes the simple observation that judicial decisions ruling on the admissibility of expert testimony between 1993, when *Daubert* was decided, and the 2000 issuance of revised Rule 702 had not excluded opinion testimony with high frequency. A number of courts, however, have converted this empirical observation into a qualitative commentary on the nature of Rule 702 and interpreted it to reinforce the misguided idea that proffered expert testimony should be presumed admissible.[16]

In conjunction with amending the language of Rule 702, the Committee should also draft a Note explaining this comment. Doing so would repair a distraction that is re-directing the attention of too many lower courts away from the directives of the rule itself.

[14] This language is adapted from *United States v. Wilson*, 634 F. App'x 718, 735 (11th Cir. 2015)("The proponent of the expert opinion bears the burden of establishing qualification, reliability, and helpfulness by a preponderance of the evidence."). *See also Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 592 n. 10 (1993).

[15] The full sentence reads "A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702 Advisory Committee Note (2000).

[16] *See*, *e.g.*, *Joe-Cruz v. United States*, Civ. No. 16-258 JCH/JHR, 2018 WL 1322139, at *3 (D.N.M. Mar. 14, 2018)("The Federal Rules encourage the admission of expert testimony. . . . The presumption under the Rules is that expert testimony is admissible. 'A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.' Fed. R. Evid. 702 Advisory Committee's note to 2000 amendment.")(citations omitted); *Chen-Oster v. Goldman, Sachs & Co.*, 114 F. Supp.3d 110, 115 (S.D.N.Y. 2015)("There is a presumption that expert evidence is admissible and 'the rejection of expert testimony is the exception rather than the rule.' Fed. R. Evid. 702 advisory committee's note (2000)")(internal quotation omitted); *Evans v. Washington Metro. Area Transit Auth.*, 674 F. Supp.2d 175, 178 (D.D.C. 2009)("The presumption under the Federal Rules is that expert testimony is admissible. . . . Fed.R.Evid. 702 Advisory Committee Note (2000) ('A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule.')")(citations and quotation omitted). *See also In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 530 (6th Cir. 2008)("But 'rejection of expert testimony is the exception, rather than the rule,' and we will generally permit testimony based on allegedly erroneous facts when there is some support for those facts in the record.")(quoting Fed. R. Evid. 702 advisory committee's note, 2000 amend.).

III. FRE 702 SHOULD EXPLICITLY PRECLUDE WITNESSES FROM EXPRESSING A DEGREE OF CONFIDENCE IN OPINIONS ABSENT A RELIABLE BASIS FOR THOSE ASSERTIONS.

The Committee's consideration of the dangers of expert "overstatement" is important in civil as well as criminal cases. Specifically, assertions of confidence in the veracity of an expert's conclusions, unless supported by a reliable methodology and limited by the established understanding of the field of expertise, create the potential for misleading juries and producing unjust results. The potential for expert overstatement to impact decision-making is very real; jury research shows that the confidence expressed by an expert has an outsized effect, which creates the potential for abuse when statements of confidence lack evidentiary basis and reflect nothing more than the expert's exuberance about the theory.[17] The rule should contain a direct restriction that prevents an expert from claiming a degree of confidence in an opinion unless that expression of certainty is drawn from reliably employed principles and methods.

One example of excessive, but unsubstantiated, expression of confidence in a conclusion commonly seen in civil cases involves opinions using a "differential diagnosis" methodology for identifying the cause of a medical condition. This practice involves eliminating known alternative causes, but it is frequently applied to conditions for which science has not established all possible causes—and so the expert cannot eliminate those presently unknown causes. Many courts (and other authorities) hold that the use of a differential etiology in such a scenario is fundamentally unreliable.[18] Yet courts addressing opinion testimony reflecting a differential diagnosis that ignores the presence of unknown causes often allow the experts not only to testify regarding causation, but also to provide bold, but scientifically unjustified, expressions of confidence in the conclusion. For example, one expert was allowed to assert that "[w]hatever other factors may have played a role in cancer development, the cancer would not have developed to clinical significance in the absence of [exposure to the product at issue]."[19] Another court allowed an expert who applied a differential diagnosis despite "scientific unknowns" to conclude that "[t]he use of [the drug] was a significant contributor in all medical

[17] *See*, *e.g.*, Neil Vidmar, *Expert Evidence, the Adversary System, and the Jury*, 95 Amer. J. Pub. Health S137, S139 (Supplement 1 2005)("The jurors reported that the factors they considered were such things as the expert's tendency to draw firm conclusions, his or her reputation, familiarity with the facts of the case, reasoning, and appearance of impartiality, including bias associated with the party that called the expert.").

[18] *See*, *e.g.*, Reference Manual on Scientific Evidence at 618 ("Although differential etiologies are a sound methodology in principle, this approach is only valid if general causation exists and a substantial proportion of competing causes are known. Thus, for diseases for which the causes are largely unknown, such as most birth defects, a differential etiology is of little benefit"); Restatement (Third) of Torts: Phys. & Emot. Harm § 28, cmt. c(4) (2010) ("When the causes of a disease are largely unknown, however, differential etiology is of little assistance."); *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008) (the expert's "attempt to use a differential diagnosis . . . fails because . . . the cause of exercise-induced asthma in the majority of cases is unknown."); *Doe 2 v. OrthoClinical Diagnostics, Inc.*, 440 F. Supp.2d 465, 477-78 (M.D.N.C. 2006) ("Although [the expert] apparently has considered a number of specific genetic disorders in performing his differential diagnosis, the Court finds that his failure to take into account the existence of such a strong likelihood of a currently unknown genetic cause of autism serves to negate [his] use of the differential diagnosis technique as being proper in this instance."); *Whiting v. Boston Edison Co.*, 891 F. Supp. 12, 21 n.41 (D. Mass. 1995) ("If 90 percent of the causes of a disease are unknown, it is impossible to eliminate an unknown disease as the efficient cause of a patient's illness.").

[19] *Costa v. Wyeth, Inc.*, No. 8:04–cv–2599–T–27MAP, 2012 WL 1069189, at *4 (M.D. Fla. Mar. 29, 2012).

certainty to the development of acute kidney injury in [the plaintiff.]"[20] These statements of certainty in the conclusion of causation, while very powerful, do not arise from any actual methodology. Such overstated expressions of confidence therefore cannot be squared with Rule 702's requirement that all expert opinions be the product of reliable principles and methods applied reliably to the facts of the case.

Amending Rule 702 to prevent testimony expressing overstated, but unsubstantiated, confidence in the conclusion that an expert has reached would help courts distinguish between an opinion for which there may be a reliable basis and an overstated or speculative expression of certainty in the veracity of a questionable opinion. The Committee should consider adding language such as the following:

> An expert shall not describe a degree of confidence in the opinions and conclusions expressed unless a basis for such confidence is independently established in accordance with the standards of this Rule.

CONCLUSION

That current Rule 702 is failing to provide clear, uniform standards for the admission of expert testimony is undeniable, given the well-observed inconsistencies including numerous regional variations that have emerged. Amendments are needed to clarify that: (1) the proponent has the burden to establish the basis for expert testimony; (2) this burden is to show sufficiency of basis and reliability of application by a preponderance of evidence; and (3) experts shall not testify to a degree of confidence in an opinion that cannot be drawn from the principles and methods applied. Additionally, the Committee should address the 2000 Note to clarify that the statement "A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule" was not meant to define or affect the standards for admissibility of expert opinion testimony.

[20] *In re Trasylol Products Liability Litigation*, No. 08-MD-01928, 2010 WL 8354662, at *8, *11 (S.D. Fla. Nov. 23, 2010)(emphasis added).

Altec
Altec, Inc.

210 Inverness Center Drive
Birmingham, AL 35242

Telephone: (205) 991-7733
Facsimile: (205) 991-9993
www.altec.com

January 31, 2020

Rebecca A. Womeldorf, Secretary
Committee on Rules of Practice and Procedure
Administrative Office of the United States Courts
One Columbus Circle, NE
Washington, D.C. 20544

Re: Amending Federal Rule of Evidence 702 to Clarify Courts' "Gatekeeping" Obligation

Dear Ms. Womeldorf:

As chief legal officers of organizations that are frequently engaged with the American civil justice system, we represent stakeholders—including employees, customers, suppliers, communities, and shareholders—who rely on the federal courts to be a just forum for the resolution of legal disputes on the merits.

The Advisory Committee on Evidence Rules ("Committee") is entrusted with the essential task of ensuring the Federal Rules of Evidence ("FRE") are fair, plainly understood, and uniformly applied. We applaud the Committee for the seriousness of purpose with which it is evaluating practices under Rule 702.

Our experience indicates that adherence to Rule 702's standards for the admission of opinion testimony is far from acceptable. We are concerned that, left on its current trajectory without Committee action, judicial practices under Rule 702 will continue to diverge materially from the Committee's purpose when it drafted the rule to give effect to the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny.

Too often, courts fail to execute or enforce the "gatekeeping" obligation. Instead, we see courts inappropriately delegate to juries the job of deciding whether an expert's opinions have the requisite scientific support. Such abrogation of the court's "gatekeeping" role deviates from the Committee's intent that Rule 702 allocate the responsibility between the judge and the jury for deciding preliminary questions under Rules 104(a) (the court must decide the preliminary question of whether a witness is qualified or the evidence admissible) and 104(b) (determining whether there are sufficient facts and data to render evidence relevant). The distinction between these tests is often unclear to both the bench and the bar. Confusion about the court's role in assessing these foundational requirements results in the admission of unreliable opinion testimony that misleads juries, undermines civil justice, and erodes our stakeholders' confidence in the courts.

Moreover, some courts refer to Rule 702's establishing a "presumption of admissibility"—a mischaracterization that inverts the proponent's burden to establish the admissibility of expert testimony. This erroneous "presumption of admissibility" appears to stem in part from the Committee's well-intended but widely misunderstood Note to the 2000 rule amendment stating that "the rejection of expert testimony is the exception rather than the rule." That statement, which was an observation

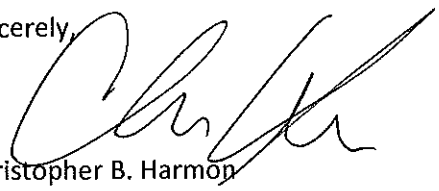
about pre-2000 practice and not intended to characterize admissibility standards, has derailed Rule 702 in many courts, causing unjust results.

We understand that the Committee balances several factors when deciding whether to amend a rule, and we don't make our suggestion lightly. We support the Committee's general caution about amendments that clarify rather than change standards; address problems of adherence to, rather than understanding of, the rule; and affect the development of legal principles in a way perhaps better left to case law. Nevertheless, the Committee has a responsibility to act when doing so would materially improve a situation of widespread disregard for or misapplication of a rule.

We urge you to move forward with an amendment to Rule 702 that would remedy the inconsistency in practice by clarifying that: (1) the proponent of the expert's testimony bears the burden of establishing its admissibility; (2) the proponent's burden requires demonstrating the sufficiency of the basis and reliability of the expert's methodology and its application; and (3) an expert shall not assert a degree of confidence in an opinion that is not itself derived from sufficient facts and reliable methods.

Thank you for your consideration.

Sincerely,



Christopher B. Harmon
General Counsel

March 2, 2020

Rebecca A. Womeldorf, Secretary
Committee on Rules of Practice and Procedure
Administrative Office of the United States Courts
One Columbus Circle, NE
Washington, D.C. 20544

Re: Amending Federal Rule of Evidence 702 to Clarify Courts' "Gatekeeping" Obligation

Dear Ms. Womeldorf:

As chief legal officers of organizations that are frequently engaged with the American civil justice system, we represent stakeholders—including employees, customers, suppliers, communities, and shareholders—who rely on the federal courts to be a just forum for the resolution of legal disputes on the merits.

The Advisory Committee on Evidence Rules ("Committee") is entrusted with the essential task of ensuring the Federal Rules of Evidence ("FRE") are fair, plainly understood, and uniformly applied. We applaud the Committee for the seriousness of purpose with which it is evaluating practices under Rule 702.

Our experience indicates that adherence to Rule 702's standards for the admission of opinion testimony is far from acceptable. We are concerned that, left on its current trajectory without Committee action, judicial practices under Rule 702 will continue to diverge materially from the Committee's purpose when it drafted the rule to give effect to the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579 (1993) and its progeny.

Too often, courts do not fully execute or enforce the "gatekeeping" obligation. Instead, we see courts allowing juries a role in deciding whether an expert's opinions have the requisite scientific support without first ensuring that the testimony is the product of reliable principles and methods and is reliably applied. This practice deviates from the Committee's intent that Rule 702 allocate the responsibility between the judge and the jury for deciding preliminary questions under Rules 104(a) (the court in its "gatekeeping" role must decide the preliminary question of whether a witness is qualified or the evidence admissible) and 104(b) (the jury may determine whether there are sufficient facts and data to render evidence relevant). The distinction between these tests is often unclear to both the bench and the bar. Confusion about the court's role in assessing these foundational requirements results in the admission of unreliable opinion testimony that misleads juries, undermines civil justice, and erodes our stakeholders' confidence in the courts.

Moreover, some courts refer to Rule 702's establishing a "presumption of admissibility"—a mischaracterization that inverts the proponent's burden to establish the admissibility of expert testimony. This "presumption" appears to stem in part from the Committee's well-intended but widely misunderstood Note to the 2000 rule amendment stating that "the rejection of expert testimony is the exception rather than the rule." That statement, which was an observation about pre-2000 practice and

not intended to characterize admissibility standards, has derailed Rule 702 in many courts, causing unjust results.

We understand that the Committee balances several factors when deciding whether to amend a rule, and we don't make our suggestion lightly. We support the Committee's general caution about amendments that clarify rather than change standards; address problems of adherence to, rather than understanding of, the rule; and affect the development of legal principles in a way perhaps better left to case law. Nevertheless, the Committee has a responsibility to act when doing so would materially improve a situation of widespread misapplication of a rule.

We urge you to move forward with an amendment to Rule 702 that would remedy the inconsistency in practice by clarifying that: (1) the proponent of the expert's testimony bears the burden of establishing its admissibility; (2) the proponent's burden requires demonstrating the sufficiency of the basis and reliability of the expert's methodology and its application; and (3) an expert shall not assert a degree of confidence in an opinion that is not itself derived from sufficient facts and reliable methods.

Thank you for your consideration.

Sincerely,

Bradley D. Dantic
Vice-President & General Counsel
ALPS Property & Casualty Insurance Company

Chris Harmon
Senior Vice President and General Counsel
Altec, Inc.

Lucy Fato
Executive Vice President and General Counsel
American International Group, Inc.

Raymond Blacklidge
Executive VP, General Counsel & Corporate Secretary
American Traditions Insurance Company

Barbara Sutherland
SVP – General Counsel
Argo Group US

David R. McAtee II
Senior Executive Vice President and General Counsel
AT&T Inc.

Stefan John
SVP & General Counsel
BASF Corporation

Scott Partridge
General Counsel and Senior Vice President
Bayer US LLC

Todd M. Bloomquist
Senior Vice President, General Counsel & Secretary
Beam Suntory Inc.

Sam Khichi
Executive Vice President, General Counsel, Public Policy & Regulatory Affairs
Becton, Dickinson and Company

Eric R. Finkelman
Senior Vice President & General Counsel
Benjamin Moore & Co.

Joseph Wayland
Executive Vice President and General Counsel
Chubb Limited

Lisa M. Floro
Vice President, General Counsel, Interventional Urology
Coloplast Corp.

Gina Gervino
Sr. Vice President, Secretary & General Counsel
Columbia Insurance Group

Thomas J. Reid
Senior Executive Vice President, General Counsel, and Secretary
Comcast Corporation

Jim Kraus
SVP, General Counsel & Secretary, Legal
Crum & Forster

Jean F. Holloway, Esq.
Senior Vice President, General Counsel, Chief Compliance Officer and Corporate Secretary
CryoLife, Inc.

Amy Wilson
General Counsel and Corporate Secretary
Dow Inc.

Michael L. Bell
Senior Assistant General Counsel – Litigation
Electrolux North America, Inc.

Doug Lampe
Counsel
Ford Motor Company

Mary F. Riley
Vice President, Litigation
Genentech, Inc.

James R. Ford
Senior Vice President and General Counsel
GlaxoSmithKline LLC

Kent Walker
Senior Vice President, Global Affairs and Chief Legal Officer
Google LLC

Anne Madden
Senior Vice President and General Counsel
Honeywell International Inc.

Thomas N. Vanderford, Jr.
Associate General Counsel, Executive Director, Litigation
Hyundai Motor America

Buren E. Jones
Vice-President, General Counsel and Corporate Secretary
Indiana Farmers Insurance

Michael H. Ullmann
Executive Vice President, General Counsel
Johnson & Johnson

Thomas C. Evans
Executive Vice President, Secretary and General Counsel
Kemper Corporation

James Kelleher
Chief Legal Officer
Liberty Mutual Insurance

Richard Grinnan
Senior Vice President, Chief Legal Officer and Secretary
Markel Corporation

Cheryl Matricciani
Chief Operating Officer
Medical Mutual Liability Insurance Society of Maryland

Brad Lerman
Senior Vice President, General Counsel and Corporate Secretary
Medtronic

Jennifer Zachary
Executive Vice President and General Counsel
Merck & Co., Inc.

Dev Stahlkopf
Corporate Vice President and General Counsel
Microsoft Corporation

Elizabeth McGee
General Counsel
Novartis Pharmaceuticals Corporation

Doug Lankler
Executive Vice President and General Counsel
Pfizer

Brian P. Roche
General Counsel
Riddell, Inc.

Richard J. Fabian
Executive Vice President, General Counsel, and Chief Strategy Officer
RiverStone Resources

Edward W. Moore
Senior Vice President, General Counsel and Chief Compliance Officer
RPM International Inc.

Catheryn A. O'Rourke
Chief Legal and Compliance Officer
Smith + Nephew

Michael Flemming
Chief Legal Officer
Smithfield Foods

Steve McManus
Senior Vice President and General Counsel
State Farm Mutual Automobile Insurance Company

Norv McAndrew
SVP and General Counsel, Global Litigation
Teva Pharmaceuticals

Lawrence La Sala
VP and Deputy General Counsel – Litigation
Textron Inc.

Scott P. Rowe
General Counsel
Tower Hill Insurance

Sandra Phillips Rogers
Group Vice President, General Counsel, Chief Legal Officer and Chief Diversity Officer
Toyota Motor North America, Inc.

Richard N. Bland
Vice President, General Counsel & Secretary
Vermont Mutual Insurance Group

Elena Kraus
Senior Vice President and General Counsel
Walgreen Co.

Kyle P. De Jong
Assistant General Counsel, Global Disputes
Whirlpool Corporation

Laura J. Lazarczyk, FIP
Executive Vice President, Chief Legal Officer & Corporate Secretary
Zurich North America

WASHINGTON LEGAL FOUNDATION
2009 MASSACHUSETTS AVENUE, N.W.
WASHINGTON, D. C. 20036
202 588-0302
www.wlf.org

March 12, 2020

Rebecca A. Womeldorf, Secretary
Committee on Rules of Practice and Procedure
Administrative Office of the United States Courts
One Columbus Circle, NE
Washington, D.C. 20544

Re: Amending Federal Rule of Evidence 702 to Clarify Courts' "Gatekeeping" Obligation

Dear Ms. Womeldorf:

Washington Legal Foundation (WLF) writes to request that you share the attached WLF Legal Studies Division publications with the members of the Advisory Committee on Evidence Rules. As these publications showcase, many federal courts have eroded the effectiveness of Federal Rule 702 and ignored the principles the U.S. Supreme Court set out for expert evidence in *Daubert*, *Joiner*, and *Kumho Tire*. This disparity deprives the civil-justice system and its stakeholders of the clarity and consistency sought by the Committee on Rules of Practice and Procedure when it promulgated Rule 702.

The first WLF WORKING PAPER, ***Weight of the Evidence: A Lower Expert Evidence Standard Metastasizes in Federal Courts*** by attorney Lawrence A. Kogan, highlights the growing acceptance of an inherently unreliable method for reaching scientific or technical conclusions on causation. The First Circuit became the first court to accept this methodology in *Milward v. Acuity Special Products Group, Inc.* The court held that testimony developed through a weighing of multiple lines of evidence and an application of the "Bradford Hill criteria" was admissible. This "weight-of-the-evidence" methodology applies non-traditional abductive reasoning and places too much discretion in the expert witness's hands to pick and choose data to evaluate.

Before *Milward*, some federal appeals courts and even the Second Edition of the Federal Judicial Center's (FJC) respected *Reference Manual on Scientific Evidence* recognized the pitfalls of finding weight-of-the-evidence a reliable methodology for developing expert testimony. But within six months of *Milward*'s release, the FJC reversed course and endorsed weight-of-the-evidence as acceptable in its manual's Third Edition. As the WORKING PAPER documents through extensive case analysis, federal courts are increasingly following *Milward*'s and the FJC's lead, admitting testimony derived from abductive reasoning.

Mr. Kogan argues that the *Reference Manual*'s Third Edition has in effect changed the way that judges conduct their review of expert evidence, usurping the role of the Committee on Rules of Practice and Procedure. As a result, some courts are exposing juries to unreliable expert evidence, an outcome that can have devastating consequences for defendants, especially those in mass-tort litigation.

The second WLF WORKING PAPER is ***Inconsistent Gatekeeping Undercuts the Continuing Promise of* Daubert**, written by Joe G. Hollingsworth and Mark A. Miller. The authors point to examples such as a California-based federal district court judge's *Daubert* decision in glyphosate products-liability litigation as support for their conclusion that gatekeeping isn't being performed consistently. Along with detailing deviations from *Daubert* in Ninth Circuit trial courts, the paper provides examples from courts in other circuits, including the Sixth and the Eleventh.

The Advisory Committee on Evidence Rules takes an understandably cautious approach to amending federal rules of evidence. As the March 2, 2020 letter from 50 corporate chief legal officers noted, the Committee acts "to clarify rather than change standards" and to "address problems of adherence to, rather than understanding of, the rule." The WORKING PAPER by Kogan makes the case that judicial decisions, following the lead of a highly respected *Reference Manual* published for (and by) the judiciary, has in effect changed the Rule 702 standard. The Hollingsworth and Miller WORKING PAPER notes instances in which courts have failed to adhere to rule.

We encourage the Advisory Committee on Evidence Rules to consider the information and analysis in these educational papers when weighing whether to formally amend Rule 702.

Thank you for your consideration.

Sincerely,

(b)(6) per EOUSA

Glenn G. Lammi
Chief Counsel, Legal Studies Division

Attachments

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Critical Legal Issues: WORKING PAPER SERIES

WEIGHT OF THE EVIDENCE:
A LOWER EXPERT EVIDENCE STANDARD METASTASIZES IN FEDERAL COURTS

By

Lawrence A. Kogan
The Kogan Law Group, P.C.

Washington Legal Foundation
Critical Legal Issues WORKING PAPER Series

Number 215
March 2020

TABLE OF CONTENTS

ABOUT OUR LEGAL STUDIES DIVISION

Since 1986, WLF's Legal Studies Division has served as the preeminent publisher of persuasive, expertly researched, and highly respected legal publications that explore cutting-edge and timely legal issues. These articles do more than inform the legal community and the public about issues vital to the fundamental rights of Americans—they are the very substance that tips the scales in favor of those rights. Legal Studies publications are marketed to an expansive audience, which includes judges, policymakers, government officials, the media, and other key legal audiences.

The Legal Studies Division focuses on matters related to the protection and advancement of economic liberty. Our publications tackle legal and policy questions implicating principles of free enterprise, individual and business civil liberties, limited government, and the rule of law.

WLF's publications target a select legal policy-making audience, with thousands of decision makers and top legal minds relying on our publications for analysis of timely issues. Our authors include the nation's most versed legal professionals, such as expert attorneys at major law firms, judges, law professors, business executives, and senior government officials who contribute on a strictly *pro bono* basis.

Our eight publication formats include the concise COUNSEL'S ADVISORY, succinct LEGAL OPINION LETTER, provocative LEGAL BACKGROUNDER, in-depth WORKING PAPER, topical CIRCULATING OPINION, informal CONVERSATIONS WITH, balanced ON THE MERITS, and comprehensive MONOGRAPH. Each format presents single-issue advocacy on discrete legal topics.

In addition to WLF's own distribution network, full texts of LEGAL OPINION LETTERS and LEGAL BACKGROUNDERS appear on the LEXIS/NEXIS® online information service under the filename "*WLF*," and every WLF publication since 2002 appears on our website at www.wlf.org. You can also subscribe to receive select publications at www.wlf.org/subscribe.asp.

To receive information about WLF publications, or to obtain permission to republish this publication, please contact Glenn Lammi, Chief Counsel, Legal Studies Division, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, DC 20036, (b)(6) per EOUSA, (b)(6) per EOUSA.

ABOUT THE AUTHOR

Lawrence A. Kogan is an international business, trade, and regulatory attorney and founder of the Kogan Law Group, P.C., a multidisciplinary legal services firm assisting U.S. and non-U.S.-based public and private enterprises. He also directs the Princeton, N.J.-based Institute for Trade, Standards and Sustainable Development, Inc. (ITSSD, www.itssdusa.org). Mr. Kogan has served as an Adjunct Professor of International Trade Law at the John C. Whitehead School of Diplomacy and International Relations at Seton Hall University, South Orange, New Jersey.

ABSTRACT

U.S. Supreme Court precedent and federal evidentiary rules require litigants to demonstrate that the evidence their expert presents is both "reliable" and "relevant." In order for the evidence to be reliable and thus admissible, the Court stressed in its seminal 1993 *Daubert* decision that the analytical methodology the expert employs must itself be reliable. Contrary to this guidance, in 2011 a federal appeals court permitted a plaintiff's expert to utilize an inherently unreliable methodology to conclude that a specific chemical could generally cause cancer. The First Circuit held in *Milward v. Acuity Special Products Group, Inc.* that testimony developed through a weighing of multiple lines of evidence and an application of the "Bradford Hill criteria" was admissible. This "weight-of-the-evidence" methodology applies non-traditional abductive reasoning and places a great deal of discretion in the expert witness's hands to pick and choose data to evaluate. Regulators, whose role is to identify possible risks and act preventatively in the "public interest," favor weight-of-the-evidence when assessing studies for the methodology's pliability.

Prior to *Milward*, some federal appeals courts and even the Second Edition of the Federal Judicial Center's (FJC) respected *Reference Manual on Scientific Evidence* recognized the pitfalls of finding weight-of-the-evidence a reliable methodology for developing expert testimony. But within six months of *Milward*'s release, the FJC reversed course and endorsed weight-of-the-evidence as acceptable in its manual's Third Edition. As this WORKING PAPER documents through extensive case analysis, federal courts are increasingly following *Milward*'s and the FJC's lead, admitting testimony derived from abductive reasoning. This development allows judges to take precautionary action as if it were a regulator, and also rewards plaintiffs whose claims are suspect. The WORKING PAPER urges practitioners, policymakers, and the federal judiciary to contemplate where this drift away from reliable scientific and technical evidence is leading, and sets out options for a return to the rigorous judicial gatekeeping *Daubert* demands.

WEIGHT OF THE EVIDENCE:
A LOWER EXPERT EVIDENCE STANDARD METASTASIZES IN FEDERAL COURTS

In *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 589 (1993), the United States Supreme Court held that trial court judges are effectively "gatekeepers" for the admissibility of expert testimony, and that they should not admit testimony from a "qualified" expert unless they determine that it is both "reliable" *and* "relevant."

Eighteen years later, in *Milward v. Acuity Special Products Group, Inc.* 639 F.3d 11 (1st Cir. 2011), the U.S. Court of Appeals for the First Circuit held that the "weight-of-evidence," inference-to-the-best-explanation methodology is a scientifically *reliable* basis for establishing general causation in toxic tort/product liability litigation. Expert evidence that survives a court's weight-of-the-evidence review, therefore, is admissible under Federal Rule of Evidence ("FRE") 702 and the U.S. Supreme Court's decisions in *Daubert*, *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). *Milward* was a negligence (toxic tort) case involving allegations that plaintiff's routine workplace exposure to benzene-containing products caused his rare type of leukemia.

Within six months of the First Circuit's March 22, 2011 *Milward* decision, the Federal Judicial Center ("FJC") released the Third Edition of its *Reference Manual on Scientific Evidence*. Established in 1967,[1] the FJC has served as "the research and education agency of the judicial branch of the U.S. government."[2] The Third Edition *Reference Manual* reverses the Second Edition's admonition that federal trial courts avoid the pitfalls of admitting expert testimony based on weight-of-the-evidence methodology. According to legal commentators, the *Milward* decision narrowed the scope of federal district courts' evidentiary gatekeeping role under FRE 702 and *Daubert*.[3]

This WORKING PAPER highlights for practitioners and policymakers the extent to which the FJC's *Reference Manual* has encouraged a growing number of federal trial court judges to lower the standard for admitting scientific and technical evidence into the judicial record based on its *reliability*. The *Reference Manual* describes this lower evidentiary standard for reliability as one that sanctions the admissibility of evidence that "contributes to the weight

[1] *See* 28 U.S.C. §§ 620–29.

[2] *See* Federal Judicial Center, https://www.fjc.gov/; 28 U.S.C. § 620(b)(3).

[3] *See* David E Bernstein and Eric G. Lasker, *Defending* Daubert*: It's Time to Amend Federal Rule of Evidence 702*, 57 WM & MARY L. REV. 1, 5 (2015), https://scholarship.law.wm.edu/wmlr/vol57/iss1/2 (discussing how, in *Daubert*, "the Court insisted that trial court judges adopt 'a gatekeeping role' to 'ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.' 509 U.S. at 596. The Court emphasized that Rule 702 'requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.' 509 U.S. at 592. And the Court explained that under the Federal Rules, a trial judge 'exercises more control over experts than over lay witnesses.' 509 U.S. at 595.").

of evidence supporting causal inferences" that an agent can cause a specific disease.[4] It is analogous to the "hazard identification process [which] often uses 'weight of evidence' approaches in which the toxicological, mechanistic, and epidemiological data are rigorously assessed to form a judgment regarding the likelihood that the agent produces a specific effect."[5] "Determinations about cause-and-effect relations by regulatory agencies often depend upon expert judgment exercised by assessing the weight of evidence."[6] The problem with this approach, however, is that it relies on the use of *subjectively* "weighted" inferences of general causation that can be based on unvalidated and unverifiable scientific/technical theories that otherwise would fail to meet the rigorous minimal reliability standards the Supreme Court imposed through *Daubert* and its progeny. This paper also tracks and analyzes instances where U.S. district and appellate courts have employed this lower reliability standard first articulated in *Milward*.

I. NARROWING COURTS' "GATEKEEPER" ROLE BY LOWERING THE EVIDENTIARY THRESHOLD

In *Daubert*, the Supreme Court held that, in order to determine whether proffered testimony constitutes scientific knowledge that would assist the trier of fact to understand or determine a fact in issue, the trial court must preliminarily assess "whether the reasoning or methodology underlying the testimony properly can be applied to the facts in issue."[7] According to the Court, although the assessment is a flexible one, it ultimately engenders a determination of whether: 1) the scientific methodology can be or has been tested, refuted and/or falsified; 2) the theory, technique, or methodology has been subject to peer review and publication, which is relevant but not dispositive of its validity; 3) the specific scientific technique has a known or potential rate of error, and there are existing and maintained standards controlling the technique's operation; and 4) the degree of general acceptance of the methodology or reasoning within the relevant scientific community.[8]

The *Milward* court, however, cleverly went beyond the accepted methodology by which scientific and technical evidence may be determined "relevant" and "reliable" within the meaning of FRE 702 and *Daubert*. By expanding the scope of the logical reasoning process against which the *Daubert* reliability test could be applied (*i.e.*, beyond classical deductive and inductive reasoning), in *apparent* consistency with the Court's holding in *Joiner*,[9] the *Milward* court indirectly diminished the "exacting standards of reliability"[10] for, and thereby,

[4] *See* Federal Judicial Center and National Research Council of the National Academies, *Reference Manual on Scientific Evidence—Third Edition* ("*Third Edition*") (2011), https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf, at 637.

[5] *Id*. at 651.

[6] *Id*. at 660.

[7] *Daubert*, 509 U.S. at 593.

[8] *Id*. at 593-94.

[9] Bernstein and Lasker, *supra* note 3, at 6 (discussing how *Joiner* had held *inter alia* that the *Daubert* "reliability test may be applied to an expert's *reasoning process*, not just to his general methodology") (emphasis added).

[10] *See Weisgram v. Marley Co*., 528 U.S. 440, 455 (2000).

the quality of, the scientific, technical, and other expert knowledge-based testimony[11] admissible at trial in traditional tort action areas to establish general causation.

Significantly, the *Milward* court found as generally reliable the application of the Bradford Hill criteria, a method that employs "abductive" reasoning through subjective interpretations of general causation based on a weighing of multiple lines of evidence revealing semi-quantitative and qualitative "associations" that may potentially lead to the "best explanation in which the conclusion is not guaranteed by the premises."[12] According to the First Circuit, abductive reasoning is unlike both deductive and inductive reasoning, insofar as it focuses not on probabilities, but on plausibilities/*possibilities*.

> This *'weight of the evidence'* approach to making causal determinations involves a mode of logical reasoning often described as *'inference to the best explanation,'* in which the conclusion is not guaranteed by the premises [fn…] *Unlike a logical inference made by deduction* where one proposition can be logically inferred from other known propositions, *and unlike induction* where a generalized conclusion can be inferred from a range of known particulars, *inference to the best explanation—or 'abductive inferences'*—are drawn about a particular proposition or event by a process of eliminating all other *possible* conclusions to arrive at the most likely one, the one that best explains the available data.[13]

Arguably, the *Milward* court found the Bradford Hill methodology generally acceptable for purposes of determining general causation[14] because, as the court observed, "'[g]eneral causation' exists when a substance is capable of causing a disease."[15] In other words, to establish *general* causation, one must show the association is merely plausible or possible, whereas, "'[s]pecific causation' exists when exposure to an agent caused a particular plaintiff's disease."[16]

The *Milward* court's acceptance of Bradford Hill as generally reliable for establishing general causation, presumably, was based on its requirement that *all* nine of its criteria[17]

[11] *See Kumho Tire Co.*, 526 U.S. at 147-49.

[12] *See Milward*, 639 F.3d at 17, citing *Bitler v. AO Smith Corp.*, 391 F.3d 1114, 1124 n. 5 (10th Cir. 2004).

[13] *Id*. at 17 n. 7, quoting *Bitler*, 391 F.3d at 1124, n. 5 (emphasis added).

[14] The *Milward* court ultimately reversed the district court's exclusion of expert general causation testimony based on the weight-of-evidence, inference-to-the-best-explanation methodology. *Id*. at 14.

[15] *Milward*, 639 F.3d at 13, quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(3) (2010).

[16] *Id*. at 13, quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(4) (2010).

[17] These nine criteria are: 1) "the strength or frequency of the association"; (2) "the consistency of the association in varied circumstances"; (3) "the specificity of the association"; (4) the temporal relationship between the disease and the posited cause"; (5) "the dose response curve between them"; (6) "the biological plausibility of the causal explanation given existing scientific knowledge"; (7) "the coherence of the explanation with generally known facts about the disease"; (8) "the experimental data that relates to it"; and (9) "the existence of analogous causal relationships." *Milward*, 639 F.3d at 17, citing Arthur Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. ROYAL SOC'Y MED. 295-99 (1965).

must be considered *before* "an observed association between a disease and a feature of the environment (*e.g.*, a chemical)" can be deemed causal.[18] However, the *Milward* court then arbitrarily dispensed with the need to establish all nine criteria, citing to the testimony of a philosophy of science professor who claimed that courts need only consider six factors when utilizing a weight-of-the-evidence methodology. These six steps are: (1) "identify[ing] an association[s] between exposure and a disease"; (2) "consider[ing] a range of plausible explanations for the association[s]"; (3) "rank[ing] the rival explanations according to their plausibility"; (4) "seek[ing] additional evidence to separate the more plausible from the less plausible explanations"; (5) "consider[ing] all of the relevant available evidence"; and (6) "integr[ating] the evidence using professional judgment to come to a conclusion about the best explanation."[19]

The court in *Milward* apparently believed that "the use of scientific judgment is necessary" with weight-of-evidence-based abductive reasoning, since "[n]o algorithm exists for applying the Hill guidelines to determine whether an association truly reflects a causal relationship or is spurious."[20] And, "[b]ecause '[n]o scientific methodology exists for this process … reasonable scientists may come to different judgments about whether such an inference is appropriate,'" ultimately, for specific causation purposes.[21] Indeed, the court reasoned that, while "the role of judgment in the weight of evidence approach is more readily apparent than it is in other methodologies," it does not render this approach "any less scientific," because "an evaluation of data and scientific evidence to determine whether an inference of causation is appropriate requires judgment and interpretation."[22]

The First Circuit, therefore, rejected defendants' assertion that a pure weight-of-the-evidence approach like that which plaintiff's expert witness had employed was inherently unreliable as a matter of science and contrary to *Daubert*. Instead, the court held that "admissibility must turn on the particular facts of the case"—*i.e.*, on whether the expert, in reaching his opinion, "applied the methodology with 'the same level of intellectual rigor' that he used in his scientific practice."[23]

[18] *Milward*, 639 F.3d at 17. *See accord*, *In re Mirena IUS Levonorgestrel-Related Products Liability Litigation* (MDL No. II), 341 F. Supp. 3d 213, 242 (S.D.N.Y. 2018) (discussing how epidemiologists "'start with an association demonstrated by epidemiology and then apply' eight or nine criteria to determine whether that association is causal."); *Fecho v. Eli Lilly and Company*, Civ. No. 1-10152-MBB (D. Mass. 2012), slip op. at 1, citing *Milward*, 639 F.3d at 17-19 (where the district court "[r]ecogniz[ed] that an observed association between a disease, in this instance, breast cancer, and in utero exposure to DES does not, without more, creation causation…").

[19] *Milward*, 639 F. 3d at 17-18.

[20] *Id*. at 18, quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(3) (2010).

[21] *Id*., quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(4) (2010).

[22] *Id*., quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(1) (2010).

[23] *Id*. at 18-19, citing *Kumho Tire*, 526 U.S. at 152.

II. FJC ELEVATES REGIONAL *MILWARD* OPINION TO NATIONAL PROMINENCE

The FJC's release of its *Reference Manual on Scientific Evidence*, Third Edition, within months of *Milward*, merits examination. Absent FJC's frequent references to *Milward* in the Third Edition, the decision's influence would likely have been limited to those district courts in the First Circuit bound to apply it as binding precedent. FJC's imprimatur, however, signaled to federal judges beyond the First Circuit that they consider interpreting FRE 702 in a substantively different manner than recommended in the *Reference Manual*'s Second Edition.

The process of substantively amending a Federal Rule of Evidence ordinarily would take place under the auspices of the Judicial Conference of the United States, which is the federal courts' national policy-making body.[24] "The Conference operates through a network of committees created to address and advise on a wide variety of subjects,"[25] including its Advisory Committee on Rules of Evidence.[26] From 2007 through 2010, the meeting agendas of the Advisory Committee on Rules of Evidence indicated that the committee had begun a project to "restyle" the FRE.[27] This effort did *not*, however, reflect that the Committee had proposed or finalized any *substantive* amendment(s) to FRE Rule.[28] As the 2009 and 2010 meeting agendas stated:

> The language of 702 has been amended as part of the restyling of the Evidence Rules to make them more easily understood and to make style and terminology consistent throughout the rules. These changes are intended to by stylistic only. *There is no intent to change any result in any ruling on evidence admissibility*.[29]

[24] *See* United States Courts, *Governance & the Judicial Conference*, https://www.uscourts.gov/about-federal-courts/governance-judicial-conference.

[25] *Id*.

[26] *See* Federal Judicial Center, *Judicial Conference of the United States: Committees (Alphabetical)*, https://www.fjc.gov/history/administration/judicial-conference-united-states-committees-alphabetical (under "Committee on Rules of Practice and Procedure, 1958-present").

[27] *See* United States Courts, *Advisory Committee on Evidence Rules–Agenda for Committee Meeting* (11-16-07), at II, at 1, 22, https://www.uscourts.gov/sites/default/files/fr_import/EV2007-11.pdf; United States Courts, *Advisory Committee on Evidence Rules–Agenda for Committee Meeting* (Oct. 23-24, 2008), at 1, 113, https://www.uscourts.gov/sites/default/files/fr_import/EV2008-10.pdf; United States Courts, *Advisory Committee on Evidence Rules–Agenda for Committee Meeting* (Nov. 20, 2009), Committee Note at 229, https://www.uscourts.gov/sites/default/files/fr_import/EV2009-11.pdf; United States Courts, *Advisory Committee on Evidence Rules–Agenda for Committee Meeting* (Oct. 12, 2010), Committee Note at 252, https://www.uscourts.gov/sites/default/files/fr_import/EV2010-10.pdf.

[28] *See* United States Courts, *Advisory Committee on Evidence Rules–Agenda for Committee Meeting* (Nov. 20, 2009), *supra*, I at 2-3; United States Courts, *Advisory Committee on Evidence Rules–Agenda for Committee Meeting* (Oct. 12, 2010), *supra* II at 1, II at 2-3.

[29] *See* United States Courts, *Advisory Committee on Evidence Rules–Agenda for Committee Meeting* (Nov. 20, 2009), *supra*, Committee Note at 229; United States Courts, *Advisory Committee on Evidence Rules–Agenda for Committee Meeting* (Oct. 12, 2010), *supra*, Committee Note at 252 (emphasis added).

Indeed, the 2010 meeting agenda of the Advisory Committee on Rules revealed that, "to determine whether any proposed change [to the Federal Rules of Evidence] was one of substance rather than style," it had defined the term "substance" as "changing an evidentiary result *or method of analysis*, or changing language that is so heavily engrained in the practice as to constitute a 'sacred phrase.'"[30] The Judicial Conference ultimately approved and finalized the committee's proposed stylistic changes to FRE 702 on April 26, 2011, and such changes became effective on December 1, 2011.[31]

Very recently, members of the Advisory Committee on Evidence Rules began seeking stakeholder input on a substantive amendment to FRE 702 "to address 'overstatement' by expert witnesses, which occurs when an expert expresses a degree of confidence that cannot be supported by the expert's principles and methods."[32] The proposed amendment would assume the form of an additional Rule 702 admissibility factor: "'(e) the expert does not claim a degree of confidence that is unsupported by a reliable application of the principles and methods.'"[33]

The FJC's *Reference Manual on Scientific Evidence* is entirely separate from the formal evidentiary rulemaking process. It is a compilation of separately authored articles or manuals. The FJC published the first edition in 1994, "at a time of heightened need for judicial awareness of scientific methods and reasoning created by the Supreme Court's decision in *Daubert* […]."[34] The second edition was published in 2000, following the Supreme Court's 1997 and 1999 decisions in *Joiner* and *Kumho Tire*, and after Advisory Committee on Evidence Rules' submission to Congress of "proposed amendments to Federal Rules of Evidence, 701, 702 and 703 that [were] intended to codify case law that [was] based on *Daubert* and its progeny."[35]

The FJC released the Third Edition on September 28, 2011[36] in conjunction with the National Research Council ("NRC"). The Third Edition arguably reflects a more confident tone and attitude of the authors and of the FJC toward the reliability, and thus, the admissibility of expert testimony based on witnesses' use of subjective weight-of-the-evidence methodology to infer general causation from multiple lines of individually non-definitive evidence.

[30] *Id*. at II at 2 (emphasis added).

[31] *See* The Committee on the Judiciary, House of Representatives, *Federal Rules of Evidence* (Dec. 1, 2014), at FRE Rule 702, https://www.uscourts.gov/sites/default/files/Rules%20of%20Evidence.

[32] *See* Alex Dahl, *Expert Evidence Standards Under Review: Committee Considers Possible Amendments to Rule FRE 702*, WLF COUNSEL'S ADVISORY, Vol. 27 No. 4 (Oct. 25, 2019), at 1, https://www.wlf.org/wp-content/uploads/2019/10/10252019CA_Dahl.pdf.

[33] *Id*.

[34] *See* Federal Judicial Center, *Reference Manual on Scientific Evidence, Second Edition* ("*Second Edition*") (2000), at v, https://nebula.wsimg.com/518f91b5b8b66fb3d91297f6e5436067?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[35] *Id*. at vi.

[36] *Third Edition*, *supra* note 4.

A. Second Edition Cautious about Admissibility of Expert Opinion Based on Inferences of Causation

The Second Edition, by contrast, stated that, "[i]n toxic tort cases in which the causal mechanism is unknown, establishing causation means providing scientific evidence from which an inference of cause and effect may be drawn."[37] It noted how "numerous unresolved issues [remained] about the relevancy and reliability of the underlying hypotheses that link the evidence to the inference of causation."[38]

The Second Edition discussed how Justice Stevens, in *Joiner*, would "have found no abuse of discretion had the district court admitted expert testimony based on a methodology used in risk assessment, *such as weight-of-evidence methodology* (on which the plaintiff's expert claimed to rely), which pools all available information from many different kinds of studies, taking the quality of the studies into account."[39] The Second Edition also discussed how some had found the "pooling of results of epidemiological studies in a meta-analysis unreliable when used in connection with observational studies," and regarding how it was even more controversial to combine studies across different fields.[40] In addition, the Second Edition stated that although a court might not object to a particular methodology's relevance in proving causation, it may disagree with how that methodology was applied in the particular case: "As the Supreme Court said in *Joiner*, 'nothing … requires a district court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert.'"[41]

Furthermore, the Second Edition concluded that although "inferences based on well-executed randomized experiments are more secure than inferences based on observational studies,"[42] the "bulk of statistical studies seen in court are observational, not experimental."[43] To this end, the Second Edition emphasized that associations inferred from observation are not causation (*i.e.*, "association is not causation"), and consequently, that "the causal inferences that can be drawn from such analyses rest on a less secure foundation than that provided by a randomized controlled experiment."[44]

The Second Edition emphasized that the "inferences that may be drawn from a study depend on the quality of the data and the design of the study."[45] And, statistical inference

[37] *See* Margaret A. Berger, The Supreme Court's Trilogy on the Admissibility of Expert Testimony, at 32, in *Second Edition*, *supra* note 34.

[38] *Id*.

[39] *Id.* at 32-33, referencing Justice Steven's partial concurrence and dissent in *Joiner*, 522 U.S. at 150-53. The Second Edition even referenced in a footnote a 1996 article authored by Carl F. Cranor, an advocate of the weight-of-evidence methodology. (emphasis added). *See id*. at n. 123, at 33.

[40] *Id*. at 33.

[41] *Id*.

[42] *See* David H. Kaye and David A. Freedman, *Reference Guide on Statistics*, at 93, in *Second Edition*, *supra* note 34.

[43] *Id*. at 94.

[44] *Id*.

[45] *Id.* at 115.

derived from valid statistical models for the data collected on the basis of a probability sample or randomized experiment will be more secure than inference derived from statistical calculations based on analogy.[46] The Second Edition also warned that "[a] correlation between two variables does not imply that one event causes the second. Spurious correlation arises when two variables are closely related but bear no causal relationship because they are both caused by a third, unexamined variable."[47] Moreover, it stated that *"[c]ausality cannot be inferred by data analysis alone*; rather, one must infer that a causal relationship exists on the basis of an underlying causal theory that explains the relationship between the two variables. […] One must also look for empirical evidence that there is a causal relationship."[48]

The Second Edition further discussed how toxicological and epidemiological evidence are used. Toxicological evidence (based on *in vivo* animal exposure/testing of chemicals, or *in vitro* animal/human cell or tissue exposure/testing of chemicals) is used, for example, to refute allegations of *specific* causation (*i.e.*, caused plaintiff's alleged disease or injury) in toxic tort litigation, and to refute allegations of *general* causation (*i.e.*, exposure effects on populations) in regulatory litigation.[49] It noted that "animal toxicological evidence often provides the best scientific information about the risk of disease [to humans] from a chemical exposure."[50] According to the Second Edition, "proffered toxicological expert opinion on potentially cancer-causing chemicals almost always is based on a review of research studies that extrapolate from [*in vivo*] animal experiments involving doses significantly higher than that to which humans are exposed."[51] While "[s]uch extrapolation is accepted in the regulatory arena," it is *not* so accepted in toxic tort cases, where "experts often use additional background information [statistical bases] to offer opinions about disease causation and risk."[52] The reliability of *in vitro* testing/exposure is usually determined by reference to established laboratory protocols.[53]

Finally, the Second Edition noted how both epidemiology ("the study of the incidence and distribution of disease in human populations") and toxicology ("the study of the adverse effects of chemicals in living organisms") help to elucidate "the causal relationship between chemical exposure and disease." Yet, it admonished readers that, while "courts generally rule

[46] *Id*. at 117.

[47] *See* Daniel L. Rubinfeld, *Reference Guide on Multiple Regression*, at 184, in *Second Edition*, *supra* note 34 ("Multiple regression analysis is a statistical tool for understanding the relationship between two or more variables. Multiple regression involves a variable to be explained – called the dependent variable – and additional explanatory variables that are thought to produce or be associated with changes in the dependent variable. […] Multiple regression is sometimes well suited to the analysis of data about competing theories to which there are several possible explanations for the relationship among a number of explanatory variables. […] Multiple regression also may be useful (1) in determining whether a particular effect is present; (2) in measuring the magnitude of a particular effect; and (3) in forecasting what a particular effect would be, for but for an intervening event."). *Id*. at 181.

[48] *Id*. at 184-85 (emphasis added)..

[49] *See* Bernard D. Goldstein and Mary Sue Henifin, *Reference Guide on Toxicology*, at 404-05, in *Second Edition*, *supra* note 34.

[50] *Id*. at 405.

[51] *Id.* at 409.

[52] *Id*.

[53] *Id*. at 410.

epidemiological expert opinion admissible […where "relevant epidemiological research data exists"…], admissibility of toxicological expert opinion has been more controversial because of uncertainties regarding extrapolation from animal and in vitro data to humans."[54] The Second Edition still noted that, "there is far more information from toxicological studies than from epidemiological studies … even for cancer causation."[55]

B. Third Edition Promotes Admissibility of Expert Opinion Based on Inferences of Causation Using a Weight-of-the-Evidence Approach

The Third Edition emphasized that Justice Stevens, in his partial concurrence and dissent in *Joiner*, had "assumed that the plaintiff's expert was entitled to rely on epidemiological studies showing "a link between PCBs and cancer if the results of all the studies were pooled, and [consequently,] that this weight-of-the-evidence methodology was reliable." [56] The Third Edition also noted how, unlike the atomized "slicing and dicing approach" the majority in *Joiner* had taken by examining the reliability of each individual study independently, "scientific inference typically requires consideration of numerous findings, which, when considered alone, may not individually prove the contention."[57] In partial support of this proposition, it cites *Milward* ("reversing the district court's exclusion of expert testimony based on an assessment of the direct causal effect of the individual studies, finding that the *'weight of the evidence'* properly supported the expert's opinion that exposure to benzene can cause acute promyelocytic leukemia."). In other words, the Third Edition embraced the *Milward* court's admission of expert opinion to establish general causation.[58]

The Third Edition emphasized generally that "[i]n applying the scientific method, scientists do not review each scientific study individually for whether by itself it reliably supports the causal claim being advocated or opposed. Rather, […] 'summing, or synthesizing, data addressing different linkages [between kinds of data] forms a more complete causal evidence model and can provide the biological plausibility needed to establish the association' being advocated or opposed."[59]

The Third Edition cleverly departed from the Second Edition by noting that, while trial judges possess the discretion "to choose an atomistic approach" to evaluate available studies individually, "[s]ome judges have found this practice contrary to that of scientists who look at knowledge incrementally, especially considering that "there are no hard-and-fast scientific rules for synthesizing evidence."[60] The Third Edition cited two federal court decisions as support for this proposition. In the first case, *In re Ephedra*, 393 F. Supp. 2d 181, 190 (S.D.N.Y.

[54] *Id.* at 403, 413-14.
[55] *Id*. at 414.
[56] *See* Margaret A. Berger, *The Admissibility of Expert Testimony*, at 15-16, in *Third Edition*, *supra* note 4.
[57] *Id*. at 19-20.
[58] *Id*. at 20, n. 51 (emphasis added).
[59] *Id*. citing n. 52.
[60] *Id.* at 23.

2005), a New York federal district court admitted (and thus dismissed the notion that *Daubert* had precluded) a scientific expert's testimony regarding "the scientific plausibility of a particular hypothesis of causality or even to the fact that a confluence of suggestive, though non-definitive, scientific studies make it more-probable-than-not that a particular substance (such as ephedra) contributed to a particular result (such as a seizure)."[61] The second case cited was *Milward*.[62]

The Third Edition, like the Second Edition, discusses the usefulness of toxicological studies, "which are [often] the only or best available evidence of toxicity," given the limited availability of epidemiological studies. "Epidemiological studies are difficult, time-consuming, expensive, and […] virtually impossible to perform," and "do not exist for a large array of environmental agents."[63] However, unlike the Second Edition, the Third Edition omits reference to the controversy surrounding the admissibility into evidence of toxicological opinions based on extrapolated *in vivo* and *in vitro* study data.

The Third Edition, instead, hedges about how there are "no universal rules for how to interpret or reconcile" animal toxicological and epidemiological studies where both are available.[64] In support of this proposition, the Third Edition cites the methodology of the International Agency for Research on Cancer (IARC), which synthesizes and evaluates, in the *regulatory* context, "all the relevant evidence, including animal studies as well as any human studies," publishes a monograph containing its evaluation and analysis, and explains that, "[s]olely on the basis of the strength of animal studies, IARC may classify a substance as 'probably carcinogenic to humans.'"[65] It also cites to a presentation made at a National Cancer Institute symposium "concluding that, 'There should be no hierarchy [among different types of scientific methods to determine cancer causation]. Epidemiology, animal, tissue culture and molecular pathology should be seen as integrating evidences in the determination of human carcinogenicity.'"[66]

[61] In *In re Ephedra*, the district court had noted that "it is apparent that no scientific study has been conducted that 'proves' that ephedra or ephedrine 'causes' any of the listed injuries in the sense of establishing the high statistical relationship […] that meets accepted scientific standards for inferring causality. Nor, for that matter, are there studies that definitively disprove the hypothesis of causality. […However, the court held that] the absence of definitive scientific studies establishing causation […should not…] deprive a jury of having before it scientific opinions that, while less definitive and more qualified than the statistically significant scientific studies called for by [defendants' counsels], nevertheless meet scientific standards for determining the plausibility of a causal relationship. 393 F. Supp. 2d at 189-90. The court further noted that, "'gaps or inconsistencies in the reasoning leading to [the expert] opinion … go to the weight of the evidence, not to its admissibility.' […] Thus, although 'an expert's analysis [must] be reliable at every step,' *Amorgianos [v. National Railroad Passenger Corp.*,] 303 F.3d [256, 258 (2d Cir. 2002)], analogy, inference, and extrapolation can be sufficiently reliable steps to warrant admissibility so long as the gaps between the steps are not too great." *Third Edition*, *supra* note 4, at 23, n. 61.

[62] *Id*.

[63] *See* Michael D. Green, D. Michal Freedman, and Leon Gordis, *Reference Guide on Epidemiology*, at 564, in *Third Edition*, *supra* note 4.

[64] *Id*.

[65] *Id*. at ns. 48, 46 (the Third Edition n. 48 mistakenly cites n. 41 in referring to IARC).

[66] *Id*. at 564, n. 48.

The Third Edition, furthermore, devoted more than one entire page to its footnote 48 discussion of how an increasing number of federal and state courts have admitted into evidence animal studies for purposes of "proving causation in a toxic substance case." After briefly citing three cases (two state cases and one federal case) that had "take[n] a very dim view of their probative value," it emphasized how "[o]ther courts have been more amenable to the use of animal toxicology in proving causation." In particular, footnote 48 cited a 1986 Maryland federal district court decision in which "the court observed: 'There is a range of scientific methods for investigating questions of causation—for example, toxicology and animal studies, clinical research, and epidemiology—which all have distinct advantages and disadvantages."[67] The Third Edition also cited *Milward* in emphasizing how the First Circuit had "endorsed an expert's use of a *'weight-of-evidence' methodology*, holding that the district court abused its discretion in ruling inadmissible an expert's testimony about causation *based on that methodology*."[68] The Third Edition emphasized that, "[a]s a corollary to recognizing weight of the evidence as a valid scientific technique, […the [*Milward*] court noted…] the role of judgment in making an appropriate inference from the evidence," and that, "as with any scientific technique, [the weight-of-the-evidence methodology] can be improperly applied."[69]

In addition to these cases, the Third Edition's footnote 48 also cited two federal court rulings that admitted toxicological studies into evidence—*In re Heparin Prods. Liab. Litig.*, 2011 WL 2971918 (N.D. Ohio July 21, 2011) ("holding that animal toxicology in conjunction with other non-epidemiologic evidence can be sufficient to prove causation") and *Ruff v. Ensign-Bickford Indus., Inc.*, 168 F. Supp. 2d 1271, 1281 (D. Utah 2001) ("affirming animal studies as a sufficient basis for opinion on general causation"), and a third federal court decision that found the failure to admit toxicological evidence was an abuse of discretion—*Metabolife Int'l, Inc. v. Wornick*, 264 F.3d 832, 842 (9th Cir. 2001) ("holding that the lower court erred in per se dismissing animal studies, which must be examined to determine whether they are appropriate as a basis for causation determination"). Furthermore, the Third Edition quoted a 1994 Third Circuit decision—*In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717 (3d Cir. 1994)—holding animal studies admissible to prove causation in humans, provided each of the steps of an experts' analysis are found reliable.[70] Moreover, the Third Edition emphasized how the Supreme Court in *Joiner* had "*suggested that there is no categorical rule for toxicological studies, observing '[W]hether animal studies can ever be a proper foundation for an expert's opinion [is] not the issue* … The [animal] studies were so dissimilar to the facts presented in this litigation that it was not an abuse of discretion for the District Court to have rejected the experts' reliance on them.'"[71]

[67] *Id*. at 564, quoting *Marder v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1094 (D. Md. 1986), *aff'd sub nom. Wheelahan v. G.D. Searle & Co.*, 814 F.2d 655 (4th Cir. 1987).

[68] *Id*. at 565, n. 48, quoting *Milward*, 639 F.3d at 17-19 (emphasis added).

[69] *Id*. at n. 48, referencing *Milward*.

[70] *Id*. at 565, n. 48, quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 743 ("[In] order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves. Thus, the requirement of reliability, or 'good grounds,' extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case.").

[71] *Id*., quoting *General Electric Co. v. Joiner*, 522 U.S. at 144-45 (emphasis added).

In *Daubert*, the Supreme Court held that, to establish the reliability of the methodology serving as the basis of expert opinion, a party must show *inter alia* that the specific scientific technique utilized has a known or potential rate of error, and existing and maintained standards are controlling the technique's operation. The Third Edition discussed this standard in the context of epidemiological studies, noting that "epidemiologists prepare their study designs and test the plausibility that any association found in a study was the result of random error by using the null hypothesis."[72] "The null hypothesis is a statistical theory which suggests that no statistical relationship and significance exists in a set of given single observed variable, between two sets of observed data and measured phenomena."[73] "An erroneous conclusion that the null hypothesis is false (*i.e.*, a conclusion that there is a difference in risk when no difference actually exists) owing to a random error is called a false-positive error (also Type I error or alpha error)."[74]

As the Third Edition noted, epidemiologists use a *p*-value to "represent[] the probability that an observed positive association could result from random error even if no association were in fact present."[75] "*Thus*, a *p*-value of .1 means that there is a 10% chance that values at least as large as the observed relative risk could have occurred by random error, with no association actually present in the population."[76] "To minimize false positives, epidemiologists use a convention that the *p*-value must fall below some selected level known as alpha or significance level for the results of the study to be statistically significant."[77] This is known as "significance testing."

The Third Edition's *Reference Guide on Epidemiology* devoted two pages to footnote 85 to discuss the controversy among epidemiologists and biostatisticians about the appropriate role of significance testing and the "[s]imilar controversy" "among the courts that have confronted the issue of whether statistically significant studies are required to satisfy the burden of production."[78] The Third Edition related that, while "[a] number of post-*Daubert* federal courts have indicated strong support for significance testing as a[n evidentiary] screening device"[79] to determine the admissibility of testimony for general causation purposes, "a number of [other] courts are more cautious about or reject using significance testing as a necessary condition, instead recognizing that assessing the likelihood

[72] *Id*. at 574-75.

[73] *See* Science Direct, *Null Hypothesis*, https://www.sciencedirect.com/topics/earth-and-planetary-sciences/null-hypothesis.

[74] *See* Green, Freedman, and Gordis, *supra* note 63, at 576.

[75] *Id*.

[76] *Id*.

[77] *Id*.

[78] *Id*. at 578 n. 85.

[79] *Id*. (citing, quoting, and summarizing *Good v. Fluor Daniel Corp*., 222 F. Supp. 2d 1236, 1243 (E.D. Wash. 2002) ("'In the absence of a statistically significant difference upon which to opine, Dr. Au's opinion must be excluded under *Daubert*.'"); *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062, 1080 (D. Kan. 2002) ("the expert must have statistically significant studies to serve as basis of opinion on causation"); *Kelley v. Am. Heyer-Schulte Corp.*, 957 F. Supp. 873, 878 (W.D. Tex. 1997) ("the lower end of the confidence interval must be above 1.0—equivalent to requiring that a study be statistically significant—before a study may be relied upon by an expert"), appeal dismissed, 139 F.3d 899 (5th Cir. 1998).

of random error is important in determining the probative value of a study"[80]—*i.e.*, *the weight of evidence*, *not* the admissibility of evidence. It then documented in footnote 85 those pre- and post-*Daubert* federal courts that have been more cautious or have rejected significance testing as a litmus test for admissibility. These courts include a Utah federal district court,[81] the Third Circuit,[82] the Sixth Circuit,[83] a District of Columbia federal district court,[84] a Minnesota federal district court,[85] a Colorado federal district court,[86] a New York federal district court,[87] and the First Circuit with *Milward*.[88] In *Milward*, the court "recogniz[ed] the difficulty of obtaining statistically significant results when the disease under investigation occurs rarely," and it "conclude[ed] that the district court erred in imposing a statistical significance threshold."[89]

[80] *Id*.

[81] *See id.*, quoting *Allen v. United States*, 588 F. Supp. 247, 417 (D. Utah 1984) (pre-*Daubert*) ("'The cold statement that a given relationship is not 'statistically significant' cannot be read to mean there is no probability of a relationship.'").

[82] *See id.*, citing *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 948–49 (3d Cir. 1990) (pre-*Daubert*) (which "described confidence intervals (i.e., the range of values that would be found in similar studies due to chance, with a specified level of confidence) and their use as an alternative to statistical significance.").

[83] *See id.*, quoting *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1357 (6th Cir. 1992) (pre-*Daubert*) ("'The defendant's claim overstates the persuasive power of these statistical studies. An analysis of this evidence demonstrates that it is possible that Bendectin causes birth defects even though these studies do not detect a significant association.'").

[84] *See id*., citing *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 706 n.29 (D.D.C. 2006) (rejecting the position of an expert who denied that the causal connection between smoking and lung cancer had been established, in part, on the ground that any study that found an association that was not statistically significant must be excluded from consideration).

[85] *See id*., citing *In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071, 1090 (D. Minn. 2008) (holding that, for purposes of supporting an opinion on general causation, a study does not have to find results with statistical significance).

[86] *See id*., quoting *Cook v. Rockwell Int'l Corp.*, 580 F. Supp. 2d 1071, 1103 (D. Colo. 2006) ("'The statistical significance or insignificance of Dr. Clapp's results *may affect the weight given to his testimony, but does not determine its admissibility under Rule 702*.'"). (emphasis added).

[87] *See id*., quoting *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 186 (S.D.N.Y. 2005) ("'[T]he absence of epidemiologic studies establishing an increased risk from ephedra of sufficient statistical significance to meet scientific standards of causality does not mean that the causality opinions of the PCC's experts must be excluded entirely.'").

[88] *See id*., citing *Milward*, 639 F.3d at 24-25.

[89] 639 F.3d at 24-25. Carl Cranor, the plaintiff's expert witness in *Milward*, has appeared to misrepresent federal courts' use of "significance testing" as a misapplication of the Bradford Hill criteria. *See* Raymond Richard Neutra, Carl F. Cranor, and David Gee, *The Use and Misue of Bradford Hill in U.S. Tort Law*, 58 JURIMETRICS J. 127, 151-53 (2018), https://www.americanbar.org/content/dam/aba/publications/Jurimetrics/Winter2018/the_use_and_misuse_of_bradford_hill.authcheckdam.pdf. Legal commentator Nathan Schachtman has shown to the contrary that the Hill criteria required use of the statistical method in interpreting medical data. *See* Nathan Schachtman, *Bradford Hill on Statistical Methods* (Sept. 24, 2013), http://schachtmanlaw.com/bradford-hill-on-statistical-methods/; Nathan Schachtman, *Carl Cranor's Conflicted Jeremiad Against* Daubert (Sept. 23, 2018), http://schachtmanlaw.com/carl-cranors-conflicted-jeremiad-against-daubert/#sdfootnote14anc (arguing *inter alia* that Cranor's "poor scholarship ignores Hill's insistence that this statistical analysis be carried out").

The Third Edition also noted how toxicological testing for chemical carcinogens by government agencies incident to performing a risk assessment[90] (in the regulatory context) can range from "relatively simple studies to determine whether the substance is capable of producing bacterial mutations[,] to observation of cancer incidence as a result of long-term administration of the substance to laboratory animals," to "a multiplicity of tests that build upon the understanding of the mechanism of cancer causation."[91] And, it noted that the "many tests that are pertinent to estimating whether a chemical or physical agent produces human cancer require careful evaluation."[92] To this end, the Third Edition identified IARC and the U.S. National Toxicology Program as having "formal processes to evaluate the *weight of evidence* that a chemical causes cancer. Each classifies chemicals on the basis of epidemiological evidence, toxicological findings in laboratory animals, and mechanistic considerations, and then assigns a specific category of carcinogenic potential to the individual chemical or exposure situation."[93]

III. THIRD EDITION'S DEVELOPMENT AND PEER REVIEW OFFER CLUES ON WEIGHT-OF-THE-EVIDENCE EMBRACE

As explained above, the Third Edition of the *Reference Manual on Scientific Evidence* departs significantly from the Second Edition on several key principles. Those departures ease plaintiffs' efforts to admit expert evidence on the pivotal issue of whether defendant caused harm. The development and peer review of the Third Edition offer some clues as to how and why the FJC arrived at these changes.

The Third Edition came about through an institutional collaboration between the FJC and the National Academy of Science ("NAS"). FJC's Director during the edition's development was Judge Barbara J. Rothstein of the U.S. District Court for the Western District of Washington.[94] The document's development and peer review were funded by the

[90] *See Third Edition*, *supra* note 4, at 650-51.
[91] *Id*. at 654.
[92] *Id*. at 655.
[93] *Id*. (emphasis added). *See* discussion *infra*.
[94] Judge Rothstein, appointed by former President Jimmy Carter in 1979, currently also serves in the capacity of a Visiting Senior Judge inter-circuit in both the United States District Court for the District of Columbia and in the United States District Court for the Western District of Pennsylvania. In addition, Judge Rothstein continues to serve simultaneously as the Chief Judge of the United States District Judge of the Western District of Washington. *See* United States District Court for the Western District of Washington, *Judge Barbara J. Rothstein Biography*,: https://www.wawd.uscourts.gov/judges/rothstein-bio; United States District Court for the District of Columbia, *Senior Judge Barbara J. Rothstein*, https://www.dcd.uscourts.gov/content/senior-judge-barbara-j-rothstein; United States District Court for the Western District of Pennsylvania, *Barbara J. Rothstein, Senior District Judge*, https://www.pawd.uscourts.gov/content/barbara-j-rothstein-senior-district-judge. *See also* Wikipedia, *Barbara Jacobs Rothstein*, available at: https://en.wikipedia.org/wiki/Barbara_Jacobs_Rothstein. Furthermore, Judge Rothstein has decided federal cases in the U.S. District Court for the Middle District of Alabama, the U.S. Court of Appeals for the 11th Circuit, the U.S. Court of Appeals for the Ninth Circuit, and the U.S. Court of Appeals for the District of Columbia Circuit. One recent law and economics research paper, which found that "judges tend to consistently hire clerks with similar measures of the judge's own ideology," scored Judge Rothstein as having the fifth most ideologically "left" mean CFscore of all U.S. district court law clerks evaluated from either political

Carnegie Foundation and the Starr Foundation and overseen by the National Research Council's (NRC) Committee on Science, Technology and the Law.[95]

A 2011 analysis of the Third Edition stated that because of the National Academy of Science's participation, "The third edition of the Manual should have even more significance than the first two editions." [96] The faith the authors of that analysis placed in the NAS/NRC's involvement in peer review may have been misplaced, however. As this author explained in a 2015 Washington Legal Foundation WORKING PAPER, the NRC's peer-reviewer selection process had previously failed to identify numerous institutional conflicts of interest in the group that reviewed seven National Oceanic and Atmospheric Administration climate-change-related scientific assessments. The Environmental Protection Agency relied heavily upon these assessments as support for its 2009 Greenhouse Gas Endangerment Findings.[97]

The NRC-selected peer-review panel for the Third Edition similarly featured an impressive array of academics, statisticians, and jurists, but it also similarly suffered from a significant lack of intellectual and professional diversity and included several members that arguably had a direct interest in lowering the admissibility standard for expert evidence.

Among the 29 individuals involved in the Third Edition's independent peer review, two were attorneys with predominantly plaintiff-sided practices who would reap substantial benefits if more judges accepted and applied the *Milward* court's approach. Another peer reviewer was the government affairs director for an environmental activist organization, Natural Resource Defense Council, whose legal and lobbying activities advance a European-style precautionary approach in civil litigation and federal regulation.[98] The NRC failed to

party. *See* Adam Bonica, Adam S. Chilton, Jacob Goldin, Kyle Rozema and Maya Sen, *The Political Ideologies of Law Clerks and their Judges*, (Coase-Sandor Working Paper Series in Law and Economics No. 754, 2016), at 4, 6, Table A3 at 68, Table A4 at 72, https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=2432&context=law_and_economics (discussing how Hillary Clinton and Barack Obama, on the ideological left side of the spectrum, have CFscores of -1.16 and -1.65, respectively; Ron Paul and Scott Walker, on the ideological right, have CFscores of 1.57 and 1.28, respectively, and Chris Christie and Joseph Lieberman, ideologically more moderate, have CFscores of 0.46 and -0.54, respectively, and illustrating in Table A3 the law clerks selected by Judge Barbara Jacobs Rothstein having a mean CFscore of -1.49, clearly closer to Barack Obama than to Hillary Clinton).

[95] *See Third Edition*, supra note 4, Foreword, at ii, iii, ix.

[96] *See* Perkins Coie, *New Peer Reviewed Edition of Reference Manual on Scientific Evidence for Judges Released*, News & Insight (Oct. 14, 2011), https://www.perkinscoie.com/en/news-insights/new-peer-reviewed-edition-of-reference-manual-on-scientific.html.

[97] *See* Lawrence A. Kogan, *Revitalizing the Information Quality Act as a Procedural Cure for Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study*, WLF WORKING PAPER, No. 191 (Feb. 2015), at 20-21, https://s3.us-east-2.amazonaws.com/washlegal-uploads/upload/legalstudies/workingpaper/2015Kogan.pdf; Lawrence Kogan, *A Second Look at EPA Findings*, FORBES.COM (Mar. 5, 2015), https://www.forbes.com/sites/realspin/2015/03/05/a-second-look-at-epa-findings/#5a6b52bf2c8d.

[98] *See* Lawrence A. Kogan, *A Chill Wind for Precaution? Broader Ramifications of Supreme Court's* Winter *Decision*, WLF WORKING PAPER No. 163 (Apr. 2009), https://s3.us-east-2.amazonaws.com/washlegal-uploads/upload/0409KoganWPFinal.pdf .*See also* Natural Resources Defense Council, *Comments from the Natural Resources Defense Council to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) on the Carcinogenic Potential of Glyphosate* (Nov. 3, 2016), https://www.nrdc.org/file/11433/download?token=mtrATIRt; Jennifer Sass, *Health Experts Rebut Trump EPA*

balance those three individuals with an attorney whose primary work was on behalf of corporate defendants, or a representative from an interest group that advocates for constitutionally protected property rights and/or for aggressive judicial gatekeeping for scientific evidence.

In addition, the Third Edition peer-review group included Professor Carl Cranor, a University of California at Riverside philosophy professor[99] and a scholar at the Center for Progressive Reform.[100] Aas discussed below, Cranor is a precautionary-principle advocate who authored law review articles and a chapter in a European Environment Agency book that discussed *inter alia* how *ex ante* precautionary-principle-based regulatory policies would complement the weight-of-evidence methodology the First Circuit embraced in *Milward*.

IV. FJC'S THIRD EDITION ENCOURAGES A METHODOLOGY MORE SUITABLE FOR REGULATION THAN FOR ESTABLISHING GENERAL CAUSATION AT TRIAL

In *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194 (5th Cir. 1996), the Fifth Circuit held that it had been "unpersuaded that the 'weight of the evidence' methodology […] used by [r]egulatory and advisory bodies such as IARC, OSHA, and EPA to assess the carcinogenicity of various substances in human beings and suggest or make prophylactic rules governing human exposure […was] scientifically acceptable for demonstrating a medical link between […] EtO exposure and brain cancer."[101] As the court found, "[t]his methodology results from the preventive perspective that the agencies adopt in order to reduce *public* exposure to harmful substances. *The agencies' threshold of proof is reasonably lower than that appropriate in tort law*, which 'traditionally make[s] more particularized inquiries into cause and effect' and requires a plaintiff to prove 'that it is more likely than not that another individual has caused him or her harm.'"[102]

Several years later, the Eleventh Circuit, in *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194 (11th Cir. 2002), echoed the Fifth Circuit's concerns in *Allen*. The Eleventh Circuit held

Censoring Science Rule, Natural Resources Defense Council Expert Blog (July 16, 2018), https://www.nrdc.org/experts/jennifer-sass/health-experts-rebut-trump-epa-censoring-science-rule; Jennifer Sass, *Comments from the Natural Resources Defense Council In Support of SB 70 – An Act to Amend Title 6 of the Delaware code Relating to Protecting the Health of Children by Prohibiting Bisphenol-A in Products for Young Children Sponsored by Senator Hall-Long*, https://www.nrdc.org/sites/default/files/hea_11062301a.pdf.

[99] *See* UC Riverside Department of Philosophy, *Carl Cranor*, https://philosophy.ucr.edu/carl-cranor/.

[100] Center for Progressive Reform, *Bio, Carl F. Cranor*, http://progressivereform.net/CPRBlog.cfm?fkScholar=12.

[101] 102 F.3d at 198.

[102] *Id*., quoting *Wright v. Willamette Industries, Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996) (emphasis added). *See also Johnson v. Arkema, Inc.*, 685 F.3d 452, 464 (5th Cir. 2012) (quoting *Allen*); *Mitchell v. Gencorp Inc.*, 165 F.3d 778, 783 n.3 (10th Cir. 1999) (holding that "The methodology employed by a government agency 'results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances."); Knight S. Anderson, *Government Action Does Not Equal Proximate Causation*, American Bar Association (June 11, 2012), https://www.americanbar.org/groups/litigation/committees/products-liability/articles/2012/gvt-action-does-not-equal-proximate-causation/.

that, "[t]he *Daubert* rule requires more"[103] scientific substantiation to prove medical causation than the FDA's standard of proof. The FDA "may choose to err on the side of caution."[104] The court had referred specifically to the FDA's public statement "that possible risks outweigh[ed] the limited benefits of the drug [Parlodel]," as "involv[ing] a much lower standard than that [the preponderance-of-the-evidence standard] which is demanded by a court of law."[105] The *Rider* court further held that, "[g]iven time, information, and resources, courts may only admit the state of science as it is. Courts are cautioned not to admit speculation, conjecture, *or inference* that cannot be supported by sound scientific principles."[106]

Contrary to the Fifth and Eleventh Circuits' decisions, *Milward* concluded that the Bradford Hill methodology permits an inference of causation as a generally acceptable and reliable way to determine *general* causation in toxic tort cases.[107] The court apparently grounded this holding on the relatively lesser burden of proof needed to establish general causation as compared to specific causation. As the court observed, "'[g]eneral causation' exists when a substance is capable of causing a disease,"[108] which requires a party to show that an association between a disease and an agent is merely plausible or possible, whereas, to establish "'[s]pecific causation,'" a party must show that "exposure to an agent caused a particular plaintiff's disease."[109]

In apparent defense of the *Milward* court's conclusion, the Third Edition emphasizes how inferences of association are commonly made in weighing evidence derived from different studies and lines of data by "many of the most well-respected and prestigious scientific bodies (such as the International Agency for Research on Cancer (IARC), the Institute of Medicine [IOM of the U.S. National Academy of Sciences], the [U.S National Research Council (NRC)], and the National Institute for Environmental Health Sciences [NIH NIEHS])" and the National Toxicology Program (NTP of the U.S. Department of Health and Human Services),[110] as well as, by the national and international regulatory advisory panels convened by the "NIH Toxicology Study Section, EPA [U.S. Environmental Protection Agency], FDA [U.S. Food and Drug Administration], WHO and IARC."[111] According to the Third Edition, such national and international organizations and bodies and their advisory panels "consider all the relevant available scientific evidence, taken as a whole, [*in the regulatory arena*,] to

[103] 295 F.3d at 1202.

[104] *Id*. at 1201.

[105] *Id*.

[106] *Id*. at 1202, citing *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) (emphasis added).

[107] The *Milward* court ultimately reversed the district court's exclusion of expert general causation testimony based on the weight-of-evidence methodology. 639 F. 3d at 14.

[108] *Milward*, 639 F.3d at 13, quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(3) (2010).

[109] *Id*., quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(4) (2010). *See also Short v. Amerada Hess Corp.*, Civ. No. 16-cv-204-JL (D.N.H. 2019), slip op. at 15, quoting *Milward*, 639 F.3d at 13 (personal injury action).

[110] *See Third Edition*, *supra* note 4, at 20; 218, n. 16; 563, n. 42; 564-565, fns. 46 and 48; 613, n. 193; 645, n. 30; 646; 655, fns 62-63; 656, fns 64-65; 660, n. 75.

[111] *Id*. at 678.

determine which conclusion or hypothesis regarding a causal claim is best supported by the body of evidence."[112] A 2016 NAS publication refers to such organizations, which "assess the evidence bearing on whether a chemical or other agent is a toxin and present their conclusion and the evidence bearing on the matter to the public," as "consensus organizations."[113]

Presumably, the authors of the Third Edition, which had been prepared and published in conjunction with the National Research Council of the NAS,[114] understood that, "unlike public health regulation, tort law requires proof that an individual defendant was responsible for an individual's harm, the reason for *specific* causation."[115] And, presumably, the Third Edition's authors well knew that, "[b]y contrast, in the area of risk regulation, such as that performed by the Environmental Protection Agency or the Food and Drug Administration, risk to a *group* of individuals or even to the entire population is sufficient for legal action. Thus, unlike, tort law, public health regulation is concerned solely with *general* causation and *not* specific causation."[116] In other words, unlike the adjudication of a tort claim, which "does not depend on whether a risk such as asbestos causes a public health calamity or one unfortunate individual suffers a unique and freakish overdose of a pharmaceutical that causes harm," "[r]isk regulation is concerned with the extent of [a risk's] impact on public health."[117] Additionally, "[w]hile a plaintiff in a civil [tort] case must establish causation, including general causation by a preponderance of the evidence, regulators have a lower burden of establishing that there is 'sufficient evidence' or in some cases 'substantial evidence' to support a determination of general causation."[118]

The 2016 NAS publication and the Third Edition describe the *ex ante* nature of the weight-of-evidence analyses that regulatory bodies routinely perform to identify and prevent the harms that agents can pose to human health in the general population. However, both curiously fail to properly identify such harms as "hazards" or "risks." The Third Edition sets forth the "standard" risk assessment definitions of hazard and risk *only* in a footnote as if to

[112] *Id*.

[113] *See* Steve C. Gold, Michael D. Green and Joseph Sanders, *Scientific Evidence of Factual Causation: An Educational Model*, for the National Academies of Science Committee on Preparing the Next Generation of Policy Makers for Science-Based Decisions (Oct. 2016), 239, https://sites.nationalacademies.org/cs/groups/pgasite/documents/webpage/PGA_174994.pdf.

[114] *See Third Edition*, *supra* note 4, at Inside Cover: The Federal Judicial Center contributed to this publication in furtherance of the Center's statutory mission to develop and conduct educational programs for judicial branch employees. […] The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. [...] The development of the third edition of the *Reference Manual on Scientific Evidence* was supported by Contract No. B5727.R02 between the National Academy of Sciences and the Carnegie Corporation of New York and a grant from the Starr Foundation.).

[115] *See* Gold, Green, and Sanders, *supra* note 113, at 14.

[116] *Id*. (emphasis added).

[117] *Id*.

[118] *Id*.

minimize their distinction and its relative significance.[119] The Third Edition then emphasizes how the "first 'law' of toxicology ['the dose makes the poison'[120]] is particularly pertinent to 'questions of specific causation" at trial, "while the second 'law' of toxicology ['the biologic actions of chemicals are specific to each chemical'[121]] is particularly pertinent to questions of *general causation*."[122]

The Third Edition next distinguishes between toxic tort litigation's focus on "plaintiffs' claims that their diseases or injuries were caused by chemical exposures" (presumably, specific causation), and regulatory litigation's focus on "government regulations concerning a chemical or a class of chemicals."[123] It also emphasizes how, "[i]n regulatory litigation, toxicological evidence addresses the issue of how exposure affects populations [generally] rather than specific causation, and agency determinations are usually subject to the court's deference."[124] It would appear from this analysis that the Third Edition and the 2016 NAS publication have cleverly obscured and conflated the terms "hazard" and "risk"[125] to justify the use of the relatively lower but judicially acceptable evidentiary standard public bodies employ in assessing *ex ante* chemical hazards as part of the regulatory risk-assessment process as the evidentiary standard to be employed *post hoc* at trial to establish general causation. Thus, these publications intimate that, where an expert can infer, based on the weighing of multiple lines of evidence in accordance with the Bradford Hill factors requiring

[119] *See Third Edition*, *supra* note 4, at 637, n. 7 ("In standard risk assessment terminology, hazard is an intrinsic property of a chemical or physical agent, while risk is dependent both upon hazard and on the extent of exposure.").

[120] *See* ChemicalSafetyFacts.org, *The Dose Makes the 'Poison,'* https://www.chemicalsafetyfacts.org/dose-makes-poison-gallery/; A.M. Tsatsakis, L. Vassilopoulou, *et al.*, *The Dose Response Principle From Philosophy to Modern Toxicology: The Impact of Ancient Philosophy and Medicine in Modern Toxicology Science*, TOXICOLOGY REPORTS 5 (2018), 1107-13, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6226566/pdf/main.pdf.

[121] *See* Encyclopedia.com, *Toxicology*, https://www.encyclopedia.com/medicine/divisions-diagnostics-and-procedures/medicine/toxicology; B. D. Goldstein and M. A. Gallo, *Profiles in Toxicology – Pare's Law: The Second Law of Toxicology*, 60 Toxicological Sciences, 194-95 (2001), https://academic.oup.com/toxsci/article/60/2/194/1644049.

[122] *See Third Edition*, *supra* note 4, at 637, n. 7 (emphasis added).

[123] *Id*. at 638.

[124] *Id*.

[125] *Id*. at 218-19 ("The next issue is crucial: Exposed and unexposed people may differ in ways other than the exposure they have experienced. For example, children who live near power lines could come from poorer families and be more at risk from other environmental hazards. Such differences can create the appearance of a cause-and-effect relationship. Other differences can mask a real relationship. Cause-and-effect relationships often are quite subtle, and carefully designed studies are needed to draw valid conclusions. […] With the health effects of power lines, family background is a possible confounder; so is exposure to other hazards. Many confounders have been proposed to explain the association between smoking and lung cancer, but careful epidemiological studies have ruled them out, one after the other."). *See also id*. at 505 ("The sciences of epidemiology[] and toxicology[] are devoted to understanding the hazardous properties (the toxicity) of chemical substances. Moreover, epidemiological and toxicological studies provide information on how the seriousness and rate of occurrence of the hazard in a population (its risk) change as exposure to a particular chemical changes. To evaluate whether individuals or populations exposed to a chemical are at risk of harm,[] or have actually been harmed, the information that arises from epidemiological and toxicological studies is needed, as is the information on the exposures incurred by those individuals or populations.").

"an informed exercise of scientific judgment,"[126] that an agent received from different sources is associated with a greater incidence of disease *in a population or group—i.e.*, it has been shown to be a sufficient, rather than, a necessary cause of that disease—a court should admit such testimony into evidence for purposes of proving general causation at trial.[127]

The plain meaning of words is critically important in this context. The plain meaning of "capable" is "susceptible; comprehensive; having attributes (such as physical or mental power) required for performance or accomplishment; having traits conducive to or features permitting something; having legal right to own, enjoy or perform; having or showing general efficiency and ability."[128] "Plausible" means "superficially fair, reasonable, or valuable, but often specious; superficially pleasing or persuasive; appearing worthy of belief."[129] "Plausible" is also defined as "possibly true; able to be believed,"[130] and "seems likely to be true or valid."[131] Synonyms of "plausible" include conceivable and possible,[132] as well as believable, likely, presumptive and probable.[133] The plain meaning of "possible" is "being within the limits of ability, capacity, or realization; being what may be conceived, be done, or occur according to nature, custom or manners; being something that may or may not occur; being something that may or may not be true or actual; having an indicated potential."[134] "Possible" also has been defined as "feasible but less than probable." Synonyms of "possible" include achievable, available, conceivable and potential,[135] as well as feasible, practicable, realizable, viable,[136] and plausible.[137] Based on these definitions and synonyms, the Third

[126] *See* Gold, Green, and Sanders, *supra* note 113, at 55.

[127] *Id*. at 4. *See also id*. at 212-13 ("[S]cientists often accept 'weight of the evidence' as *sufficient* support for regulatory decisions based on hypotheses of toxicity that cannot be directly tested experimentally." (emphasis added). "One federal court of appeals reversed a trial court's decision excluding an expert's 'weight of the evidence' testimony as to general causation. *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11 (1st Cir. 2011)." On remand, a different district judge excluded the testimony of the plaintiff's expert on specific causation. *Milward v. Acuity Specialty Products Group, Inc*., 969 F. Supp. 2d 101 (D. Mass. 2013), aff'd, 820 F.3d 469 (1st Cir. 2016).

[128] *See* Merriam-Webster, *Capable*, https://www.merriam-webster.com/dictionary/capable. *See accord*, Oxford Dictionaries, *Capable*, https://en.oxforddictionaries.com/definition/capable ("1 (capable of doing something) Having the ability, fitness, or quality necessary to do or achieve a specified thing. […] 2 Able to achieve efficiently whatever one has to do; competent."); Cambridge Dictionary, *Capable*, https://dictionary.cambridge.org/us/dictionary/english/capable ("having the skill or ability or strength to do something").

[129] *See* Merriam-Webster, *Plausible*, https://www.merriam-webster.com/dictionary/plausible.

[130] *See* Cambridge Dictionary, *Plausible*, https://dictionary.cambridge.org/us/dictionary/english/plausible.

[131] *See* Collins Dictionary, *Plausible*, https://www.collinsdictionary.com/us/dictionary/english/plausible.

[132] *See* Plausible, Thesaurus.com, https://www.thesaurus.com/browse/plausible. *See also* Collins Dictionary, Plausible – Synonyms (referring to "possible"), https://www.collinsdictionary.com/dictionary/english/plausible.

[133] *See* Merriam-Webster Thesaurus, *Plausible, Synonyms for Plausible*, https://www.merriam-webster.com/thesaurus/plausible.

[134] *See* Merriam-Webster, *Possible*, https://www.merriam-webster.com/dictionary/possible.

[135] *See* Possible, Thesaurus.com, https://www.thesaurus.com/browse/possible.

[136] *See* Merriam-Webster Thesaurus, *Possible, Synonyms for Possible*, https://www.merriam-webster.com/thesaurus/possible.

[137] *See* Collins Dictionary, *Synonyms of 'Possible,'* https://www.collinsdictionary.com/us/dictionary/english-thesaurus/possible.

Edition clearly insinuates that, in order to establish general causation at trial, one must show that an association is merely plausible or possible, rather than likely. This arguably is equivalent to treating that association as a hazard as opposed to a risk.

Furthermore, while the Third Edition identifies certain international organizations and bodies for their use of weight-of-the-evidence methodology, the edition does not discuss how other such entities have clearly defined and distinguished the critically important terms "hazard" and "risk." For example, the Federal Republic of Germany's prestigious Federal Institute for Risk Assessment has defined "hazard" as "the potential of a substance or situation to cause an adverse effect when an organism, system or (sub) population is exposed to that substance or situation." "The term 'hazard' refers to the inherent property of a substance (or a situation) to cause an adverse effect. In this context for example the [World Health Organization] International Programme on Chemical Safety (IPCS) defines a 'hazard' as the: 'Inherent property of an agent or situation having the *potential* to cause adverse effects when an organism, system, or (sub) population is exposed to that agent. (IPCS 2004, 12).'"[138] The Federal Institute for Risk Assessment has defined the term "risk," by contrast, as "the *likelihood* of an adverse effect in an organism, system or a (sub) population on exposure to a substance or situation under specific conditions."[139] The IPCS defines "risk" as "The *probability* of an adverse effect in an organism, system, or (sub) population caused under specified circumstances by exposure to an agent. (IPCS 2004, 13)."[140] "This definition [of risk] highlights the fact that the difference between 'hazard' and 'risk' lies in exposure. A risk exists when there is exposure to a 'hazard,' in a nutshell: risk=(hazard, exposure)."[141] "Based on these definitions, information about a 'hazard' is different from information about a 'risk' even if this difference is not always made clear."[142]

Moreover, the Third Edition conspicuously omits mention of the 1994 report findings and recommendations of another international body—the International Joint Commission (IJC).[143] The IJC had previously equated use of the weight-of-evidence approach, which "is not a value-neutral exercise," with the application of a *precautionary* inference, which focuses on the identification of *hazards* "[w]hen the harm is large, the uncertainty is great, and our ability to predict the future is limited." [144] In fact, "[i]n 1993, the Governments of the United

[138] *See* Federal Republic of Germany, Federal Institute for Risk Assessment, *Evaluation of Communication on the Differences between "Risk" and "Hazard," Final Report* (E.Ulbigetal.eds., 2010), at 6-7, https://www.bfr.bund.de/cm/350/evaluation_of_communication_on_the_differences_between_risk_and_hazard.pdf (emphasis added).

[139] *Id*. at 6 (emphasis added).

[140] *Id*. at 8 (emphasis added).

[141] *Id*.

[142] *Id*. at 6.

[143] Article VII of the Canada–U.S. Boundary Waters Treaty of 190 established the International Joint Commission (IJC) 9. *See* Treaty Between the United States and Great Britain Relating to Boundary Waters, and Questions Arising Between the United States and Canada, U.K.-U.S., Jan. 11, 1909, 36 Stat. 2448, https://www.ijc.org/sites/default/files/2018-07/Boundary%20Water-ENGFR.pdf. The 1909 Boundary Waters Treaty covers water quantity and water quality issues in shared waterways and related watersheds along the entire Canada–U.S. border. *See id*. at "Preliminary Article."

[144] *See* Jack Weinberg & Joe Thorton, *Scientific Inference and the Precautionary Principle*, *in* APPLYING WEIGHT OF EVIDENCE: ISSUES AND PRACTICE, A REPORT ON A WORKSHOP HELD OCTOBER 24, 1993 (Michael Gilbertson & Sally

States and Canada "accepted the […] IJC['s] recommendation to use a weight of evidence approach in reaching conclusions about proposals to eliminate persistent toxic substances from the ecosystem."[145] The 1994 IJC report recommended that the European precautionary principle "must be built into the rules of inference," even though it "derives neither from scientific principles nor from some thoughtful consideration of public ethics and morality."[146] The 1994 IJC report also reassured advocates of the precautionary principle that, although

> [s]ome argue that the IJC's *'weight of evidence approach'* is weaker than the 'precautionary principle' [, said] interpretation [was] false, however, and in sharp conflict with the IJC's usage. The weight of evidence approach does not simply involve weighing positive against negative or inconclusive evidence according to traditional standards of proof. The Commission, rather, has called precaution the 'basic underpinning' of their strategy. The use of a precautionary context changes both the purpose and the practice of weighing evidence. The issue now being explored is the development of a methodology for *weighing evidence in a precautionary framework* – or what might be called '*precautionary inference*.'[147]

The 1994 IJC report also emphasized that the precautionary weight-of-evidence "approach reverses the burden of proof, framing the question with the null hypothesis: 'What evidence must we IGNORE to conclude that a causal relationship does not exist.'"[148] Moreover, according to the 1994 IJC report, "[p]recautionary inference requires a holistic consideration of an integrated body of direct and circumstantial evidence. *The focus shifts from whether or not causal relationships have been definitively proven to considering whether a body of direct and/or circumstantial evidence suggest a plausible hypothesis that harm has occurred*."[149]

Researchers from the University of British Columbia (UBC) have more recently shown how precautionary action can be incorporated within the weighting of the Bradford Hill criteria, at least, for *ex ante* regulatory purposes, "when risks of harm associated with false negatives are high but those of false positives are low."[150] These researchers first applied a

Cole-Misch eds., 1994), at 23, https://nebula.wsimg.com/42e8204136024527b478aceb735b44c8?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[145] *Id*. at 23.

[146] *Id*.

[147] *Id.* at 24 (emphasis added).

[148] *Id*. at 25.

[149] *Id*. at 26 (emphasis added).

[150] *See* Daniel Steel and Jessica Yu, *The Precautionary Principle Meets the Hill Criteria of Causation: A Case Study of Tuberculosis Among Gold Miners in South Africa* (2016), at 23-26, https://blogs.kent.ac.uk/jonw/files/2016/10/Slides_Steel.pdf; Daniel Steel and Jessica Yu, *The Precautionary Principle Meets the Hill Criteria of Causation*, 22 ETHICS, POL'Y & ENV'T 72 (2019), https://www.tandfonline.com/doi/abs/10.1080/21550085.2019.1581420?journalCode=cepe21.

simplified version of the Bradford Hill criteria (as revised into the three categories of *direct evidence*, *mechanistic evidence* and *parallel evidence*"[151]) to 12 criteria for precautionary action articulated by David Gee, a retired senior advisor at the European Environment Agency.[152] Gee also had been an editor and co-author of that agency's seminal publication, "Late Lessons from Early Warnings of Hazards from Chemicals, Food Additives, and Radiation, 1896-2013."[153] Of these 12 criteria the researchers then found that only two—intrinsic toxicity/ecotoxicity data and analogous evidence from known hazards—"fall into the category of parallel evidence [*i.e.*, replicability and similarity[154]], wherein related studies with similar results are called upon to bolster a causal claim."[155] Based on the above, they concluded that "[p]arallel evidence is sufficient to justify precautionary action when scientific uncertainty, false negative harm intensifiers, and false positive harm mitigators are present."[156]

Europe's precautionary principle "in its strongest version, […] is triggered once 'there is at least *prima facie* scientific evidence of a hazard,' rather than a risk."[157] "In this version, the [precautionary principle] creates an administrative presumption of risk which favors *ex ante* regulation, and tends to reverse the administrative and adjudicatory burden of proof (production and persuasion) from government to show potential harm to industry to show no potential of harm. Consequently, since it is impossible to prove the absence of risk, the outcome invariably is that the *hazard* is regulated."[158] "Where the burden of proof initially rests on the regulator, the strict reliance on peer-reviewed scientific evidence is replaced with use of broader, qualitative, rather than quantitative, evidence, and a 'weight-of-the-

[151] *See* Jeremy Howick, Paul Glasziou, and Jeffrey K. Aronson, *The Evolution of Evidence Hierarchies: What Can Bradford Hill's 'Guidelines For Causation' Contribute?*, 102 J R SOC. MED. 186, 187 at Table 1, 192 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2677430/pdf/186.pdf.

[152] *See* National Institute of Health, National Institute for Environmental Health Sciences, *Gee Shares European Approach to Early Hazard Warning*, ENVT'L FACTOR (June 2016), https://factor.niehs.nih.gov/2016/6/science-highlights/gee/index.htm.

[153] *See* David Gee, *Chapter 27 – More or Less Precaution?*, in "Late Lessons from Early Warnings: Science, Precaution, Innovation, European Environment Agency, Implication (European Union , May 2013), at 653 Box 27.4, https://bit.ly/2vpqAvI.

[154] *See* Howick, Glasziou, and Aronson, *supra* note 151, at 190.

[155] *See* Daniel and Yu, *supra* note 150, at 26, citing Howick, Glasziou, and Aronson at 186, 190 ("If all the parallel studies gave similar results, then the causal hypothesis will be more strongly supported; if they don't, then we will have grounds to suspect either some of the parallel studies or the causal hypothesis itself.").

[156] *Id*. at 26.

[157] *See* Lucas Bergkamp & Lawrence Kogan, *Trade, the Precautionary Principle and Post-Modern Regulatory Process: Regulatory Convergence in the Transatlantic Trade and Investment Partnership*, EUR. J. RISK REG. 499 (2013), https://bit.ly/3bwxa48, quoting Peter Saunders, "The Precautionary Principle," in Organization for Economic Cooperation and Development, *Policy Responses to Societal Concerns in Food and Agriculture, Proceedings of an OECD Workshop* (2010), at 47, 52, https://portal.research.lu.se/portal/files/5991882/1770253 (describing how precautionary principle proponents define the term consistent with the 1998 Wingspread Declaration (Science and Environmental Health Network 1998): "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." In other words, "the precautionary principle […] does not come into play unless there is at least prima facie evidence of a ***hazard***.") (emphasis added).

[158] *Id*. at 499-500.

evidence,' rather than 'strength-of-the-evidence' approach at the regulatory level."[159]

At least one European commentator has opined that, "when we act on the basis of evidence that is not conclusive, we are saying that we have reason to be concerned that something is *hazardous* and we are sufficiently worried about the consequences that we are willing to go without it, or at least to delay its introduction until we have more evidence."[160] This commentator also has argued that the Bradford Hill criteria's creator developed the criteria in 1965 to address the scenario that regulators currently address through application of Europe's precautionary principle—*i.e.*, where although "epidemiology can show there is an association between two variables, that does not necessarily mean that one is the cause of the other. Something more is needed to establish causation. This led […] Sir Austin Bradford Hill, a professor of medical statistics in London University, to produce what are now called the Bradford Hill criteria."[161] These "criteria […] suggest the sorts of questions we should ask when we are faced with a *prima facie* case for hazard and we are trying to decide whether action is warranted."[162] Indeed, other commentators have construed a single quote from Sir Bradford Hill as "echo[ing] the precautionary principle."[163]

The Third Edition agrees that "the precautionary principle in many ways is a *hazard*-based approach."[164] The 2016 NAS publication since then identified how, in the context of risk regulation, "[s]ome [federal] statutes specify that regulations must be constructed conservatively so as to provide an adequate margin of safety, often referred to as the 'precautionary principle.'"[165] Yet, these publications, unlike the 1994 IJC report and the 2016 UBC analysis discussed above, stop short of explicitly acknowledging the precautionary

[159] *Id*. at 500, citing Joel Tickner, "Putting Precaution into Practice: Implementing the Precautionary Principle," in Integrating Foresight and Precaution into the Conduct of Environmental Science, Report of the International Summit on Science and the Precautionary Principle (Sept.20–22, 2001). *See also* Massachusetts Precautionary Principle Project, *Putting Precaution into Practice: Implementing the Precautionary Principle*, Science and Environmental Health Network (Mar. 5, 2013), https://www.sehn.org/sehn/putting-precaution-into-practice-implementing-the-precautionary-principle; World Health Organization Europe, *The Precautionary Principle: Protecting Public Health, the Environment and the Future of Our Children*, (Marco Martuzzi and Joel A. Tickner, eds.) (2004) at 194, http://www.euro.who.int/_data/assets/pdf_file/0003/91173/E83079.pdf ("Consider the weight of the evidence on association, exposure and magnitude together to determine the potential threat to health or the environment.").

[160] Peter Saunders, "The Precautionary Principle," in Organization for Economic Cooperation and Development, *Policy Responses to Societal Concerns in Food and Agriculture, Proceedings of an OECD Workshop* (2010), *supra* note 157, at 48 (emphasis added).

[161] *Id*. at 50.

[162] *Id*. at 51.

[163] *See* Collaborative on Health and the Environment, *Sir Austin Bradford Hill: Echoing the Precautionary Principle*, https://www.healthandenvironment.org/environmental-health/social-context/history/sir-austin-bradford-hill-echoing-the-precautionary-principle ("There is a quote by Hill that echoes the precautionary principle: 'All scientific work is incomplete - whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have or postpone the action that it appears to demand at a given time.'"). *See also* Steel and Yu, *supra* note 150, at 13 (quoting Hill).

[164] *See* Bernard D. Goldstein and Mary Sue Henifin, *Reference Guide on Toxicology*, at 650, note 47, in *Third Edition*, *supra* note 4 (emphasis added).

[165] *See* Gold, Green, and Sanders, *supra* note 113, at 14

principle's incorporation within the weight-of-evidence methodology that *Milward* embraced and the Third Edition promotes.[166]

The writings of Dr. Carl Cranor, the *Milward* plaintiff's scientific methodology expert and a recognized precautionary-principle advocate,[167] provide the critical inverse link between Europe's hazard-based regulatory approach and the use of Bradford Hill weight-of-evidence methodology to prove general causation. Cranor deftly persuaded the First Circuit to effectively lower the admissibility threshold for expert testimony intended to show an association between an agent and a disease in a situation where the science is uncertain. The court allowed an expert to combine his subjective professional judgment with the qualitative or semi-quantitative risk assessments of consensus organizations (*e.g.*, WHO, IARC, NAS-IOM, NAS-NRC, NIH) in weighing and integrating those different lines of evidence to derive a "nondeductive inference[] to the best explanation."[168] Cranor has since asserted that the Third Edition "endorses the use of such scientific inferences in several articles,[] and further notes that this procedure is quite appropriate for toxicology and for circumstances in which toxicological, epidemiological, and other scientific evidence must be considered together."[169] Cranor also has emphasized that when national and international consensus bodies such as

[166] Although Joseph Rodricks, the author of the Third Edition's *Reference Guide on Exposure Science*, did not mention the precautionary principle in that chapter, he has since argued in a 2019 article that *ex ante* precautionary policies "are inevitable when science is uncertain and decisions have to be made." *See* Joseph V. Rodricks, *When Risk Assessment Came to Washington: A Look Back*, Dose-Response (Jan.-Mar. 2019), at 13, https://journals.sagepub.com/doi/pdf/10.1177/1559325818824934.

[167] *See, e.g.,* Carl Cranor, *Chapter 24 – Protecting Early Warners and Late Victims*, 581-606, at 582, 584-85, 587, 591, 595-96, 600-03, https://www.eea.europa.eu/publications/late-lessons-2/late-lessons-chapters/late-lessons-ii-chapter-24/view, in European Environment Agency, "Late Lessons From Early Warnings: Science, Precaution, Innovation," EEA Report No. 1/2013 (Jan. 22, 2013), https://www.eea.europa.eu/publications/late-lessons-2; *see also*, Carl F. Cranor, *Do You Want to Bet Your Children's Health on Post-Market Harm Principles - An Argument for a Trespass or Permission Model for Principles - An Argument for a Trespass or Permission Model for Regulating Toxicants Regulating Toxicants*, 19 VILL. ENVTL. L.J. 251, 288 n. 157, 292 n. 171, 293 (2008), https://digitalcommons.law.villanova.edu/cgi/viewcontent.cgi?article=1059&context=elj; Carl F. Cranor, *Toward Understanding Aspects of the Precautionary Principle*, 29 J. OF MED. AND PHIL., 259 (2004), https://www.tandfonline.com/doi/pdf/10.1080/03605310490500491.

[168] *Milward*, 639 F. 3d at 13, 17-18. *See also*, Carl F. Cranor, Milward v. Acuity Specialty Products*: Advances in General Causation Testimony in Toxic Tort Litigation*, 3 WAKE FOREST J. LAW & POL'Y 105, 113-15, 116-18, 121-25 (2013), https://wfulawpolicyjournaldotcom.files.wordpress.com/2016/05/6-cranor.pdf; Carl Cranor, Milward v. Acuity Specialty Products*: How the First Circuit Opened Courthouse Doors for Wronged Parties to Present Wider Range of Scientific Evidence*, CPR Blog (July 25, 2011), http://progressivereform.net/CPRBlog.cfm?idBlog=616EE094-D602-ED68-85FD84E7EB0A212E; Carl F. Cranor, *Some Legal Implications of the Precautionary Principle: Improving Information-Generation and Legal Protections*, 11 Human and Ecological Risk Assessment: An International Journal 31, 48 (2005), http://rachel.org/files/document/Some_legal_implications_of_the_Precautionary_P.pdf and https://www.tandfonline.com/doi/abs/10.1080/10807030590919873 (discussing, in part, how, although "personal injury law is a post-market legal device with retrospective remedies, it has relatively modest deterrence effects that can be either enhanced or frustrated by how it functions. *In the US as a first step the tort law could function better if courts would admit all the evidence and respectable expert testimony that the scientific community recognizes, instead of imposing comparatively high standards of admissibility counter to respectable science as some courts have done*.") (emphasis added).

[169] Cranor, 3 WAKE FOREST J. LAW & POL'Y, *supra* note 168, at 115-16.

NIH and IARC employ nondeductive reasoning in their weight-of-evidence methodologies, those bodies "are identifying carcinogens, they are identifying *hazards* that can come from exposures to a substance. A cancer hazard is 'an agent that is capable of causing cancer under some circumstances, while a cancer 'risk' is an estimate of the carcinogenic effects expected from exposure to a cancer hazard.'"[170]

Legal commentator Sheila Jasanoff similarly supports the Third Edition's deference to consensus-based scientific organizations, their expert scientific advisory committees, and their organizational processes: "The central question to ask about science *in legal proceedings* […] is not how good it is, but how much deference the scientific community's claims deserve in specific legal contexts."[171] Jasanoff has proposed "a cascade of deference as science moves from high to low degrees of certainty and reliability" which features "[f]our stopping points: objectivity, consensus, *precaution* and [epistemic] subsidiarity." She roughly equates the scientific consensus achieved within public organizations and expert committees with objectivity, given the apparent transparency and understandability of their governance processes.[172] In fact, Jasanoff suggests that "[t]he existence of a strong scientific consensus [among such entities evidencing social choice] may dilute the need to scrutinize [the] scientific claims"[173] experts proffer regarding their evaluation and weighing of multiple lines of evidence at trial that may incorporate similar value choices.[174] "The exercise of expert judgment, moreover, necessarily involves making value choices, from the framing of relevant questions *to the weight accorded to specific piece of evidence*."[175] Thus, the precautionary principle and the associated subjective moral and societal value judgments of laypersons reflected in the decisions of "scientific" public bodies (what should be done, as opposed to what can be done) should apply at trial where there is scientific uncertainty and serious harm is likely.[176]

Legal commentator Barbara Pfeffer-Billauer more recently emphasized that because experts possess the ability to influence courtroom determinations, especially in toxic tort cases (as opposed to medical malpractice cases) which "are 'expert-determinative,'" expert testimony has become "one of the prominent areas in which science and law collide."[177]

[170] *Id.* at 122, quoting National Toxicology Program, U.S. Dep't of Health and Human Services, Report on Carcinogens 3 (12th ed. 2011) and WHO-IARC *Preamble*, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 12 (Int'l Agency for Research on Cancer, World Health Org., 2006) (emphasis in original).

[171] *See* Sheila Jasanoff, *Serviceable Truths: Science for Action in Law and Policy*, 93 TEXAS L. REV.1723, 1724 (2015), http://texaslawreview.org/wp-content/uploads/2015/08/Jasanoff.Final.pdf (emphasis added).

[172] *Id*. at 1725, 1737. ("Scientific authority is on strongest ground when it lays claim to objectivity (i.e., unbiased knowledge of how things *are*), but consensus remains only a slightly weaker basis for demanding deference. […] If most or all members of the relevant thought collective are in agreement, then that collective judgment surely demands a high degree of respect from society in general and the law more particularly. Many governance processes in modern societies contain built-in mechanisms for producing scientific or technical consensus.") (italicized emphasis in original).

[173] *Id*. at 1741-42.

[174] *Id*. at 1742-43.

[175] *Id*. at 1743 (emphasis added).

[176] *Id*. at 1744-46.

[177] *See* Barbara Pfeffer-Billauer, *The Causal Conundrum: Examining the Medical-Legal Disconnect in Toxic Tort Cases From a Cultural Perspective or How the Law Swallowed the Epidemiologist and Grew Long Legs*

Since "testimon[ies] regarding causal proof are struggles over 'the authority of knowledge'" between conventional scientists and 'frontier' scientists, "challenges between accredited traditional experts are intense."[178] Pfeffer-Billauer notes Jasanoff's "recogni[tion of the] subjective elements experts bring to the courtroom," and that Jasanoff has "recommend[ed] deconstructing expert testimony and 'exposing … underlying subjective preconceptions…'"[179]

Pfeffer-Billauer notes the need for more subjective elements of expert testimony to fill in professional as well as public-knowledge gaps due to the dearth of probabilistic and statistics-driven "objective" epidemiological studies available to establish a causal connection. "When there is not enough 'objective' science to prove a causal connection," "intrepid advocates" have pursued "the matter using unconventional means of persuasion such as media and advocacy."[180] Pfeffer-Billauer also remarks that, as the result of the "deficiencies in epidemiology," and the search for "'epidemiological best evidence,'" scientists and lawyers involved in policymaking introduced at the regulatory level *quantitative* risk assessment, data quality, data relevancy, consistency and strength of evidence, evidentiary bias and methodology, while "social scientists introduced 'the precautionary principle" calling for administrative and legal, if not, scientific action.[181] According to Pfeffer-Billauer, this translated into "junk epidemiology" at trial which, in turn, inspired the *Daubert* trilogy "to prevent more bad science from polluting precedent."[182] She failed to note how the precautionary principle's pollution of human-health and environmental-risk assessments performed by both international *and* national consensus-based organizations[183] led to the enactment of the federal Information Quality Act.[184] Pfeffer-

and a Tail, 51 CREIGHTON L. REV. 319, 356 (2018), https://dspace2.creighton.edu/xmlui/bitstream/handle/10504/117639/51CreightonLRev319_2018.pdf?sequence=1&isAllowed=y. *See also id*. at 323 and n. 28. (Pfeffer-Billbauer explains that, "in comparison with medical malpractice cases where many states allow licensed physicians to testify regardless of specialty, toxic tort cases are more restrictive." She cites one source as "(showing that as of 2014, twenty-three states had few or no rules governing the specialty of a medical expert allowed to testify in malpractice cases).").

[178] *Id.* at 356-58.

[179] *Id.* at 356 (quoting Sheila Jasanoff, "Science at the Bar: Law, Science, and Technology in American" (1995), https://monoskop.org/images/a/ae/Jasanoff_Sheila_Science_at_the_Bar_Law_Science_and_Technology_in_America_Twentieth_Century.pdf).

[180] *Id*. at 350.

[181] *Id*. at 368.

[182] *Id*. at 369.

[183] *See, e.g.*, Steel and Yu, *supra* note 150; Peter Saunders, *supra* note 157. *See also* Lawrence A. Kogan, *REACH Revisited: A Framework for Evaluating Whether a Non-Tariff Measure Has Matured Into an Actionable Non-Tariff Barrier to Trade*, 28 AM. U. INT'L L. REV. 489, 575-582 (2013), https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1769&context=auilr (discussing in the context of various prior and emerging World Trade Organization (WTO) disputes involving the use of disguised nontariff regulatory barriers to trade, "the ongoing efforts of these same WTO member governments at a more fundamental level to reform the international 'standards, guidelines,' and 'recommendations' (principles of risk analysis) developed by the several 'relevant international organizations' explicitly recognized and referenced within the text of the WTO SPS Agreement," so as to permit the more widespread performance and use of qualitative and semi-quantitative risk, and thus, hazard analysis-focused risk assessments with little or no reference to actual dose and exposure).

[184] *See* Kogan, *Revitalizing the Information Quality Act*, *supra* note 97.

Billauer also has overlooked how the precautionary principle's implementation through weight-of-evidence methodology at trial will only further erode the empirical nature of those assessments over time.[185]

Pfeffer-Billauer emphasizes that federal courts' and litigants' apparent confusion over the general-causation standard[186] (including whether it is tied to any particular dose or exposure level) opened the door for *Milward* and its embrace of weight of the evidence.[187] Factual causation in toxic tort cases requires the plaintiff to establish general causation. In *McClain v. Metabolife Intl., Inc.*,[188] the Eleventh Circuit quoted both the Tenth Circuit's holding in *Mitchell v. Gencorp*,[189] and the Eight Circuit's holding in *Wright v. Willamette Indus., Inc.*,[190] that, "to carry the burden in a toxic tort case, 'a plaintiff must demonstrate 'the levels of exposure that are *hazardous* to human beings generally [general causation], as well as the plaintiff's actual level of exposure to the defendant's toxic substance [specific causation] before he or she may recover.'"[191] Pfeffer-Billauer notes that the New York Court of Appeals, in *Parker v. Mobil Oil Corp.*,[192]—which had cited these cases[193] with the

[185] *See, e.g.,* Lawrence A. Kogan, *The Europeanization of the Great Lake States' Wetlands Laws & Regulations (At the Expense of Americans' Constitutionally Protected Private Property Rights)*, 2019 MICH. ST. L. REV. 687, 734-43 (2019), https://digitalcommons.law.msu.edu/lr/vol2019/iss3/3/, (discussing how the National Research Council's 2014 review of USEPA's Draft Integrated Risk Information System (IRIS) had found that USEPA had utilized weight-of-evidence methodology (from which to draw *inferences* from a chemical's or compound's inherent toxicity or the putative mechanism by which a chemical might (possibly) cause harm in a scientifically unreliable manner, and discussing how the weight-of-evidence guidelines the USEPA SAB Risk Assessment Forum had released in December 2016, just prior to the close of the Obama administration, which define weight of the evidence "as an *inferential* process that assembles, evaluates and integrates evidence to perform a technical inference in an assessment" (emphasis added), had violated the federal Information Quality Act (IQA)'s objectivity and peer review standards.).

[186] *Id*. at 384-85. ("Does [general causation] mean: *Can* the substance cause disease in theory, because of its biological makeup? Or is mathematical certainty (or statistical significance) required? *Can* the substance cause disease in animals that serve as acceptable human surrogates? *Can* the substance cause disease in small doses? *Can* the substance cause any cancer, or just the cancer complained [of] by the plaintiff? Does general exposure include levels at which the plaintiff was exposed?") (emphasis added).

[187] *Id*. at 329-32 (discussing how, I*n re E.I. DuPont De Nemours & Co. C-8 Pers. Injury Litig.*, No. CV 2:13-md-2433, 2016 WL 2946195, at *1 (S.D. Ohio May 19, 2016), defendants' counsels believed they had only conceded by agreement the issue of general causation, not specific causation based on the extent of exposure, as well, and discussing how industry groups in their *amicus* brief had argued that general causation is not tied to any exposure level.). *See* Joint *Amicus Brief* of the U.S. Chamber of Commerce, Am. Tort Reform Ass'n, and Am. Chem. Council, *In re DuPont De Nemours & Co. C8 Pers. Injury Litig.*, No. 16-3310, 2016 WL 34115291 (6th Cir. June 20, 2016), at 2, 4-7, https://bit.ly/2tNxjzg.

[188] 401 F.3d 1233 (11th Cir 2005). *See also*, *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 676–77 (6th Cir. 2011).

[189] 165 F.3d 778 (10th Cir. 1999). *See also*, *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005).

[190] 91 F.3d 1105 (8th Cir 1996).

[191] 401 F.3d at 1241, quoting 165 F.3d at 781 and 91 F.3d at 1106 (emphasis added).

[192] *See* Pfeffer-Billauer, *supra* note 177, at 322-23, citing *Parker v. Mobil Oil Corp.*, 857 N.E.2d 1114 (N.Y. 2006), 7 N.Y.3d 434 (2006).

[193] 7 N.Y.3d at 448 (2006) (In *Parker*, the New York Court of Appeals cited these cases and held that "the factors needed to prove causation in toxic tort cases are: (1) exposure, (2) general causation, and (3) specific causation. Exposure addresses whether the amount of toxin to which the plaintiff was exposed was

understanding that general causation is a separately required element—had defined general causation as whether a "toxin is capable of causing *the particular illness*."[194] "Most, but not all, [U.S.] jurisdictions require showing both aspects—but even where jurisdictions do not require both, evidence in favor of either form of causation can be probative as to establishing factual causation."[195]

Ultimately, Pfeffer-Billauer recommends that courts adopt the following presumption to ensure a "uniform scientific conclusion that a substance *can* cause" a disease: "if a substance is characterized as *probably* (more likely than not) carcinogenic by a reputable and neutral scientific organization, or regulated by a national environmental agency, general causation is established and the issue of sufficient exposure should be shunted to specific causation."[196] In support of this presumption, she states that, "[p]erhaps it can be said that 'public health' is concerned with 'general causation' (more accurately causal associations), while clinical medicine is concerned with specific causation."[197]

Pfeffer-Billauer's formulation of a presumption which requires a *risk and probability evidentiary threshold* would arguably be helpful in establishing general causation. The reality, however, as noted above, is that numerous regulatory policymakers, social scientists, and legal academicians have increasingly supported the incorporation of precautionary-principle-based safety margins expressed in qualitative and semi-quantitative terms of *hazard* and *possible/plausible harm* within the risk assessments of public consensus-based organizations where statistically significant quantitative epidemiological and dose-response data are lacking.[198] The use of these safety margins in the absence of such data arguably facilitated the

sufficient to cause the disease in question. […] General causation asks whether a substance can cause the disease. Specific causation asks whether the substance did cause the disease in this plaintiff.")

[194] *Id*. (emphasis added). In *Parker*, the Court of Appeals had affirmed the Appellate Division (trial court)'s prior rejection of expert testimony as unable to meet the general causation standard. Such testimony had relied, in part, upon studies merely stating "that no level off benzene exposure can be considered 'safe,'" which the court found as "not tantamount to stating that any exposure to benzene causes AML," and upon regulatory standards regarding benzene exposure, which the court had found "are not measures of causation but rather are public health exposure levels determined by agencies pursuant to statutory standards." *See* 7 N.Y.3d at 449-450, affirming *Parker v. Mobil Oil Corp.*, 16 A.D.3d 648, 653 (2005) ("Key to this litigation is the relationship, if any, between exposure to gasoline containing benzene as a component and AML. Landrigan fails to make this connection perhaps because, as defendants claim, no significant association has been found between gasoline exposure and AML. Plaintiff's experts were unable to identify a single epidemiologic study finding an increased risk of AML as a result of exposure to gasoline. In addition, standards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation. Thus, the experts' opinions were properly excluded.").

[195] *See* Note, *Causation in Environmental Law: Lessons from Toxic Torts*, 128 HARVARD L. REV. 2256, 2261, n. 29 (2015), http://harvardlawreview.org/wp-content/uploads/2015/06/causation_in_environmental_law.pdf (distinguishing examples of separate general causation factors in federal court, from a single causation factor in some state courts). *See also* David E. Bernstein, *Getting to Causation in Toxic Tort Cases*, 74 BROOKLYN L. REV. 51, 53 (2008), https://www.law.gmu.edu/assets/files/publications/working_papers/0966GettingtoCausation.pdf (discussing how "proof of specific causation implicitly requires proof of general causation.").

[196] *See* Billauer, *supra* note 177, at 384 (italicized emphasis in original; underlined emphasis added).

[197] *Id*. at 387.

[198] *See* Gold, Green, and Sanders, *supra* note 113, at 14-15 ("Some statutes specify that regulations must be constructed conservatively so as to provide an adequate margin of safety, often referred to as the

Milward court's and its progeny's acceptance of a lower threshold of evidence that would allow for the use of differential diagnosis,[199] biological plausibility,[200] and parallel evidence[201] to establish general causation at trial. Unfortunately, *Milward*'s approach also allows for the exercise of subjective professional judgment to mask the incorporation of the precautionary principle when weighing these different subsidiary lines of cumulative evidence to reach an abductive inference to the best explanation.[202]

V. ABDUCTIVE PRECAUTIONARY REASONING UNDERLIES WEIGHT-OF-THE-EVIDENCE METHODOLOGY AT TRIAL

Significantly, in *Milward*, the First Circuit distinguished between three distinct logical methods of reasoning or inference: deductive, inductive, and abductive.

A. Deductive Inferences

Deductive inference or reasoning begins with a general premise, proposition, or principle and ends with a specific conclusion. "A conclusion obtained through deductive

'precautionary principle.' Thus, regulatory risk assessments may be relevant to whether general causation exists but rarely have any salience for the matter of specific causation."). *See also*, Joseph V. Rodricks, *When Risk Assessment Came to Washington: A Look Back*, Dose-Response (Sage Publ. Jan.-Mar. 2019), at 6, 13, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6366000/pdf/10.1177_1559325818824934.pdf ("The temptation to leap beyond what is truly established knowledge can be great if that leap can advance some desired policy agenda, but doing so can threaten scientific credibility and backfire. At the same time, these 2 great minds agreed, in the area of public health protection, it may be necessary, for policy reasons, to introduce certain precautionary elements into the interpretation and uses of scientific information. […] "But, as I have tried to make clear in this article, such [precautionary] policies are inevitable when science is uncertain and decisions have to be made.").

[199] *See Third Edition*, *supra* note 4, at 672 ("In taking a careful medical history, the expert examines the possibility of competing causes, or confounding factors, for any disease, which leads to a differential diagnosis."). *See also id*. at Glossary, p. 681 ("**differential diagnosis**. A physician's consideration of alternative diagnoses that may explain a patient's condition.") (boldfaced emphasis in original); *id.* at 690-91 ("In the legal context, differential diagnosis refers to a technique "in which physician first rules in all scientifically plausible causes of plaintiff's injury, then rules out least plausible causes of injury until the most likely cause remains, thereby reaching conclusion as to whether defendant's product caused injury…[] In the medical context, by contrast, differential diagnosis refers to a set of diseases that physicians consider as possible causes for symptoms the patient is suffering or signs that the patient exhibits."[]).

[200] *Milward*, 639 F.3d at 15, 25-26. The district court in *Milward* had previously rejected differential diagnosis and theories based on biological plausibility as inadmissible under Federal Rule of Evidence 702 and *Daubert*. *Milward*, 664 F. Supp. 2d at 146-48.

[201] Both the district and appellate courts in *Milward* rejected plaintiff's expert testimony to establish general causation based on parallel evidence of a carcinogenic effect. 664 F. Supp. 2d at 146-47; 639 F.3d at 21-22.

[202] *Milward*, 639 F.3d at 18, citing *Restatement Third, Torts* § 28 cmt.(1) and *Cruz v. Bridgestone/Firestone N. Am. Tire, LLC*, 388 Fed. Appx. 803, 806-07 (10th Cir. 2010) ("The use of judgment in the weight of the evidence methodology is similar to that in differential diagnosis […] (explaining that differential analysis in general is best characterized as a process of reasoning to the best explanation)." *See also id*., at 23-26.

reasoning is certain. Mathematics is based on deductive reasoning."[203] "[A] deductive statement is always true – because it is true by definition."[204] In other words, "deduction is the formation of a specific conclusion based on generally accepted statements or facts. […] Its specific meaning in logic is 'inference in which the conclusion about particulars [always] follows necessarily from general or universal premises.'" "[I]n deduction, the truth of the conclusion is guaranteed by the truth of the statements or facts considered."[205]

"Deductive inference guarantees that one can be *reasonably certain* (certain after the use of one's reasoning), providing that the argument is ***valid***. A valid argument is 'one in which it is necessary that, if the premises are true, then the conclusion is true.' One way of ensuring a valid argument is to utilize a valid argument form" of deductive logic.[206] *Modus ponens* is one such form: "If *p*, then *q*; therefore, *q*. […] *In a forensic analysis, the conditional statement ['p'] is a scientific principle derived from the biological and physical sciences*. […] […*'q'*] is the physical evidence related to witness evidence." (italics in original).[207] *Modus tollens* is another such form: "If *p*, then *q*; not *q*; therefore, not *p*. […] With *modus ponens*, the witness account is consistent with the physical evidence as long as the physical evidence is adequately explained by the witness accounts according to a scientific principle expressed as a conditional statement. With *modus tollens*, the witness accounts are not consistent with the physical evidence when the physical evidence denies the truthfulness of the witness accounts according to a scientific principle expressed as a conditional statement."[208] Hence, a deductive inference is a necessary inference.[209]

B. Inductive Inferences

"Inductive reasoning begins with a particular "proposition and ends either with a general proposition ('reasoning by generalization') or with a particular proposition ('reasoning by analogy'). […] A conclusion obtained through inductive reasoning is probable, not certain," because an inductive statement "is subject to being disproved upon discovery of new empirical evidence."[210] "In logic, induction refers specifically to 'inference of a generalized conclusion from particular instances.' In other words, it means forming a generalization based on what is known or observed. […I]nduction is a method of reasoning involving an element of probability."[211] Inductive reasoning can lead to a strong argument—

[203] *See* Ronald S. Granberg, *Legal Reasoning* (2012) at 1, https://granberglaw.com/wp-content/uploads/2012/07/legal_reasoning.pdf.

[204] *Id*.

[205] *See* Merriam-Webster, *Usage Notes: 'Deduction' vs. 'Induction' vs. 'Abduction,'* https://www.merriam-webster.com/words-at-play/deduction-vs-induction-vs-abduction.

[206] *See* Thomas Young, *Putting It All Together: The Logic Behind the Forensic Scientific Method and the Inferential Test*, Heartland Forensic Pathology, LLC, http://www.heartlandforensic.com/writing/putting-it-all-together-the-logic-behind-the-forensic-scientific-method-and-the-inferential-test. (Emphasis in original).

[207] *Id*.

[208] *Id*. (italics in original).

[209] *See* Stanford Encyclopedia of Philosophy, *Abduction*, at Sec. 1.1, https://plato.stanford.edu/entries/abduction/.

[210] *See* Granberg, *Legal Reasoning, supra* note 203, at 2.

[211] *See* Merriam-Webster, *Usage Notes: 'Deduction' vs. 'Induction' vs. 'Abduction,' supra* note 205.

i.e., one that is probable, "if the premises are true then the conclusion is true."[212] Inductive inferences "are based purely on statistical data, such as observed frequencies of occurrences of a particular feature in a given population."[213] With inductive reasoning, "there is only an appeal to the observed frequencies or statistics."[214] Since "the conclusion goes beyond what is (logically) contained in the premises, an inductive inference is a "non-necessary inference."[215]

C. Abductive Inferences

Abductive inference (backward reasoning) is defined as "'a syllogism in which the major premise is evident but the minor premise and therefore the conclusion is only probable." It engenders "forming a conclusion from the information that is known. […] Abduction will lead [one] to the best explanation."[216] With abductive reasoning, the conclusion goes beyond what is logically contained in the premises. However, "in abduction there is an implicit or explicit appeal to explanatory considerations," and there also may be an appeal to frequencies or statistics. "[I]t may be possible to infer abductively certain conclusions from a *subset* of *S* of premises which cannot be inferred abductively from *S* as a whole."[217]

Abductive reasoning, therefore, is essentially argument based on explanatory power—*i.e.*, a hypothesis from which known facts can be inferred. "If explanations inferred from statements by witnesses explain phenomena observed by scientists during an autopsy or other scientific procedure, this increases the likelihood of the truthfulness of the statements."[218] However, "[i]f an expert offers abductive inferences as opinions 'made to a reasonable degree of medical or scientific certainty or probability' on the witness stand, then such opinions are probably incorrect (not truthful)." This result obtains because the ability of properly performed science to correct itself through formal and regular questioning of results and correcting of errors "does not exist among scientists for issues brought before a court. Instead, many experts make positive assertions on the witness stand and appeals to their own authority to do so. Having done this, they possess neither the interest nor the ability to determine if their own assertions are truthful or not."[219]

A witness, in other words, "who abductively infers with certainty has neither the knowledge of the limitations for what he or she is doing nor the capacity to consider carefully the accounts of witnesses who were present to see what happened."[220] To such end, these witnesses appeal to their own unreliable authority, and thus, commit an *ad verecundiam*

[212] *Id*.
[213] *See* Stanford Encyclopedia of Philosophy, *Abduction*, at Sec. 1.1, *supra* note 209.
[214] *Id*.
[215] *Id*.
[216] *See* Merriam-Webster, *Usage Notes: 'Deduction' vs. 'Induction' vs. 'Abduction,' supra* note 205.
[217] *See* Stanford Encyclopedia of Philosophy, *Abduction*, at Sec. 1.1, *supra* note 209 (italics in original).
[218] *See* Young, *supra* note 206.
[219] *Id*.
[220] *Id*.

fallacy. Conversely, "an expert who acknowledges the limitations of his or her science, who knows how to compare witness statements to physical evidence in deductive fashion, and who knows better than to infer abductively on the witness stand has a great capacity to self-correct. Such witnesses actually learn from their experience, so their experience is probably reliable for courtroom purposes."[221] Furthermore, an expert witness who abductively infers with certainty also commits "a *fallacy of incomplete evidence*." "Experts who abductively infer from the witness stand familiarize themselves with a *q* but characteristically know little about *p* at the outset of a case, either unwittingly or by choice. This leads them to affirm the consequent consistently at the outset." And, such witnesses, thereafter, typically display "little interest in changing their initial impressions if further information and arguments are advanced regarding *p* […*i.e.*,] an unwillingness to acknowledge the information or even to evaluate it carefully with an open mind […] perhaps for reasons of pride, arrogance, or self-preservation."[222]

VI. FEDERAL COURTS ACCEPTING AND EMBRACING ABDUCTIVE REASONING IN *MILWARD*'S IMAGE

Legal commentators critical of weight-of-the-evidence methodology have argued that since "the purported 'weighing' of scientific evidence cannot be tested, it cannot be falsified, it cannot be validated against known or potential rates of error," as *Daubert* and FRE 702 require.[223] Consequently, one cannot determine whether the reasoning or 'weighting' methodology underlying the expert's testimony can be applied properly to the facts in issue.[224]

Notwithstanding these documented scientific and legal shortcomings, a growing number of federal district and appellate courts have accepted the type of abductive reasoning the First Circuit employed in *Milward*. The following federal caselaw review and Appendix A reveal, by reference to tradititional and nontraditional tort areas, that the FJC's institutionalization of *Milward* has metastasized throughout the federal circuits.

First Circuit (Where *Milward* Is Binding Precedent)

Jenks v. New Hampshire Motor Speedway (D.N.H. 2012)[225] (Products Liability)

Jenks was an employee of the New Hampshire Motor Speedway assigned to provide security services in the infield track area of the Speedway to volunteers. Another Speedway employee gave Jenks a ride on a golf cart to his assigned areas. Jenks rode in the rear area designed for placement of golf bags. The cart swerved and Jenks fell off, injuring his head.

[221] *Id*.
[222] *Id*.
[223] *See* Bernstein and Lasker, *supra* note 3, at 41, citing *Daubert*, 509 U.S. at 593.
[224] *Daubert*, 509 U.S. at 593.
[225] Civ. No. 09-cv-205-JD (D.N.H. 2012).

Defendant Textron, ABL, Inc., the golf cart's manufacturer, sought to exclude the injured employee's expert testimony *inter alia* "on the ground that they [were] not based on reliable methods and principles as required under [FRE] 702."[226] "Textron contende[d] that [the plaintiff's e]xpert opinions [were] unreliable in three ways: i) he employed a flawed methodology when forming his opinion concerning the inadequacy of the golf car[t]'s warnings; ii) he did not 'perform scientific testing' on his proposed alternate warning; and iii) his proposed alternate warning was not subject to peer review and ha[d] not been implemented by other golf car[t] manufacturers."[227]

The district court disagreed with Textron, ruling that "[e]xpert opinion is admissible under [FRE] 702 if, among other things, 'the testimony is the product of reliable principles and methods.'" To this end, the U.S. Supreme Court, in *Daubert*, articulated four factors that "*may be considered* in determining whether an expert witness' opinion is based on reliable principles and methods."[228] "These factors 'do not function as a definitive checklist or test, but form the basis for a flexible inquiry into the overall reliability of a proffered expert's methodology.'"[229]

The district court, however, found that plaintiffs' expert Vigilante had based his analysis of the golf cart warnings on "more than his subjective evaluation," and had included consideration of "established standards and guidelines for product warnings, as well as warnings and human factors literature and his own extensive experience and training in human factors analysis."[230] The district court held that since Vigilante had "determined that Textron's warnings did not meet the American National Standards Institute guidelines for 'product safety signs and labels,' and was inconsistent with criteria set forth in various articles and literature on adequate product warnings, [s]uch opinions [went] beyond the mere 'ipse dixit of the expert,' and [were] sufficiently reliable to survive a *Daubert* challenge."[231]

The district court also held that "Textron's dissatisfaction with those opinions" because Vigilante "did not subject his proposed alternative warning to scientific testing," "[was] not appropriately addressed at this stage." The court instead characterized the issue as one entailing "'the correctness of the expert's conclusion…[which] are factual matters to be determined by the trier of fact.'"[232] Similarly, the district court held that Vigilante's failure to have his proposed warning subjected to third-party peer review was irrelevant for *Daubert* purposes. According to the court, "the proper inquiry is not whether Vigilante's proposed

[226] Slip op. at 2.
[227] *Id*.
[228] *Id*. quoting *Milward v. Acuity Special Products Group, Inc.* 639 F.3d 11, 14 (1st Cir. 2011) (emphasis added).
[229] *Id*. at 2 quoting *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998).
[230] *Id*. at 3.
[231] *Id*.
[232] *Id*. at 4, quoting *Milward*, 639 F.3d at 22.

warning itself ha[d] been peer reviewed, but whether Vigilante's technique or theory ha[d] been subjected to peer review and publication."[233]

West v. Bell Helicopter Textron, Inc. (D.N.H. 2013)[234] (Products Liability)

The pilot of a "Bell 407 helicopter equipped with a Rolls Royce engine featuring a 'Full Authority Digital Engine Control' system, including an […electronic control unit ('ECU')]," initiated a flight from an airfield in Connecticut. Approximately 45 minutes into the flight, the helicopter unexpectedly crashed on the ground in Bow, New Hampshire.

The pilot, who possessed twenty years of experience, survived the crash by employing a technique known as "autorotation" to land the helicopter on a residential street. He, nevertheless, filed suit against the helicopter's manufacturer, the helicopter engine manufacturer, and the successor-in-interest to the helicopter's ECU alleging that "the force of the landing caused him injuries," including "a worsening of his pre-existing gastrointestinal syndrome," and "post-traumatic stress disorder."[235]

Plaintiff retained Dr. Agarwal, the chief of trauma, acute care surgery, and burn and surgical care at the University of Wisconsin Hospital, as an expert. While serving previously at Boston University Medical Center, Dr. Agrawal focused on both trauma surgery and "acute care surgery (treating patients suffering from emergent conditions like gall bladder disease, obstructed hernias, and a variety of colonic diseases)."[236] Defendants moved to exclude the opinion of this expert, who concluded, after "reviewing plaintiff's medical records and speaking with him for an hour or so by telephone," that "the helicopter crash '*caused, or significantly contributed to causing*, [an] exacerbation' in [plaintiff's] condition so that he 'ha[d] virtually lost all ability to pass solid waste on his own,' *i.e.*, without assistance from an enema."[237]

Agarwal testified that he had reached his opinion by reason of his experience, by reviewing medical literature establishing "that local impact to the abdomen, as well as the body's systematic response to trauma generally, can worsen functional gastrointestinal disorders," and by "employ[ing] the 'standard scientific technique, widely used in medicine, of identifying a medical 'cause' by narrowing the more likely causes until the most likely culprit is isolated.' […] This technique is known as '*differential diagnosis*.'"[238]

[233] *Id*. at 4, citing *Milward*, 639 F.3d at 14.
[234] Civ. No. 10-cv-214-JL (D.N.H. 2013).
[235] *Id*. at 1.
[236] *Id*. at 3.
[237] *Id*. (emphasis added).
[238] *Id*. at 3-4. *See also* Federal Judicial Center and National Research Council of the National Academies, *Reference Manual on Scientific Evidence—Third Edition* (2011) ("*Third Edition*") at 512-13, ns. 21, 22 and 26 (emphasis added), (stating that, even in the absence of quantification of exposure, causation may sometimes be established by reconstructing the past through indirect qualitative evidence based on differential diagnosis, citing as support *Best v. Lowe's Home Ctrs, Inc.*, 563 F.3d 171 (6th Cir. 2009); *Adams v. Cooper Indus. Inc.*, 2007

The district court noted that the universe of evidence identified as support for Agarwal's "view of the usual progression of pelvic floor dysmotility syndrome [was] not limited," and that it included: (1) testimony based on "medical articles and textbooks and an examination of "the timeline of disease for most of the patients that came to him "with problems of pelvic dysmotility" who he referred to other specialists; and (2) his finding that "this [is] a slow progression problem' so that 'most patients don't automatically go from mild disease to severe disease."[239]

The district court held that Agarwal's testimony "suffice[d] to show, at least at the pre-trial stage," that said expert's "opinion ruling out the natural progression of [plaintiff's] pelvic floor dysmotility as the cause of his post-accident symptoms is based on sufficient facts and data—namely, his personal experience in treating patients with that condition on a long-term basis, as well as the articles describing the typical evolution of the disease."[240] The district court also held, that while Agarwal's testimony was "arguably self-contradictory on some points and vague on others, the [First Circuit] Court of Appeals has cautioned that, '[w]hen the factual underpinning of an expert's opinion is weak, it is a matter affecting the *weight* and credibility of the testimony,' not its admissibility."[241]

WL 2219212, 2007 U.S. Dist. LEXIS 55131 (E.D. Ky. 2007); *Westberry v. Gislaved Gummi AB,* 178 F.3d 257 (4th Cir. 1999); *Allen v. Martin Surfacing*, 263 F.R.D. 47 (D. Mass. 2009); *Hayward v. U.S. Dep't of Labor*, 536 F.3d 376 (5th Cir. 2008); *Hannis v. Shinseki*, 2009 WL 3157546 (Vet. App. 2009). *See also id*. at 613, n. 194, quoting *Cavallo v. Star Enterprises*, 892 F. Supp. 756, 771 (E.D. Va. 1995), *aff'd in relevant part*, 100 F.3d 1150 (4th Cir. 1996) ("The process of differential diagnosis is undoubtedly important to the question of "specific causation." If other possible causes of an injury cannot be ruled out, or at least the probability of their contribution to causation minimized, then the "more likely than not" threshold for proving causation may not be met. But, it is also important to recognize that a fundamental assumption underlying this method is that *the final, suspected 'cause' remaining after this process of elimination must actually be capable of causing the injury*. That is, the expert must 'rule in' the suspected cause as well as 'rule out' other possible causes. *And, of course, expert opinion on this issue of "general causation" must be derived from a scientifically valid methodology*.") (emphasis added). *See also id*. at 617, n. 210 ("Indeed, this idea of eliminating a known and competing cause is central to the methodology popularly known in legal terminology as differential diagnosis. […] Physicians regularly employ differential diagnoses in treating their patients to identify the disease from which the patient is suffering.") and at 617-18, n. 212 ("Courts regularly affirm the legitimacy of employing differential diagnostic methodology. *See, e.g.*, *In re Ephedra Prods. Liab. Litig*., 393 F. Supp. 2d 181, 187 (S.D.N.Y. 2005); *Easum v. Miller*, 92 P.3d 794, 802 (Wyo. 2004) ("Most circuits have held that a reliable differential diagnosis satisfies *Daubert* and provides a valid foundation for admitting an expert opinion. The circuits reason that a differential diagnosis is a tested methodology, has been subjected to peer review/publication, does not frequently lead to incorrect results, and is generally accepted in the medical community." (quoting *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000)); *Alder v. Bayer Corp., AGFA Div.*, 61 P.3d 1068, 1084–85 (Utah 2002)."). *See also id*. at 672 ("In taking a careful medical history, the expert examines the possibility of competing causes, or confounding factors, for any disease, which leads to a differential diagnosis."). *See also id*. at 681 ("**differential diagnosis.** A physician's consideration of alternative diagnoses that may explain a patient's condition.") (emphasis in original). *See also id*. at 690-91.

[239] *Id*. at 4.

[240] *Id*. at 4-5.

[241] *Id*. at 5, quoting *Milward*, 639 F.3d at 22. (emphasis added).

Zagklara v. Sprague Energy Corp. (Zagklara II) (D. Me. 2013)[242] (Negligence/Wrongful Death)

The widow of the port captain of a cargo ship employed by Armada (Greece) CO., Ltd., an affiliate of Armada Singapore, brought this personal-injury action alleging negligence and wrongful death.[243] The ship had arrived in Portland, Maine "to discharge rock salt for storage at […] Merrill Marine Terminal."[244]

The port captain had been "responsible for Armada's equipment, including the grabs and the power reels […] to be utilized aboard the [ship] to discharge the salt."[245] After the ship docked, plaintiff/port captain and the ship's crew, "using the ship's cranes, brought the grabs and power reels aboard the vessel and proceeded to connect them to the cranes." "Whenever it was necessary to move the power reel boxes, [the port captain] was responsible for moving and positioning this equipment."[246] The port captain "was injured while attempting to move one of the power reel boxes on the deck of the vessel."[247] The port captain's widow alleged that he had been seriously injured due to the negligent/hazardous operation, by two of defendant Sprague Energy Corp.'s employees, of the second of five shipboard cranes while the port captain had been working on equipment attached to that crane after the ship had docked. At the time of the injury, one of defendant's employees operated the crane, while the other directed him from the vessel's deck.

Before trial, defendant Sprague Energy Corp. filed a *Daubert* motion to exclude the testimony of plaintiff's expert at trial. The trial judge denied defendants' motion to exclude without prejudice.[248] The district court reasoned that, "[s]o long as an expert's scientific testimony rests upon 'good grounds,' based on what is known, it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities."[249] The court also reasoned that, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."[250]

[242] Civ. No. 2:10-cv-445-GZS (D. Me. 2013).

[243] *Zagklara v. Sprague Energy Corp.*, Civ. No. 2:10-cv-445-GZS (D. Me. 2012) ("*Zagklara I*").

[244] *Id*. at 9.

[245] *Id*. at 9-10.

[246] *Id*. at 11.

[247] *Id*. at 12.

[248] *Zagklara II*, Civ. No. 2:10-cv-445-GZS, slip op. at 1. Prior to filing this pretrial motion in limine, Defendant Sprague Energy Corp. had filed a pre-trial motion to exclude plaintiff's expert report on the grounds that plaintiff had failed without explanation to deliver the report to defendant before it was to be used to support plaintiff's opposition to defendants' filing of a summary judgment motion. *See "Zagklara I,"* slip op. at 5-6. Thus, although the district court granted defendants' pretrial motion to exclude plaintiff's expert report, it then proceeded to deny defendants' subsequent pretrial motion to exclude plaintiff's expert's testimony.

[249] *Id*. at 1.

[250] *Id*. at 1-2, quoting *Milward*, 639 F.3d at 15. *See* accord *Bertrand v. General Electric Co.*, Civ. No. 09-11948-RGS (D. Mass. 2011), slip op. at 4, quoting *Daubert*, 509 U.S. at 596 and *Milward*, 639 F.3d at 15.

The district court held that any objections regarding the factual underpinnings of an expert's investigation go to the weight of the proffered testimony, and not to its admissibility, and "is readily probed via cross-examination."[251] The court thus concluded that "on the [then] current available record," plaintiff's expert's "proposed testimony falls within [FRE] 702's limits."[252]

Calisi v. Abbott Laboratories (D. Mass. 2013)[253] (Products Liability)

The plaintiff, who suffered from rheumatoid arthritis, alleged that defendant had failed to warn plaintiff and her treating rheumatologist of Humira's alleged risk of lymphoma. Although "rheumatoid arthritis itself is a risk factor for lymphoma," plaintiff also alleged that defendant had "heavily market[ed] and promote[d] Humira by 'educating physicians' including by directing its salespeople to tell doctors that 'all the risk of malignancy and/or lymphoma on the illness not the disease in its sales messages to [plaintiff's rheumatologist]."[254]

The defendant subsequently moved for summary judgment and exclusion of the testimony of plaintiff's four expert witnesses, especially the testimony of her "warnings" expert, Dr. Michael Hamrell, on issues of causation and the adequacy of Humira's label. The court focused on Hamrell's expert opinion on warning labels in the context of determining whether Abbott, as opposed to plaintiff's rheumatologist, had assumed a duty to warn[255] plaintiff about the alleged risk of lymphoma.[256] The court ultimately excluded Hamrell's expert testimony on the adequacy of defendant's warning, and the adequacy of the product's warning labels and granted defendant summary judgment.[257]

The district court reasoned that, the "*Daubert* analysis focuses on 'principles and methodology' used by the expert and a court may reject 'opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.'"[258] As the district court found, "'[t]his does not mean that trial courts are empowered 'to determine which of several competing

[251] *Id*. at 2-3.

[252] *Id*. at 3.

[253] Civ. No. 11-10671-DJC (D. Mass. 2013).

[254] *Id*. at 4.

[255] The Massachusetts "voluntary assumption of duty" doctrine is an exception to the Massachusetts "learned intermediary" doctrine, which "provides that a 'prescription drug manufacturer's duty to warn of dangers associated with its product runs only to the physician; it is the physician's duty to warn the ultimate consumer.'" Slip op. at 5 quoting *Cottam v. CVS Pharmacy*, 436 Mass. 316, 321 (2002) (quoting *McKee v. American Home Prods. Corp.*, 113 Wash. 2d 701, 709 (1989)). Pursuant to the "voluntary assumption of duty" exception, the court was required to determine "whether through the 'totality of … communications' [defendant] voluntarily assumed a duty that it would not otherwise have." *Id*. at 5-6.

[256] *Id*. at 5.

[257] *Id*. at 1, 4, 7-8.

[258] *Id*. at 9 quoting *Milward*, 639 F.3d at 14 (quoting *Daubert*, 509 U.S. at 595; *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

scientific theories has the best provenance.'" [259] "Instead, the proponent of the expert testimony must show 'by a preponderance of proof' that the expert has used a 'sound and methodologically reliable' reasoning process to reach his or her conclusion, and that 'an expert, whether basing testimony on professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'"[260] The district court, moreover, noted how the First Circuit had "cautioned that 'so long as an expert's scientific testimony rests upon 'good grounds,' based on what is known, it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities.'"[261] "'Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'"[262]

After evaluating Dr. Hamrell's expert opinion on the adequacy of Abbott's warnings, including its labeling accuracy and completeness, the district court concluded that such opinion, based on the record, was not admissible under *Daubert*/FRE 702.[263] According to the court, plaintiff failed to satisfy, the burden of showing "that Hamrell's opinion on adequacy [was] not 'connected to existing data only by the *ipse dixit* of the expert.'"[264]

The court reasoned that it was "not clear whether "Hamrell possessed sufficient facts or data to provide a basis for this opinion that the Humira labels 'failed to provide adequate information to doctors,' since Hamrell had not established a "baseline of what information" a doctor needed to make "his/her prescribing decision."[265] It also reasoned that Hamrell was "not a medical doctor and [did] not have 'qualifications to opine on what is clinically appropriate in terms of treating patients,'" and also that he had failed "to point to facts, such as those acquired through his experience, as to how the label's relevant target audience would interpret the Humira labels," and thus, to "what [facts] prescribing doctors would find adequate."[266] Consequently, the court concluded that Hamrell did not establish that his "adequacy" opinion had been based "on sufficient data so as to be reliable."[267]

The district court furthermore found that Hamrell did not show either, under FRE 702(c) "that his testimony would be the product reliable principles and methods," or under FRE 702(d) "that he reliably applied the principles and methods to the facts of the case." "Hamrell use[d] methodology other than his experience to assess the effect of the label on a

[259] *Id*., quoting *Milward*, 639 F.3d at 15.
[260] *Id*., quoting *Milward*, 639 F.3d at 15, (quoting *Kumho Tire Co.*, 526 U.S. at 152; *Daubert*, 509 U.S. at 592 & n. 10.
[261] *Id*., quoting *Milward*, 639 F.3d at 15 (quoting *Daubert*, 509 U.S. at 590).
[262] *Id*.
[263] *Id*. at 11, n. 6, 12-14.
[264] *Id*. at 14-15, quoting *Milward*, 639 F.3d at 14.
[265] *Id*. at 15.
[266] *Id*. at 17.
[267] *Id*.

prescribing medical doctor. He took no steps to determine if the label is misleading, confusing or downplayed any relevant risk."[268] Because Hamrell lacked the training, knowledge, and expertise of a prescribing physician, the district court found that he was "not qualified to opine as to the adequacy for prescribing purposes or confusion that this may generate in the label's target audience."[269] Consequently, the court held that plaintiff had failed to show "that Hamrell's testimony as to adequacy or physician perception would be the product of reliable principles or methods or that he […] reliably applied the principles and methods to the facts of the case."[270] The district court concluded for the same reason that Hamrell "would not be qualified to testify as to [a] (proposed, alternative) label's impact on prescribing physicians."[271]

In sum, the district court held that plaintiff had failed to meet her burden "to show that Hamrell would base his testimony on sufficient facts or data, […] that Hamrell's testimony [was] the product of reliable principles and methods, or that he ha[d] reliably applied the principles and methods (*i.e.*, his knowledge to the facts of the case," and consequently excluded Hamrell's testimony as to adequacy and labeling.[272] The court also held that, because plaintiff had failed to establish Hamrell's qualification to opine "as to the impact of marketing communications on prescribing doctors," it excluded his testimony on such topic.[273]

The district court came to the same conclusion on Hamrell's expert opinion testimony (*i.e.*, expert report and deposition testimony) on Abbott's conduct with respect to lymphoma and Humira and its failure to meet the standard of care. The court reasoned that "[t]he proponent of expert evidence must show that 'the expert's conclusion has been arrived at in a scientifically sound and methodically reliable fashion.'"[274] It also reasoned that "Hamrel's proffered basis for his expert opinion [was] conclusory and circular,"[275] because he did "not know if there is 'a standard of care with respect to labeling,' […] did not use […the] 'industry practices and guidances on providing information' [to which he referred, and] did not meaningfully explain how he used the FDA labeling regulations (or other reasoning) to determine that Abbott's 'conduct f[ell] below the standard of care for a reasonably prudent pharmaceutical company.'"[276]

[268] *Id*. at 17-18.
[269] *Id*. at 18.
[270] *Id*.
[271] *Id*. at 19-20.
[272] *Id*. at 20-21.
[273] *Id*. at 21.
[274] *Id*. at 22, quoting *Milward*, 639 F.3d at 15 (citing *Daubert*, 509 U.S. at 85).
[275] *Id*. at 23.
[276] *Id*.

Torres v. Mennonite General Hospital, Inc. (D.P.R. 2013)[277] (Medical Malpractice)

Plaintiff alleged that the "emergency" treatment provided to plaintiff's deceased husband by Mennonite General Hospital physician Dr. Omar Nieves caused his death. Dr. Nieves "had 'Associate' privileges," was "part of the on-call physician list of the Cardiology Department," "was the only Cardiologist available," and "was at the Emergency Room at the time of plaintiff's husband's emergency.[278] The court denied a motion in limine the defendant had filed to exclude the opinion testimony of plaintiff's medical expert, Dr. Carl Adams.[279]

The district court found that Adams was "'a witness qualified as an expert by knowledge, skill, experience, training, or education' and [that] his opinions [would] aid the trier [of fact] better to understand a fact in issue, *i.e.*, if Dr. Nieves applied the proper standard of care while treating the deceased."[280] The district court concluded that Adams possessed the requisite qualifications "to opine on the standard of care that should have been met by Dr. Nieves, a clinical cardiologists, in treating the deceased." It reasoned that Dr. Adams was "a licensed, board-certified cardiovascular, thoracic and board-certified trauma surgeon with over 32 years treating patients with cardiovascular disease."[281]

In response to defendant's claim that Dr. Adams' opinion was not supported by established guidelines and/or were irrelevant, the district court stated that, "the question of admissibility 'must be tied to the facts of a particular case.'"[282] The court further reasoned that, "'trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable.'"[283] It also noted that "[t]his does not mean, however, that trial courts are empowered 'to determine which of several competing scientific theories has the best provenance.'"[284]

According to the district court, "'*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct.'"[285] Rather, "[t]he proponent of the evidence must show only that 'the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.'"[286] The district court also emphasized that "[t]he object of *Daubert* is 'to make certain that an expert, whether basing testimony on professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes

[277] 988 F. Supp. 2d 180 (D.P.R. 2013).
[278] *Id*. at 189-90.
[279] *Id*. at 182.
[280] *Id*. at 183.
[281] *Id*.
[282] *Id*. at 184, quoting *Milward*, 639 F.3d at 14-15.
[283] *Id*., quoting *Milward*, 639 F.3d at 15.
[284] *Id*., citing *Ruiz-Troche*, 161 F.3d at 85.
[285] *Id*.
[286] *Id*.

the practice of an expert in the relevant field.'"[287]

On defendant's motion-in-limine challenge to Dr. Adams' reliability, the court held that "'[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'"[288] The court reasoned that Dr. Adams' opinion testimony "with regards to the standard of care used by Dr. Nieves while treating the deceased" had "[met] the requirements of Rule 702, Daubert and its progeny."[289] The court reasoned that Adams' testimony "both rest[ed] upon 'good grounds' and on a sufficiently reliable foundation based on the record and what [was] known," and that it was "also relevant to the task at hand, i.e., determining Dr. Nieves' (and Defendants') role, if any, on the demise of the deceased and if the proper standard of care was followed by Dr. Nieves (and Defendants) in treating the deceased."[290]

Campos v. Safety-Kleen Systems, Inc. (D.P.R. 2015)[291] (Toxic Torts)

Plaintiffs (husband, wife, and their minor child) sought damages under Puerto Rican territorial law against defendants for exposure to a chemical agent (SK-105) that allegedly caused plaintiffs to develop chronic myelogenous leukemia ("CML").[292] Following discovery, defendants filed motions in limine to exclude plaintiffs' expert testimony, opinions, and reports as unreliable under FRE 702 and *Daubert*.

The court emphasized that district courts' role as gatekeepers of reliable evidence was "a flexible one" the focus of which "is based solely on principles and methodology, not the conclusions that expert testimony generates."[293] The district court held the four *Daubert* factors were intended to "assist a trial court in determining the admissibility of an expert's testimony." Such "factors do not constitute a definitive checklist or test," given the different kinds of experts, expertise, and issues to be addressed. "These factors may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."[294] The court, furthermore, held that, "[a]s long as the expert's testimony rests upon 'good grounds based on what is known,' it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities."[295]

[287] *Id*.

[288] *Id*., quoting *Daubert*, 509 U.S. at 590, and citing *Currier v. United Techs. Corp.*, 393 F.3d 246, 252 (1st Cir. 2004) and *Milward*, 639 F.3d at 15.

[289] *Id*. at 184.

[290] *Id*. at 184-85.

[291] Civ. No. 12-1529 (PAD) (D.P.R. 2015).

[292] *Id*. at 1.

[293] *Id*. at 2, quoting *Daubert*, 509 U.S. at 580.

[294] *Id*. at 2, quoting *Milward*, 639 F.3d at 14, citing *Kumho Tire Co., Ltd.*, 526 U.S. at 150.

[295] *Id*. at 3, quoting *Milward*, 639 F.3d at 15, citing *Daubert*, 509 U.S. at 590, 596.

The district court denied defendant's motion to exclude the opinions of plaintiff's first expert, Goldsmith. It found that: (1) his opinion that benzene exposure may cause CML [was] consistent with published literature, medical institutions as well as the defendants' expert"; (2) Goldsmith had "examined all peer-reviewed published literature on benzene and CML, and there [were] no studies regarding the relationship between SK-105/mineral spirits and CML/leukemia"; and (3) Goldsmith "based his conclusions on the Bradford Hill Criteria, relying on the same methodology he use[d] in his epidemiology classes."[296] The district court, thus, held that Goldsmith's "opinions [were] based on reliable scientific evidence."[297]

The district court also denied defendant's motion to exclude the opinions of plaintiff's third expert, Frank. Defendants alleged that: (1) Frank had "considered the wrong substance in his report, inasmuch as SK-105 is not benzene"; (2) "the authorities on which Frank relie[d] [did] not support his opinion that benzene can cause CML"; (3) Frank "selectively picked studies favoring his conclusions while discarding the ones that did not"; (4) "because CML has no known cause, differential diagnosis alone is insufficient to pass the *Daubert* scrutiny"; (5) Frank's "diagnosis employs an unreliable methodology as there is no support for the opinion that benzene can cause CML"; and (6) Frank had "failed to consider the specific dose of benzene to which [plaintiffs were] exposed, and [could not] reliably rule out other potential sources of benzene apart from SK-105."[298] The district court held that "the core of defendants' arguments" went to the *weight* and credibility of [said expert's] contemplated testimony," and thus, were "more properly suited for cross-examination and presentation of contrary evidence."[299]

Quilez-Velar v. Ox Bodies, Inc. (1st Cir. 2016)[300] (Wrongful death/Negligence)

The plaintiff filed this wrongful death/negligence and products liability action in 2013 after a Jeep Liberty SUV crashed into the rear of a stopped or slowly moving Municipality of San Juan truck. The truck was fitted with an underride guard designed by defendant Ox Bodies.[301] The force of the accident resulted in "[t]he front of [the Jeep…] underrid[ing] the truck's trash body such that the truck penetrated the Jeep's passenger compartment and struck" the 28-year-old wife and mother (Maribel Quilez), who died from lacerations to her head and face.[302]

Ox Bodies filed a pre-trial motion in limine to exclude the testimony of plaintiff's expert, Ponder. Defendant argued that "Mr. Ponder's report was 'devoid of any scientific analysis or calculations that would support' his conclusion that his proposed alternative

[296] *Id*. at 3.
[297] *Id*.
[298] *Id*. at 4.
[299] *Id*. (emphasis added).
[300] 823 F.3d 712 (1st Cir. 2016).
[301] *Id*. at 715.
[302] *Id*.

underride guard design 'would have been a safer design in the instant accident,' and that his opinions should be excluded under *Daubert* [...]"[303]The presiding magistrate judge denied the motion to exclude Ponder's testimony.[304] The district court found that defendant had failed to show that specific tests Ox Bodies argued Ponder should have performed "must have been carried out to provide a foundation for Ponder's opinions." The district court also found that Ponder's report contained well-explained conclusions and appeared to reflect the appropriate use of crash-test data.[305]

At the conclusion of trial, the jury found defendant "strictly liable for defective design and awarded plaintiffs damages totaling $ 6 million." It "assigned 20% of responsibility for the damages to defendant Ox Bodies [$1.2 million], 80% to the Municipality of San Juan, which was not a party in the suit, and 0% to" the deceased 28-year-old wife and mother.[306] Defendant Ox Bodies appealed the verdict and the district court order supporting judgment in that amount. It "contend[ed] that the court should not have allowed the plaintiff's expert to testify on an alternative underride guard design, and that absent such testimony, no reasonable jury could have found for the plaintiffs."[307]

The appellate court held that the district court did not abuse its discretion "in concluding that Ponder's testimony on alternative design was sufficiently reliable to survive the admissibility threshold."[308] The appellate court "decline[d] to adopt […] a bright-line rule" requiring that "an expert himself must have tested an alternative design, much less by building one."[309] It also held that the reliability "factors *Daubert* mentions do *not* constitute a 'definitive checklist or test'"[310] (*i.e.*, *inter alia*, the factor relating to) "whether a theory or technique can be and has been tested."[311] According to the court, *Daubert required only that the district court had "conduct[ed] a fact-specific 'reliability' inquiry*."[312]

Second Circuit

Drake v. Allergan, Inc. (D. Vt. 2015)[313] (Products Liability/Negligence)

In *Drake*, the parents of a 5 ½-year old minor child ("J.D.") afflicted with cerebral palsy

[303] *Id*. at 715-16, n. 3.
[304] *Id*., citing *Quilez-Velar v. Ox Bodies, Inc.*, No. CIV. 12-1780, 2015 WL 418151, at *7 (D.P.R. Feb. 1, 2015).
[305] *Id*.
[306] *Id*. at 712, 716 citing *Quilez-Velar v. Ox Bodies, Inc.*, No. CIV. 12-1780, 2015 WL 898255, at *1–3 (D.P.R. Mar. 3, 2015).
[307] *Id*. at 712.
[308] *Id*. at 718.
[309] *Id*. at 719.
[310] *Id*. (emphasis in original).
[311] *Id*. at 12, 13 and n. 7.
[312] *Id*. at 12 citing and quoting Milward, 639 F.3d at 16-20. (emphasis added).
[313] 111 F. Supp. 3d 562 (D. Vt. 2015).

filed suit against Allergan, Inc., the manufacturer of Botox. J.D. developed a seizure disorder after his physician injected Botox into J.D.'s calves to treat his lower limb spasticity.

During the first day of trial, the court denied Allergan's motion to strike the testimony of plaintiff's medical causation expert, Hristova. At the conclusion of the trial, by which time plaintiffs had narrowed their claims to negligence and Vermont Consumer Fraud Act violations, the jury awarded plaintiffs approximately $2.78 million in total compensatory damages and $4 million in punitive damages. Allergan then moved for a judgment notwithstanding the jury verdict. The defendant reasoned that plaintiffs *inter alia* had "failed to provide sufficient evidence to support a finding of causation."[314]

The district court held that it had correctly denied Allergan's pre-trial motion to strike Hristova's testimony on the ground that "she relied on the 'totality of circumstances.'"[315] The district court reasoned that during the pretrial phase, the court had not found the individual categories of evidence to be unreliable, [or that] they present[ed] 'too great an analytical gap between the data and the opinion proffered.'"[316] The district court held, rather, that "some pieces of evidence that may have been insufficient to support a finding of causation in isolation could be sufficient when considered together."[317]

The district court next cited *Milward* to justify its effective acceptance of Hristova's use of weight-of-evidence methodology. According to the district court, the First Circuit found that "[t]he trial court failed to appreciate that the expert *inferred causality 'from the accumulation of multiple scientifically acceptable inferences from different bodies of evidence*.'"[318] The district court held that, it was "valid for an expert to infer causation based on the totality of evidence when combined it supports such an inference."[319]

Sullivan et al. v. Saint-Gobain Performance Plastics Corp. (D. Vt. 2019)[320] (Toxic Tort)

Plaintiffs, individual residents from Bennington and North Bennington, Vermont, filed suit against defendant, St. Gobain Performance Plastics Corp. In 2000, St. Gobain acquired Chem-Fab Corporation. Chem-Fab previously operated a plant located in Bennington where it produced Teflon-coated fabrics and other products from 1969 to 1979. Chem-Fab had also opened a second plant in 1978 in North Bennington where it continued to produce fabric in the same manner. In 2002, defendant St. Gobain closed the second plant and moved the fabric-coating process out of state to New Hampshire. The fabric-coating process employed by these plants required that fiberglass cloth and other fabrics be soaked in a water-based

[314] *Id*. at 566.
[315] *Id*. at 567-68.
[316] *Id*. at 568, quoting *Joiner*, 522 U.S. at 146.
[317] *Id*.
[318] *Id*., quoting *Milward*, 639 F.3d at 26 (emphasis added).
[319] *Id*., citing *Milward*, 639 F.3d at 23.
[320] Case No. 5:16-cv-125 (D. Vt., July 16, 2019).

solution containing Teflon, which, in turn, contained perflouroctanoic acid ("PFOA") as a dispersant. The court found, as a matter of fact, that PFOA is "highly resistant to degradation in the natural environment," is "readily transported by wind in the form of airborne particles as well as by ground and surface water," is known to "enter[] the food chain and [to] accumulate[] in the bodies of people and animals," and "is now detectable at low levels throughout the world."[321]

The results of a 2016 Vermont Department of Environmental Conservation ("VDEC") test of residential ground wells in and around Benning triggered plaintiffs' concerns about PFOA. "The results ranged from non-detectable levels to nearly 3,000 parts per trillion," with "[t]he contaminated wells [] primarily located in a 'zone of contamination' within the towns of Bennington and North Bennington."[322] These results prompted VDEC and the state health department to take immediate regulatory action, which included providing bottled water or individual filtration systems to residents with contaminated wells.

Plaintiffs' claims sought the establishment of "a system of medical monitoring to detect medical conditions such as certain cancers, high blood pressure in pregnant women, elevated cholesterol, and other conditions" alleged to be "strongly associated with exposure to PFOA." Plaintiffs also sought monetary damages for the contamination of their groundwater, lost property value, and for emotional harm.[323]

Plaintiffs proffered seven experts in support of their claims, four on the deposit of PFOA in groundwater, Hopke, Yoder, Siegel, and Mears, two on medical monitoring, Ducataman and Grandjean, and one on lost property values, Unsworth. Defendant thereafter filed *Daubert* motions to exclude the testimony of each of these experts. The district court understood the *Daubert* decision's "reliability" test as "entail[ing] a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid."[324] The court found that the *Daubert* Court had posited a "list of non-exclusive factors" for testing methodology, "includ[ing] testing, peer review and publication, error rate, the existence of standards for its application, and acceptance within the relevant scientific community."[325] It concluded, furthermore, that the *Daubert* "majority opinion [had] expressed a preference for resolving disputed issues through admission of contrary evidence and cross examination, not through rigid exclusion," and that the U.S. Supreme Court's majority opinion in *Joiner* "recognized the need for the court[, as gatekeeper, in evaluating the 'reliability' of expert opinions] to consider the strength of the logical connection between data and opinion."[326]

[321] *Sullivan*, slip op. at 3.
[322] *Id*. at 5.
[323] *Id*. at 6.
[324] *Id*. at 9, citing *Daubert*, 509. U.S. at 592-93.
[325] *Id*.
[326] *Id*., citing *Daubert,* 509 U.S. at 596, and *Joiner*, 522 U.S. at 146.

The court also compared the *Joiner* majority opinion—which held that it "'was within the [trial court's] discretion to conclude that the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions that Joiner's exposure to PCB's contributed to his cancer…'"[327]—with the *Kumho* majority opinion's emphasis on "the lack of a known, validated, measurable connection between observed data and conclusion that doomed the tire expert's testimony"—*i.e.*, its evaluation of "the *deductive* process by which the expert derives a conclusion from data and observation."[328] It then compared these majority opinions with Justice Stevens' concurring and dissenting opinion in *Joiner*, where he emphasized that "'*Daubert* quite clearly forbids trial judges to assess the validity or strength of an expert's scientific conclusions, which is a matter for the jury.'"[329]

The district court assessed the reliability of plaintiffs' experts' testimony by distinguishing between the requirement to evaluate an expert's methodology and the requirement to refrain from evaluating the *correctness* of the experts' opinion. It then "summarize[d] the data relied upon by the expert and then [sought] to identify and evaluate the method by which the data [led] *by inference* to a conclusion."[330] The court also noted that two of plaintiffs' medical-monitoring experts—Ducatman and Grandjean—had employed the "weight-of-evidence" approach in considering multiple studies.

Ducatman, a public health and occupational medicine specialist, opined in his report and testimony that drinking water-well contamination increased the levels of PFOA in the blood of hundreds of Bennington residents above average levels found in the general population. He also opined that "[t]he presence of PFOA in the bloodstream increases the risks of development of certain illnesses[,…] includ[ing], kidney and testicular cancer, hypertension and thyroid disease during pregnancy and problems with breast feeding, thyroid disease without pregnancy, liver disease, hyperlipidemia, gout, and ulcerative colitis."[331] Ducatman concluded that there was an *association* between PFOA and these illnesses, based, in part, on a 2017 Vermont Health Department report.[332] In addition he opined that since primary care physicians and other clinicians were "commonly unfamiliar with the effects of environmental toxins in general, and the class of PFAS of which PFOA is a member," medical monitoring would "increase the likelihood of early detection and improved outcomes for these conditions."[333]

[327] *Id*. at 10, quoting *Joiner*, 522 U.S. at 146-47.

[328] *Id*. at 11, citing *Kumho Tire Co.*, 526 U.S. 137 (emphasis added).

[329] *Id*. at 10, quoting *Joiner*, 522 U.S. at 154.

[330] *Id*. (emphasis added).

[331] *Id*.

[332] *Id*. at 28-29. Apparently, Ducatman had reviewed the 2017 report prepared by the Vermont Department of Health entitled "Exposure to Perfluorooctanoic Acid (PFOA) in Benning and North Bennington, Vermont," which listed most of these illnesses as having an "*association*" with "PFOA in blood." (emphasis added).

[333] *Id*.

The court found that Ducatman used a weight-of-evidence approach because "there were very few clinical studies of the effects of PFOA on humans."[334] As a result, he "relied on a literature search of epidemiological studies" of which there were many, to draw "a conclusion that PFOA is associated with increased incidence of certain cancers and other conditions."[335] He also relied on Agency for Toxic Substances and Disease Registry ("ATSDR") regulations the agency uses to determine "whether medical monitoring is appropriate in cases subject to the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. §§ 9601 *et seq.*," which were "not directly applicable" to the case at bar. Ducatman relied on these regulations "to conclude that medical monitoring would be an appropriate way to reduce the danger of these conditions through early detection."[336]

The court held that Ducatman's overall methodological approach "satisfie[d] *Daubert* [reliability] criteria." First, the court reasoned that, although medical monitoring (effectively a public health recommendation) cannot be tested, Ducatman's familiarity with other medical monitoring programs, his experience "in monitoring for occupational exposure to harmful substances such as asbestos," and "[h]is familiarity with the successes and shortcomings of these efforts provides a reasonable assurance that medical monitoring has been 'tested' in the real world."[337] Second, the court reasoned that although Ducatman "ha[d] published extensively in peer-reviewed journals on the subject of medical monitoring," he derived his expert opinion that PFOA exposure poses a danger to human health from third-party peer-reviewed research.[338] Third, the court reasoned that Ducatman's reliance on the ATSDR regulatory standards qualified as the identification of "an independent authoritative source to guide his analysis," for *Daubert* purposes, whether or not the parties agreed on whether the ASTDR factors would support medical monitoring.[339] Fourth, the court reasoned that "[m]edical monitoring is recognized as appropriate in certain circumstances" and has been generally accepted as a concept "at least since promulgation of the ATSDR regulations in 1995."[340] The court held that "[t]hese traditional *Daubert* factors support the admissibility of Ducatman's testimony."[341]

The district court noted that Grandjean was a "highly distinguished public health researcher" holding "joint appointments at the University of Southern Denmark and the Harvard School of Public Health," having approximately 500 published scientific papers, and serving as advisor to both United States and European government agencies.[342] Grandjean opined in his rebuttal report and testimony that, despite the limited data available about the

[334] *Id*. at 26, 32.
[335] *Id*. at 32.
[336] *Id*.
[337] *Id*. at 32-33.
[338] *Id*. at 33.
[339] *Id*.
[340] *Id*. at 34.
[341] *Id*.
[342] *Id*. at 35.

health hazards PFOA pose to the overall population and researchers' focus on PFOA only during the past ten years, his review of the available literature (published data and research papers and of court-ordered reports from cases in Ohio and West Virginia) led him to conclude that "PFOA is *associated* with the development of autoimmune diseases such as ulcerative colitis, reproductive disorders in both genders, complications of pregnancy, high cholesterol, and certain cancers."[343] Grandjean opined that "evidence of adverse health results is incomplete but strong enough to support *a link* between PFOA and the onset of certain serious diseases that is sufficient to justify some form of medical monitoring."[344]

The district court found that Grandjean's research and report and his overall methodological approach "satisf[ied] the *Daubert* criteria," viewing the admissibility of that testimony "through the lens of a court that has already decided that medical monitoring is a legal remedy for exposure to a toxic chemical."[345] The court concluded, consistent with Justice Stevens' concurring and dissenting opinion in *Joiner*, that "[i]t is not intrinsically 'unscientific' for experienced professionals to arrive at a conclusion by weighing all available scientific evidence," that "the weight of the evidence process through which Grandjean considered the available scientific evidence is a legitimate and accepted method of arriving at a scientific conclusion."[346] According to the court, "Grandjean's opinion – that '[…] elevated human exposure to PFASs pose a substantial present and potential hazard to human health' – is likely to prove relevant and *sufficiently reliable* to play a role in guiding the court on the issue of causation."[347]

The district court reasoned, first, that although Grandjean primarily relied on "cross-sectional and longitudinal studies of population health which could not be reproduced and tested like a chemistry experiment," the consistency in results of these papers, his consideration of dozens of papers on the health effects of PFOA in which he identified similar results, and his consideration of animal studies that could be duplicated satisfied the court's concern that "the data on health effects was subjected to as much testing as can be undertaken without experimentation on human subjects."[348] Second, the court reasoned that Grandjean's testimony on PFOA was "reliable" because he relied on peer-reviewed studies, has been published in many peer-reviewed journals, and has worked "in the area of the effects of human exposure to chemicals in the environment [which] has been subjected to many years of peer review."[349] Third, the court reasoned that "it would be difficult to assign a particular error rate to a determination that the *weight of the evidence* supported an association between PFOA exposure and certain diseases," and that it was satisfied he had

[343] *Id*. at 35-36 (emphasis added).
[344] *Id*. at 36 (emphasis added).
[345] *Id*. at 36-37.
[346] *Id*. at 39, quoting *Joiner*, 522 U.S. at 153.
[347] *Id*. at 37 (emphasis added).
[348] *Id*. at 36.
[349] *Id*. at 38; *see also id*. at 40.

"not unduly exaggerated the strength of his conclusions."[350] Fourth, the court accepted the statement contained in Grandjean's report that he "employed a weight of the evidence approach, as is commonly accepted in the scientific community in reviewing studies on a particular topic," and concluded that Grandjean "also favor[ed] studies that have been accorded weight by regulatory agencies" because it "'allows [him] to focus on the key studies that carry the most weight.'"[351] Finally, the court reasoned that, although Grandjean's methods were "subjective in the sense that their application to the choice of one paper over another is not documented, … they are objective in the sense that he limits his inquiry to published work that is listed at length in his 'cited publications.'" Grandjean thereby "provided a description of his source materials and an explanation of the criteria by which he chooses research papers." The court found that such "documentation – 277 papers in all – provide[d] assurance that he [] appli[ed] a consistent method which can be assessed by the fact-finder."[352]

Thus, Grandjean's "weight of the evidence review [was] not a subjective, 'black box' opinion that c[ould] not be examined."[353] The court ruled that since '[p]opulation-based studies and the 'weight of the evidence' assessment have achieved wide acceptance in the field of epidemiology," the methods [Grandjean] employed in reaching his conclusions are generally accepted."[354]

Third Circuit

In re Fosamax (D.N.J. 2013)[355] (Products Liability)

In this MDL proceeding, plaintiffs alleged that Fosamax, FDA-approved for the treatment and prevention of osteoporosis, causes atypical femur fractures ("AFF") and that it caused plaintiff's (Glynn)'s femur fracture.[356] Before trial, defendant Merck, Sharp & Dohme Corp. filed an omnibus *Daubert* motion to exclude the testimony of plaintiff's experts (Cornell, Klein, Madigan, and Blume). The district court denied the motion as to all four expert witnesses after the close of oral argument.

The court noted how Dr. Cornell "formed his opinion [on whether Fosamax causes AFFs] using the Bradford Hill criteria."[357] It also noted "[i]n applying the nine Bradford Hill

[350] *Id*. at 38 (emphasis added).
[351] *Id*. at 38-39.
[352] *Id*. at 39.
[353] *Id*.
[354] *Id*. at 40.
[355] *In re Fosamax (Alendronate Sodium) Products Liability Litigation*, Civil No. 11-5304, 08-08 (D.N.J. 2013), aff'd Civ. No. 12-2250 (3d Cir 2014).
[356] *Id*., slip op. at 1.
[357] *Id*. at 3, quoting *Gannon v. United States*, 292 Fed. Appx. 170, 173 (3d Cir. 2008). Notably, the Third Edition emphasizes that "*an association is not equivalent to causation*," (emphasis in original) citing as support the Third Circuit case of *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 461 (W.D. Pa. 2003) (finding that

factors, [Cornell] reviewed [p]laintiff's medical records, his office notes and depositions of her treating physicians, 'past and current medical literature on the topics of osteopenia, osteoporosis and their prevention and treatment with bisphosphonate drugs including alendronate,'" and particular publications focusing on studies describing "the appearance of AFFs."[358] Cornell had also "'review[ed] the original trials, the randomized trials, which led to the approval of Fosamax for the treatment of osteoporosis.'"[359] According to the district court, Cornell "attempted to 'present a balanced analysis,' […] pointed out studies on both sides of the issue," and "concluded that Fosamax can cause AFFs and 'Fosamax use was a substantial contributing factor to Mrs. Glynn's femur fracture.'"[360] The court found that the methodology Cornell used "[was] sufficiently reliable." It reasoned that the Bradford Hill criteria are "'broadly accepted' in the scientific community 'for evaluating causation,' […] and 'are so well established in epidemiological research.'"[361]

The district court dismissed defendant's objections that plaintiffs did "not explain the scientific methodology used by Dr. Cornell or show that his methodology [was] sufficiently reliable," and that "Cornell's 'weight-of-the-evidence' methodology just list[ed] some studies, only some of which support[ed] causation, and conclude[d] that the *weight of the evidence* shows that Fosamax causes AFFs."[362] The court also dismissed defendant's objection that Cornell's "method [was] inadequate because Dr. Cornell does not discuss how these studies establish causation or why certain studies outweigh others that do not find causation."[363] It reasoned that, while defendant was "free to address these issues on cross-examination, […such] concerns do not prohibit Dr. Cornell from testifying as an expert because he is qualified and the methodology he used [was] sufficiently reliable."[364]

The district court noted how Dr. Klein, "[i]n applying the nine Bradford Hill criteria, reviewed human and animal studies, and studies performed by [d]efendant to form his opinion, [which] studies revealed a strong association between bisphosphonates, like Fosamax, and microdamage in the bones as well as decreased bone toughness."[365] The court also emphasized how Klein's report "noted a strong association between delayed fracture

the Bradford Hill criteria had been "developed to assess whether an association is causal." *See Third Edition*, *supra* note 14, at 552, n. 7. However, this does not undo the potential prejudicial effect such testimony, once admitted, will have upon the trier of fact.

[358] *Id*. at 3-4.

[359] *Id*. at 4.

[360] *Id*.

[361] *Id*. at 4, quoting *Gannon*, 292 Fed. Appx. at 173. n. 1; I*n re Avandia Mktg., Sales Practices & Products Liab. Litig.*, 2011 WL 13576, at *3.

[362] *Id*. at 4 (emphasis added).

[363] *Id*.

[364] *Id*. at 4 citing and quoting *Milward*, 639 F. 3d at 15 ("stating '*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct'; instead, the proponent of the evidence must show only that 'the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.'").

[365] *Id*. at 6.

healing, due to altered bone quality, in patients and animals taking bisphosphonates," and that such "findings [had been] replicated in several studies discussed in Dr. Klein's report."[366] In addition, the court identified how Klein's report had cited studies "recogniz[ing] the '*duration*-dependent, as well as, dose-dependent effect bisphosphonates have on the skeleton,'" and "noted that the 'cessation of bisphosphonate treatment may be prudent for women on therapy who sustain nonvertebral fracture.'"[367] The court further found that Klein's review of such studies informed his conclusion that 'alendronate significantly alters the cellular property of bisphosphonate-treated bone."[368] The district court concluded that Klein had formed his opinion that "there [was] a causal relationship between Fosamax and AFFs" based on his use of "a sufficiently reliable methodology, the Bradford Hill criteria."[369]

The district court dismissed defendant's objections that "the Bradford Hill criteria apply to epidemiological studies" not discussed in Klein's report; that Klein failed to "provide[] support for the proposition that a general causation conclusion can be established using the Bradford Hill criteria and human or animal biopsy data"; that Klein failed to "demonstrate he is qualified to interpret that evidence because he has no expertise in epidemiology"; that Klein failed to establish "the mechanism regarding how bisphosphonates cause AFFs"; and failed to "prove[] with human data […] the theories [he] uses to support his conclusion about mechanism – microdamage, decrease in tissue heterogeneity, bone brittleness, and delayed healing."[370] Klein had "properly applied the Bradford Hill criteria to epidemiological studies," and cited the Third Edition for the proposition that "'toxicological models based on live animal studies … may be used to determine toxicity in humans' in addition to observational epidemiology."[371] The court also held that, "[f]or his testimony to be admissible, Dr. Klein is not required to show that the mechanism has been definitely established. Instead, he just needs to show that the methodology he used to arrive at his opinion is sufficiently reliable."[372]

The district court noted how Dr. Blume had reviewed published studies and other medical literature, other expert witness reports, epidemiological studies, FDA's Adverse Event Reporting System database, and FDA regulations and regulatory procedures specifically applicable to drug approval, labeling, post-marketing, surveillance and reporting, "using 'her years of experience' in 'the industry,'" to opine in her report that such information "confirmed the increasingly adverse risk-benefit profile related to long-term Fosamax use in the indicated populations."[373] The court also noted how Blume opined that defendant "should have changed the Fosamax label 'to include escalating warning and *precautionary*

[366] *Id.*
[367] *Id*.
[368] *Id*.
[369] *Id*.
[370] *Id*.
[371] *Id*. at 7, quoting *Third Edition*, *supra* note 14, at 563.
[372] *Id*., citing and quoting *Milward*, 639 F.3d at 15 (the same passage it quoted above).
[373] *Id*. at 10-11.

risk information related to' AFFs," since having "received reports that AFFs were '*associated with* Fosamax use as early as 2002,'" but failed to do so until 2009.[374]

The district court dismissed defendants' objections to admitting Blume's opinions, which included regulatory requirements and defendant's compliance with them; defendants' delay in amending the label to include femur fracture information and failure to add a precautionary warning; defendant's failure to timely investigate a potential link between Fosamax and AFF; defendant's alleged motives and state of mind; the causation or mechanism of AFF; and regarding safer alternative drugs. The court held that "it [wa]s not the appropriate time for [d]efendant to request that the Court preclude Dr. Blume from testifying about certain topics," and that defendant "may question Dr. Blume's opinions or methodology on cross-examination."[375]

In re Zoloft (Sertraline Hydrochloride) (3d Cir. 2017)[376] (Products Liability)

In re Zoloft is one of federal cases discussed in this paper where the court cited *Milward* for the proposition that the weight-of-the-evidence approach for general causation is a generally reliable methodology, and that the Bradford Hill criteria implementing that methodology is generally reliable. Like the *Milward* court, however, the Third Circuit also ruled the experts' testimony inadmissible under *Daubert* because the expert had failed to properly apply the weight-of-the-evidence methodology to the facts of the case.[377]

The Third Circuit evaluated the reliability of the expert's weight-of-the-evidence analysis, which "'involves a series of logical steps used to 'infer[] to the best explanation[.]'"[378] The court emphasized that, because the weight-of-the-evidence methodology "can be implemented in multiple ways[,…] each application is distinct and should be analyzed for reliability."[379] Indeed, the appeals court noted how the district court had previously identified that "'[t]he particular combination of evidence considered and weighed here ha[d] not been subjected to peer review.'"[380]

The Third Circuit acknowledged the flexibility of a weight-of-the-evidence approach, stating that "[a]n expert can theoretically assign the most weight to only a few factors, or

[374] *Id*. at 11 (emphasis added).

[375] *Id*. at 11, quoting *Milward*, 639 F.3d at 15 ("'[s]o long as an expert's scientific testimony rests upon 'good grounds,' based on what is known…, it should be tested by the adversarial process, rather than excluded'").

[376] 858 F.3d 787 (3d Cir. 2017).

[377] *See infra* discussions of *Jones v. Novartis Pharmaceuticals Corporation*, 235 F. Supp. 3d 1244 (N.D. AL 2017) (11th Circuit) and *In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation*, MDL No. 15-2666 (D.C. MN 2019) (8th Circuit).

[378] *In re Zoloft*, 858 F.3d at 795, quoting *Milward*, 639 F. 3d at 17.

[379] *Id*., citing *In re Paoli*, 35 F.3d at 758.

[380] *Id*. at 796, citing *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002).

draw conclusions about one factor based on a particular combination of evidence."[381] The court then proceeded to compare the "flexible" generally accepted differential diagnosis that doctors had employed in *In re Paoli* to the analogously flexible weight-of-the-evidence analysis that plaintiffs' expert had employed in *In re Zoloft* to establish a general causal connection between Zoloft and birth defects.[382]

Notwithstanding its acceptance of weight-of-the-evidence analyses, the court emphasized that the manner in which the expert applies that methodology to the facts of the case must also be reliable, consistent with *Daubert* principles:

> The specific way an expert conducts such an analysis must be reliable; 'all of the relevant evidence must be gathered, and the assessment or weighing of that evidence must not be arbitrary, but must itself be based on methods of science.' [fn] To ensure that the […] weight of the evidence criteria 'is truly a methodology, rather than a mere conclusion-oriented selection process…there must be a scientific method of weighting that is used and explained.' [fn] For this reason, *the specific techniques by which the weight of the evidence […] methodology is conducted must themselves be reliable* according to the principles articulated in *Daubert*. [fn] (underlined emphasis added).[383]
>
> Ultimately, the fact [the expert] *applied […] different techniques inconsistently, without explanation*, to different subsets of the body of evidence raises real issues of reliability. Conclusions drawn from such unreliable application are themselves questionable."[384]

The appeals court embraced the district court's previous findings that the expert had failed to "consistently assess the evidence supporting each [weight-of-the-evidence] criterion or explain his method for doing so."[385] According to the court, "[c]laiming a consistent result without meaningfully addressing […] alternate explanations as noted in *In re Paoli*, undermines reliability."[386] The court then held that because the expert "unreliably applied the techniques underlying the weight of the evidence analysis," he rendered his testimony unreliable, and consequently, inadmissible under the *Daubert* standards, which are intended "to ensure that the testimony given to the jury is reliable and will be more informative than

[381] *Id*.
[382] *Id*. at 795.
[383] *Id*. at 796 quoting *Magistrini*, 180 F. Supp. 2d at 602, 607.
[384] *Id*. at 798 (emphasis added).
[385] *Id*. at 799.
[386] *Id*., citing *In Re Paoli*, 35 at 760 "(noting the importance of explaining why a conclusion remains reliable in the face of alternate explanations.").

confusing."[387] "By applying different techniques to subsets of the data and inconsistently discussing statistical significance, [the expert] does not reliably analyze the weight of the evidence."[388]

The Third Circuit's *In re Zoloft* decision appears to scale back the less-rigorous approach previously taken by the District Court of New Jersey in *In re Foxamax*.

Fifth Circuit

***Levitt v. Merck Sharp & Dohme Corp.* (In re Vioxx Prods.)** (E.D. La. 2016)[389] (Products Liability)

This MDL involved Vioxx, which Merck had designed, developed, manufactured, and marketed to relieve pain and inflammation resulting from osteoarthritis, rheumatoid arthritis, menstrual pain, and migraine headaches. FDA approved Vioxx on May 20, 1999, and then ordered its withdrawal from the market on September 30, 2004 after data from a clinical trial indicated that its use increased the risk of cardiovascular thrombotic events such as myocardial infarction (that is, heart attack) and ischemic stroke.[390]

[387] *Id*. at 800.

[388] *Id*. At least one court sitting in the Second Circuit has expressed its agreement with the Third Circuit's assessment in *In re Zoloft* on the reliability of Bradford Hill methodology. According to the district court, in *In re Mirena IUS Levonorgestrel-Related Products Liability Litigation* (MDL No. II), 341 F. Supp. 3d 213 (S.D.N.Y. 2018), the Third Circuit had made clear that the nine proposed Bradford Hill criteria "'are metrics that epidemiologists use to distinguish a causal connection from a mere association.'" 341 F. Supp. 3d at 242, quoting *In re Zoloft*, 858 F.3d at 795. It found that they "'start with an association demonstrated by epidemiology and then apply' eight or nine criteria to determine whether that association is causal." 341 F. Supp. 3d at 242, quoting *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1234 (D. Colo. 1998). In addition, the district court held that it was "imperative that experts who apply multi-criteria methodologies such as Bradford Hill or the 'weight of the evidence' rigorously explain how they have weighted the criteria. Otherwise, such methodologies are virtually standardless and their applications to a particular problem can prove unacceptably manipulable." 341 F. Supp. 3d at 247. As support for this proposition, the district court quoted the Third Circuit's decision in *In re Zoloft*: "'To ensure that the Bradford Hill/weight of the evidence criteria is truly a methodology, rather than a mere conclusion-oriented selection process … there must be a scientific method of weighting that is used and explained.'" 341 F. Supp. 3d at 247, quoting *In re Zoloft*, 858 F.3d at 796. *Cf. In re Mirena IUS Levonorgestrel-Related Products Liability Litigation* (MDL No. II), 387 F. Supp. 3d 323, 356 (S.D.N.Y. 2019) (holding that "the items on which plaintiffs rely – following exclusion of their expert witnesses – to establish Mirena's causation of IIH do not do so. None comes remotely close."). *See id*. at 348, quoting *In re Zoloft*, 858 F.3d 787, 796 (3d Cir. 2017) ("To ensure that the Bradford Hill/weight of the evidence criteria is truly a methodology, rather than a mere conclusion-oriented selection process…there must be a scientific method of weighting that is used and explained."). *See also id*., quoting *Milward*, 639 F.3d at 26 (holding that the First Circuit "has required that, in analyzing the Bradford Hill factors, the expert must employ 'the same level of intellectual rigor' that he employs in his academic work.").

[389] *Levitt v. Merck Sharp & Dohme Corp. (In re Vioxx Prods.)*, MDL No. 1657 Section L (E.D. La. 2016).

[390] *Id*. at 1.

Thousands of individual suits and numerous class actions were thereafter filed against Merck in state and federal courts alleging various products liability, tort, fraud, and warranty claims. Levitt brought this action against Merck in the Western District of Missouri. Her complaint alleged that she suffered two heart attacks in 2001 as a result of taking Vioxx and sought compensatory and punitive damages. On November 8, 2006, the matter became part of the Vioxx MDL before the Eastern District of Louisiana.[391]

Although the parties had reached a $4.85 billion master settlement agreement on November 9, 2007, Levitt chose not to participate as an "interested claimant," and proceeded instead to litigate her claim. Levitt, designated five expert witnesses to which Merck responded by moving to exclude their testimony.

Levitt *inter alia* selected Dr. David Madigan, a professor and chair of statistics at Columbia University who held a Ph.D. in statistics. He was not a medical doctor, had no clinical experience, had never held a position in a medical school, had no experience in weighing the risks and benefits of medical treatment, including pharmaceuticals, was not an epidemiologist, and had no experience designing or conducting clinical drug trials.[392] Dr. Madigan also was "not an expert in pharmacology, cardiology, rheumatology, gastroentology, neurology, vascular biology, or any other medicine related to Vioxx."[393] Yet, Dr. Madigan had "proffered opinions relating to statistical issues with Merck's internal studies regarding the potential risks of Vioxx," *and regarding "an undisclosed statistical analysis that a different Plaintiff's expert, Dr. Egilman, ha[d] testified that he intends to rely on*."[394]

Merck challenged Madigan's opinions on Merck's disclosure-of-risk information. Merck claimed that "only an expert qualified in the field of medicine can speak to the analysis of the cardiovascular risk data in the studies at issue," and that "Madigan should be prohibited from testifying regarding Merck's assessment of the value of trial data."[395]

The court found that Madigan's "expert experience [was] exclusively in the fields of mathematics and statistics." It also acknowledged that, while "[r]eliance upon specialized knowledge is an acceptable ground for admission of expert testimony […], an expert cannot 'go beyond the scope of his expertise in giving his opinion.'"[396] The court then held that

> since Madigan does have extensive experience with mathematics and statistics, […he] may offer opinions […] related to these fields […] regarding the field of statistics, how they are compiled, and

[391] *Id*.
[392] *Id*. at 4.
[393] *Id*. at 4-5.
[394] *Id*. at 2 (emphasis added).
[395] *Id*. at 4.
[396] *Id*. at 5, quoting *Kumho Tire Co.*, 526 U.S. at 152; *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 247 (5th Cir. 2002); and *Goodman v. Harris County*, 571 F.3d 388, 399 (5th Cir. 2009).

> their general use. Inasmuch as Dr. Madigan's recently completed report aids in this testimony, he should be permitted to rely on it, as the report is no so prejudicial as to warrant exclusion. … Nonetheless, Dr. Madigan should not be allowed to opine on Merck's actions or inactions in disclosing or not disclosing various results. Similarly, Dr. Madigan should not offer opinions regarding Merck's interpretations of the test results or their significance. Such testimony would be outside his field of expertise.[397]

Levitt also "presented Dr. David Egilman as an expert in cardiology, toxicology, molecular biology, neurology, psychiatry, prescription drug marketing, regulatory compliance, ethics, corporate state of mind, and the law." Merck moved to exclude Egilman's testimony because he was "merely a retired general-practice physician who lack[ed] sufficient medical expertise to testify regarding any alleged risk of Alzheimer's disease, dementia, cognitive dysfunction, restenosis, or accelerated atherosclerosis," and that since he was "not qualified in the field of psychiatry," he was "unqualified to opine regarding Merck's state of mind, Merck's allegedly unethical marketing strategies, Merck's alleged noncompliance with regulatory opinions, and Merck's allegedly illegal activities."[398] Merck argued that "Dr. Egilman's study suggests that Vioxx is causally linked to a set of heart-related incidents that includes unstable angina, but does not in and of itself prove that Vioxx causes unstable angina. Merck contends that other cardiovascular endpoints such as cardiac arrest are driving the association in the study."[399]

Levitt countered that Egilman had "extensive training and experience that qualifie[d] him to opine on these points," namely, his Masters of Public Health degree from Harvard University, his "published articles on conflicts of interest in the context of public health," his testimony in the first Vioxx bellwhether trial in Texas, and his testimony "in numerous courts throughout the country on issues similar to the opinions presented in this case."[400] Merck responded that "Egilman may not rely on Dr. Madigan's causation analysis.[…that he] should not be permitted to testify regarding Dr. Madigan's study finding that Vioxx is linked to acute coronary syndrome, and therefore, to unsable angina. […] According to Merck, Fifth Circuit law requires statistical analyses to isolate the particular injury suffered by a plaintiff, and not merely a[n] umbrella category of diseases containing that specific disease."[401]

The court found that Dr. Egilman was "a board certified doctor and internist" who had "completed advanced study in the areas of epidemiology, occupational medicine, warnings, and risk communication, among other topics," and had "written extensively on the topic of medical epistemology," and thus, was "qualified to offer opinions based on his expertise,

[397] *Id*.
[398] *Id*. at 8.
[399] *Id*.
[400] *Id*.
[401] *Id*. at 9.

including epidemiology."[402] The court continued, "Egilman's experience as a family doctor provide[d] him an adequate basis for rudimentary observations regarding Levitt's psychiatric and emotional well-being," and he was "qualified to offer basic opinions in the fields of neurology to the extent such opinions are limited to what may be observed by a general family doctor."[403] The court, however, precluded Egilman from offering any "diagnostic opinions regarding Levitt's emotional or psychiatric state, or extensive conclusions in the specialized field of neurology," which were "outside his area of expertise, and therefore inadmissible."[404] Furthermore, since FRE 703 enables an expert to "base opinions on facts or data he has been made aware of during the case[, which] includes other expert reports in the case," the court held that "Dr. Egilman's conclusions based on Dr. Madigan's report are admissible."

Moreover, the court agreed with Merck that under Fifth Circuit precedent, "Egilman's testimony would be restricted to the relationship between Vioxx and the specific injury at issue here – unstable angina." Consequently, the court held that, "[u]nder this rule, Dr. Egilman cannot utilize a study linking Vioxx to general cardiac events – which may include unstable angina – to prove that Vioxx is directly linked to unstable angina."[405] In other words, "Dr. Egilman's testimony that Vioxx is causally associated with unstable angina—as opposed to general cardiac events—likely has too great of an analytical gap between the data and his opinion to meet the *Daubert* standard."[406]

Most significantly, the court emphasized that, notwithstanding Fifth Circuit law, "this case [would] not be tried in the Fifth Circuit, and this Court [was] unaware of any Eighth Circuit or Missouri cases directly addressing this issue." In addition, the court noted that "the United States Court of Appeals for the First Circuit [in *Milward*] has taken a different approach, and has allowed experts to testify that a particular exposure was linked to a specific injury when statistical studies demonstrated the exposure caused a class of various injuries, including the specific disease at issue."[407] The court thus concluded that "the trial court should determine whether Dr. Egilman's testimony that Vioxx is causally associated with unstable angina meets the *Daubert* requirements under Missouri law." The court also emphasized that, although one Western District of Missouri case had relied on the Fifth Circuit *Allen* case, in which the court had applied Texas law to "exclude[] expert testimony, in part, because the expert was unable to provide a direct link between the exposure and the particular cancer at issue," the First Circuit had taken a different position in *Milward*. It had "allowed an expert to testify that because benzene causes acute myeloid leukemia …, it was also capable of causing a specific subtype of AML," where the expert had "noted 'all subtypes of AML likely have a common etiology,' and this particular subtype ha[d] been reported in

[402] *Id*. at 10.
[403] *Id*.
[404] *Id*.
[405] *Id*. at 10, citing *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996).
[406] *Id*. at 11.
[407] *Id*. at 11, citing *Milward v. Acuity Specialty Prod. Grp., Inc.*,639 F.3d 11, 20 (1st Cir. 2011).

many other workers who were also exposed to benzene."[408] The court granted in part, and denied in part, Merck's motion to exclude.[409]

Sparling ex rel. Sparling v. Doyle (W.D. Tex. 2016)[410] (Products Liability)

Plaintiffs alleged that the decedent died after using defendants'[411] dietary supplement product containing DMAA—the compound 1,3-Dimethylamylamine.[412] Defendants sought to exclude the testimony of four of the Plaintiffs' six experts, arguing that their testimonies were unreliability under FRE 702. The magistrate judge granted defendants' motion to strike the testimony of three experts and denied their motion to strike the fourth.[413] Plaintiffs appealed to the district court.

The district court found that the magistrate judge had not committed clear error when concluding that one expert's "'mere assurances that dogs are a good model to predict human effects'" were "insufficient," and that another expert had failed to provide "support for his extrapolation from the dog data to human data other than his assurances that literature existed on the subject," and had "stated that even assuming such literature does exist, he 'freely admitted that he did not rely on that material to form his opinion.'"[414] The district court reasoned that, "[b]ecause 'studies of the effects of chemicals on animals must be carefully qualified in order to have explanatory potential for human beings' and Plaintiffs' experts did not take the steps necessary to qualify the dog studies for human extrapolation based on the circumstances of this case, [the magistrate judge] properly found that the opinions derived from the dog studies were unreliable."[415]

In addition, the district court referenced plaintiffs' argument that no evidence had been presented to demonstrate that the one expert "'was not qualified to make the analysis [n]or that the analysis was flawed."[416] The district court also noted plaintiffs' citation of "out of circuit cases for the proposition that the 'entire body of evidence relied on by the expert should be taken into consideration in evaluating the reliability of the opinion, and the court should refrain from an 'atomistic' approach that determines that each piece of evidence is

[408] *Id*. at 11, quoting and citing *Milward*, 639 F.3d at 20.

[409] The Eastern District of Louisiana issued its decision on September 16, 2016, recommending that the case be transferred back to the transferor court in Missouri, and the Judicial Panel on Multidistrict Litigation issued a conditional remand on October 14, 2016, remanding said case to the Western District of Missouri.

[410] *Sparling ex rel. Sparling v. Doyle*, Civ. No. EP-13-CV-00323 DCG (W.D. Tex. 2016).

[411] *Sparling ex rel. Sparling v. Doyle*, Civ. No. EP-13-CV-323-DCG (W.D. Tex. 2015).

[412] *Id.*

[413] *Sparling ex rel. Sparling v. Doyle*, Civ. No. EP-13-CV-00323 DCG (W.D. TX 2016), Slip op. at 2.

[414] *Id.* at 10. The district court noted how the magistrate judge had "determined that the conclusions of Plaintiffs' experts based on studies of dogs were not reliable because Plaintiffs' experts failed to account for differences between the dog studies and the circumstances at issue in this case, specifically the delivery mechanism and the dosage.").

[415] *Id*.

[416] *Id*. at 11.

insufficient, on its own, to support the expert's conclusion.'"[417] According to plaintiffs, one expert's [Cantilena's] "'calculations bridge[d] the gap the Magistrate said existed in the class effect discussion by accounting for differences in route of administration, pharmacokinetics, potency, and by providing an established mechanism of action.'"[418]

The district court emphasized that plaintiffs relied primarily on *Milward*, which the court found "instructive […] for the issue at hand," notwithstanding that the Fifth Circuit had "generated a wide body of law to guide the Court's rulings."[419] The district court found helpful *Milward*'s "determination [in that action] that the trial court had improperly crossed over from gatekeeper to factfinder in making its reliability assessment."[420] The court also found helpful *Milward*'s warning to trial courts on the burden of proof for expert testimony. In particular, it "warned trial courts that proponents of expert testimony need not demonstrate that the assessments of their experts are correct," and warned trial courts that they were "not empowered 'to determine which of several competing scientific theories has the best provenance.'"[421]

The district court, furthermore, found helpful *Milward*'s word of caution to trial courts to ensure that proponents of expert testimony "show that 'the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.'"[422] In other words, trial courts "may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable.'"[423] Moreover, the district court found that the magistrate judge had not made a "factual assessment of the weight of the experts' opinions," but rather had "focused on the reliability of using the studies that underpinned Dr. Cantilena's proffered opinion to 'bridge the gap,' explaining that 'Dr. Cantilena provides no indication that other experts in his field use similar methodologies to extrapolate between sympathomimetrics and he pointed to no literature making these comparisons to validate his approach.'"[424] Thus, the court "found that because the underlying studies were unreliable and could not be used to support Dr. Cantilena's conclusions, [the court] was left with nothing but the *ipse dixit* of the expert."[425] "Consequently, [the court] determined that Dr. Cantilena was unreliable."[426]

[417] *Id*.

[418] *Id*.

[419] *Id*.

[420] *Id*. at 11-12, quoting *Milward*, 639 F.3d at 22. *See also id*. at 12 ("It based its conclusion in part on its finding that he trial 'court's analysis repeatedly challenged the factual underpinnings of [the expert's] opinion, and took sides on questions that are currently the focus of extensive scientific research and debate—and on which reasonable scientists can clearly disagree.'").

[421] *Id*. at 12, quoting 639 F.3d at 22 ("'[T]he fact that another explanation might be right is not a sufficient basis for excluding [the expert]'s testimony.'").

[422] *Id*., quoting *Milward*, 639 F.3d at 15, citing *Daubert*, 509 U.S. at 85.

[423] *Id*.

[424] *Id.* at 12.

[425] *Id.* at 12-13.

[426] *Id.* at 13.

Sixth Circuit

In re Heparin Products Liability Litigation (N.D. Ohio 2011)[427] (Products Liability)

In this MDL, plaintiffs alleged that defendants' sale of contaminated heparin triggered a myriad of adverse reactions leading to serious injuries and deaths. Defendants moved for summary judgment based, in part, on several ancillary *Daubert* evidentiary challenges. Defendants had sought to exclude the general causation testimony proffered by plaintiffs' experts, Drs. Hoppensteadt, Jeske, Kiss, Buncher, Luke, and Ohr.[428]

Among defendants' *Daubert*-related claims, they alleged that the court must exclude the testimony of plaintiffs' experts "because the epidemiological evidence contradicts the evidence on which plaintiffs' experts rel[ied]."[429] The court recognized that courts "have rejected non-epidemiological evidence as unreliable where there is an overwhelming body of epidemiological evidence to the contrary."

However, the court found that there was "no such overwhelming body of contrary epidemiological evidence" in the case at bar. Although neither of the two epidemiological studies plaintiffs' experts cited were "designed to determine whether there was an association between contaminated heparin and any of the conditions identified" in defendants' summary judgment motion, and thus, did not "provide support for" plaintiffs' experts' theories, they also did not contradict them.[430]

Consequently, the court declined to "categorically exclude" plaintiffs' scientific evidence "solely on the basis that it [was] not epidemiological in nature." According to the court, *Daubert* required "only that the expert's methodology be sound," and the Sixth Circuit, as well as "numerous other [federal circuit] courts had made clear, '[n]o requirement exists that a party *must* offer epidemiological evidence to establish causation."[431] In partial support of this proposition, the court cited *Milward* ("'epidemiological studies are not per se required as a condition of admissibility regardless of context.'").[432]

[427] *In re Heparin Products Liability Litigation*, 803 F. Supp. 2d 712 (N.D. Ohio 2011).

[428] *Id*. at 719.

[429] *Id*. at 727, citing *Turpin v. Merrell Dow Pharmaceutical Inc.*, 736 F. Supp. 737, 743 (E.D. Ky. 1990).

[430] *Id*. at 728.

[431] *Id*., quoting *In re Meridia Prods. Liab. Litig*., 328 F. Supp. 2d 791, 801 (N.D. Ohio 2004) (emphasis in original). *See also id*. at 800 ("Epidemiological evidence may be the 'primary generally accepted methodology for demonstrating a causal relation between [a] chemical compound and a set of symptoms or a disease,' but it is not the *only* methodology that scientists use.") (emphasis in original).

[432] *Id*. at 728, 756 n. 6, quoting *Milward*, 639 F.3d at 24.

DeGidio v. Centocor Ortho Biotech, Inc. (N.D. Ohio 2014)[433] (Products Liability)

Plaintiff, who was suffering from Crohn's disease, claimed under Ohio state law that defendant failed to warn him that the immunosuppressant drug Remicade "can cause non-infectious interstitial lung disease."[434] Plaintiff was took Pentasa "(generic name mesalamine), a prescription drug used to treat ulcerative colitis," on a daily basis. Doctors at University of Michigan Hospital later reviewed plaintiff's lung biopsy and determined he had been suffering from 'Remicade-induced eosinophilic pneumonitis with no clear infectious etiology.'"[435] Defendant filed a partial summary judgment motion premised its *Daubert* motions, which, if granted, would leave the plaintiff without any admissible evidence to prove proximate cause.[436]

Plaintiff's expert witness, Dr. Mark Thorton, implicitly concluded that Remicade could cause interstitial pneumonitis based, in part, on case reports appearing in medical journals. Those reports "describe[d] 'clinical events in one or more individuals … [namely] …"new disease presentations, manifestations, or suspected associations between two diseases, effects of medication, or external causes.'"[437] Thorton had explained that, "as early as 2001, 'case reports began … noting the onset of noninfectious pulmonary complications of TNF inhibitor therapy, including eosinophilic pneumonitis, pulmonary fibrosis/interstitial lung disease, granulomatous disease and alveolar hemorrhage.'"[438]

One report Thorton had referenced concerned findings by Tel Aviv Medical Center doctors that, of thirteen patients treated with Remicade for Chrone's disease, four had been observed to suffer "from anaphylactic shock, disseminated eruption and eosinophilic pneumonitis."[439] Another report Thorton had cited "concerned a Crohn's patient who, "'[w]thin 48 hours after the second infliximab infusion,' developed 'severe respiratory distress,' which "near-fatal condition included 'partially organized intraaveolar hemorrhage,' or bleeding into the lungs."[440] The authors of this report had "hypothesized that infliximab [had been] responsible for the patient's injury"; yet, they also "acknowledged that '[t]he exact mechanism by which infliximab may have caused the observed lung results remain[ed] unknown.'"[441]

Thorton furthermore looked to the Bradford Hill criteria to support his professional opinion. Although Bradford Hill posited nine criteria, the *DiGidio* court emphasized that

[433] *DeGidio v. Centocor Ortho Biotech, Inc.*, 3 F. Supp. 3d 674 (N.D. Ohio 2014).
[434] *Id.* at 675.
[435] *Id*., citing *De Gideo v. Centocor Ortho Biotech*, 2010 WL 4628903, at *1 (N.D. Ohio 2010).
[436] *Id.* at 675.
[437] *Id.* at 677.
[438] *Id*.
[439] *Id*.
[440] *Id.* at 678.
[441] *Id*.

Thorton's report addressed only two of them—"1) the temporal relationship between infliximab infusions and the onset of symptoms associated with interstitial lung disease; and 2) 'challenge/re-challenge,' which evaluates whether a patient's condition improves after a given medication is withdrawn or worsens after the same medication is reintroduced."[442]

Thorton also testified about the third Bradford Hill criterion—coherence—"which holds that '[c]oherence between epidemiological and laboratory findings increases the likelihood of an effect.'"[443] According to the district court, "Thorton's testimony on this issue[, however,] exposed a wide gulf between what the law and epidemiologists understand to be a proper opinion on general causation and Thorton's own opinion."[444] The court found that Thorton's testimony failed to "attempt to 'link' an association between Remicade and an 'event,' by which he mean[t] an injury or disease." The court found that Thorton's analysis only referred to coherence in the context of "'a post-marketing pharmacovigilance mindset of what makes sense within the disease[.]'"[445] It also found that Thorton's "analysis concerned the 'regulatory strength' of the association between Remicade and interstitial lung disease, not the 'statistical strength' of that association."[446]

The court also found that, while Thorton had acknowledged plaintiff had been taking "Pentasa concurrently with [Remicade]," and that "Pentasa is strongly associated with interstitial lung disease," he "did not try to determine whether Pentasa could have caused plaintiff's lung injury," and had relied instead on "another expert's conclusion that Remicade was more likely than Pentesa to have caused plaintiff's injuries."[447]

The court held *inter alia* that, although "the absence of epidemiological studies [was] not fatal to plaintiff's case," plaintiff's experts bore "the burden to explain how their general-causation methodologies remain reliable in the absence of that important evidence."[448] To this end, the court also held that Thorton and plaintiff's other experts had "relied exclusively on case reports to support their opinions that Remicade can cause interstitial pneumonitis and diffuse alveolar damage." And, it held how that methodological approach was problematic since federal courts had recognized that "'case reports along cannot prove causation.'"[449]

Among the many shortcomings of the case reports, the district court emphasized their failure: 1) "to screen out alternative causes for a patient's condition"; 2) to compare the rate

[442] *Id*.
[443] *Id.* at 679.
[444] *Id*.
[445] *Id*.
[446] *Id*.
[447] *Id.* at 679-80.
[448] *Id.* at 684.
[449] *Id*., citing and quoting *In re Meridia Prods. Liab. Litig*., 328 F. Supp. 2d 791, 808 (N.D. Ohio 2004). *See also* 3 F. Supp. 3d at 685.

at which the observed "phenomena occur in the general population or in a defined control group"; 3) to "isolate and exclude potentially alternative causes"; 4) to "investigate or explain the mechanism of causation"; and 5) to include relevant facts about the patient's condition […] thereby hampering one's ability to apply any conclusions made in a given report to other cases." [450] Consequently, since "plaintiffs' experts' sole basis for opining that Remicade can cause interstitial pneumonitis [was] case reports," the district court held that, "those experts' methodologies [were] unreliable under *Daubert*, and their testimony [was] inadmissible on that basis alone."[451]

Eighth Circuit

Kuhn v. Wyeth, Inc. (8th Cir. 2012)[452] (Toxic Tort)

A National Institutes of Health ("NIH") Women's Health Initiative ("WHI") ("NIH-WHI") study prematurely released in 2002 and reported in the *AMA Journal* triggered lawsuits combined into an MDL. The study found that "the use of estrogen plus progestin increase[d] the risk of breast cancer. Plaintiffs Pamela Kuhn and Shirley Davidson each took Prempro, a Wyeth, Inc. hormone therapy drug for approximately three years, and nearly two years, respectively, and each developed breast cancer.[453] Prempro was "a combination hormone therapy composed of conjugated equine estrogen and medroxyprogesterone acetate. It [was] used to treat symptoms of menopause, including vasomotor symptoms and vaginal atrophy."[454]

Kuhn and Davidson filed separate lawsuits in the Western District of Arkansas alleging that Wyeth had failed to warn them of the increased risk of breast cancer posed by Prempro. The Judicial Panel on Multidistrict Litigation ordered the lawsuits' transfer to multidistrict proceedings in the Eastern District of Arkansas.[455]

The MDL judge chose Kuhn's and Davidson's claims for a bellwether trial. In proceedings before a magistrate judge, plaintiffs' expert, Dr. Donald Austin, "opined that short-term use of Prempro increase[d] the risk of breast cancer." That judge found Austin's testimony insufficiently reliable under *Daubert*. The district court affirmed the magistrate judge's *Daubert* order and granted Wyeth summary judgment.[456] Plaintiffs appealed, and an

[450] *Id.* at 684, citing *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995), and *Reference Manual on Scientific Evidence* 475 (Fed. Judicial Ctr.2000) ("'[c]ausal attribution based on case studies must be regarded with caution'"). The court cited the Second Edition, rather than, the Third Edition of the Reference Manual.

[451] *Id.* at 685.

[452] *Kuhn v. Wyeth, Inc.*, 686 F.3d 618 (8th Cir. 2012).

[453] 686 F.3d at 620-21.

[454] *Id*. at 621.

[455] *Id*. at 620.

[456] *Id*.

Eighth Circuit panel reversed the district court, ruling that the magistrate judge had abused his discretion in precluding plaintiff's expert's testimony, and remanded the case for further proceedings.[457] Below is a detailed discussion of the trial-court proceedings and the Eighth Circuit's reversal.

Before the MDL judge in Arkansas began pre-trial proceedings, Wyeth advised the court that a claim similar to Kuhn's and Davidson's was going to trial in the District of Puerto Rico. Wyeth intended to file a *Daubert* challenge to plaintiff's general-causation expert, who would be offering testimony similar to the expert in the Kuhn/Davidson trial. The Arkansas and Puerto Rico courts agreed to hold a joint *Daubert* hearing. During that November 29, 2010 hearing, which considered defendant's previously filed *Daubert* challenge to the general causation opinions of plaintiffs' experts, Wyeth moved to exclude the testimony on the ground there "existed no reliable scientific basis" for the conclusion that "taking Prempro for less than three years increase[d] a woman's risk of developing breast cancer."[458] Wyeth relied on the NIH-WHI report's finding that "women who took Prempro for three years or less had fewer incidents of breast cancer than those who took the placebo," and it argued that the NIH-WHI study had been well accepted in the medical and scientific communities, and that the studies upon which plaintiffs had relied were "methodologically flawed."[459] Wyeth also alleged that plaintiffs had "cherry-picked" from the observational studies comprising the NIH-WHI report, "relying upon the ones that showed an increased risk of breast cancer rather than the great weight of the studies that showed no increased risk."[460]

Prior to the November 2010 hearing, plaintiffs' expert, Austin, had filed a declaration setting "forth his standards for reviewing observational studies, including that he would not rely on 'underpowered' studies, which he defined as studies that were not likely to identify an association or an effect, if one existed."[461] He also opined that the NIH-WHI "study's estimate of short-term risk was 'quite poor' due to shortcomings 'that diminish[ed] the estimate of the effect of short-term exposure.'"[462] For example, the average age of the post-menopausal women who had participated in the study had been much older than the age of "the women who typically started[ed] hormone therapy. Moreover, the study tended to exclude women who were experiencing moderate hot flashes" who were "more likely to be susceptible to the carcinogenic effects of [estrogen plus progastrin] E + P."[463] And, Austin opined that the NIH-WHI "study's analysis necessarily underestimate[d] the relative risk because approximately forty percent of the participants dropped out of the study and about

[457] *Id*. at 621.
[458] *Id.* at 622.
[459] *Id*.
[460] *Id.* at 623. Interestingly, "[h]ormone therapy plaintiffs typically […] relied on the [NIH-]WHI study to show that the study was not powerful enough to detect whether short-term use of Prempro caused an increased risk." *Id.* at 622.
[461] *Id.* at 623
[462] *Id*.
[463] *Id*.

eleven percent of the placebo group began taking E + P."[464]

Although the district court had not considered Austin's declaration at the November 2010 hearing, which had been "limited to counsels' arguments," it later "ordered a second *Daubert* hearing and called for live testimony from the parties' experts," which took place on January 12, 2011 before a Magistrate Judge.[465] During the second hearing, Austin conceded that two of the studies upon which his opinion relied "should not have been included in his expert report," and that, he had "thus based his opinion that short-term use of Prempro causes breast cancer" on three other observational studies.[466] The Magistrate Judge ultimately granted Wyeth's motion to preclude expert testimony and entered summary judgment. He reasoned that Austin's expert testimony had "failed to discredit the [NIH-]WHI study's results and failed to base his opinion on epidemiological studies that 'reliably support[ed] his position.'"[467] The district court affirmed that decision.

In reviewing the magistrate judge's decision to exclude plaintiff's expert's testimony for an abuse of discretion, the Eighth Circuit cited *Milward* for the proposition that, "[p]roponents of expert testimony need not demonstrate that the assessments of their experts are correct, and that trial courts are not empowered 'to determine which of several competing scientific theories has the best provenance.'"[468] It also cited *Milward* for the proposition that a " district court's focus on 'principles and methodology, [and] not the conclusions that they generate,'" as the Supreme Court had directed in *Daubert*, "'need not completely pretermit judicial consideration of an expert's conclusion.'"[469]

The appellate court initially determined that plaintiffs did not bear the burden to disprove the NIH-WHI study, as the district court had found; rather, plaintiffs needed to "show that Dr. Austin arrived at his contrary opinion in a scientifically sound and methodological fashion."[470] It then determined that the magistrate judge had "abused his discretion in deciding that Dr. Austin's criticisms of the [NIH-]WHI study were unfounded and inconsistent with his reliance on the study in other hormone therapy cases."[471]

Unlike the district court, the Eighth Circuit found credible Austin's testimony that, while the NIH-WHI study "was an ideal study design – ' the gold standard for what it was designed for' – […] it was designed to show what effect E + P had on heart disease." "[A]lthough the study monitored incidents of breast cancer, the women were not selected to

[464] *Id*.
[465] *Id.* at 624.
[466] *Id*.
[467] *Id*. More specifically, it found that Austin had "failed to meet his burden 'to present reliable science to support his conclusion regarding the unreliability of the WHI.'" *Id*. at 626.
[468] *Id.* at 625, quoting *Milward*, 639 F.3d at 15.
[469] *Id.* at 625, quoting *Daubert*, 509 U.S. at 595 and *Milward*, 639 F.3d at 15.
[470] *Id.* at 626.
[471] *Id.* at 627.

test whether Prempro causes breast cancer."[472] The court held that, Dr. Austin's "reliance on the [NIH-]WHI study *to prove general causation* d[id] not foreclose his opinion that the study did not accurately assess the risk of breast cancer associated with the short-term use of Prempro."[473] In other words, "his previous reliance on and testimony regarding the [NIH-]WHI study d[id] not render his opinion inadmissible."[474] The court furthermore found that the three observational studies (one American and two foreign) upon which Dr. Austin's testimony relied, despite their limitations, "provide[d useful information and] support for Austin's opinion […] that short-term use of Prempro increases the risk of breast cancer. Taken together, the Calle study and the foreign studies constitute appropriate validation of and good grounds for Dr. Austin's opinion."[475]

O'Neal v. Remington Arms Co. (D.S.D. 2016)[476] (Products Liability)

The widow of the deceased, who had been shot and killed in a hunting accident, brought suit in the District of South Dakota against Defendants Remington Arms, Co., LLC, Sporting Goods Properties, Inc. and E.I. Dupont de Nemours and Co. Defendants moved for summary judgment and to exclude the testimony of plaintiff's expert witness, Charles Powell.[477] The district court granted defendants' summary judgment motion, but it denied their motion to exclude Powell's testimony "as moot."[478] The Eighth Circuit reversed and remanded, concluding that "the record contained sufficiently disputed material facts to preclude entry of summary judgment in Defendants' favor."[479]

On remand, defendants renewed their motion for summary judgment and to exclude Powell's expert testimony. As the district court noted, the Eighth Circuit directed it to apply a three-part test when screening expert testimony under FRE 702: 1) the relevancy/usefulness of the scientific, technical, or other specialized knowledge to the trier of fact; 2) the qualification of the expert to assist the trier of fact; and 3) the reliability or trustworthiness of the evidence in an evidentiary sense.[480] The Eighth Circuit continued, "To satisfy the reliability requirement, the party offering the expert testimony must show by a preponderance of the evidence 'that the methodology underlying [the expert's] conclusions is scientifically valid,'" employing various factors.[481] The appeals court then quoted the *Kuhn* decision, which in turn had quoted *Milward*: Since, "[a]t times, conclusions and methodology are not entirely distinct from one another, […] the court 'need not completely pretermit judicial consideration of an

[472] *Id*.
[473] *Id*. (emphasis added).
[474] *Id.* at 627-28.
[475] *Id.* at 629, 631, 632.
[476] *O'Neal v. Remington Arms Co.*, Civ. No. 4:11-CV-04182 (KES) (D.S.D. 2016).
[477] *Id*. at 1.
[478] *Id*.
[479] *O'Neal v. Remington Arms Co., LLC*, 803 F.3d 974, 982 (8th Cir. 2015).
[480] *O'Neal v. Remington Arms Co.*, *supra* note 252, slip op. at 2-3.
[481] *Id*. at 3, quoting *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010).

expert's conclusions.'"[482]

Because the Eighth Circuit did not rule on the admissibility of Powell's testimony, it directed the district court on remand "to address the issue in the first instance."[483] The essence of Powell's expert testimony was that the Remington Model 700 rifle that killed plaintiff's deceased husband was manufactured in 1971, a year when Remington assembled Model 700 rifles "with the 'Walker' fire control system, the relevant parts of which included the trigger, the connector, the sear, and the safety lever."[484] After Powell's review of internal Remington documents, several law-enforcement reports from officers who had investigated Mr. O'Neal's death, statements from witnesses, the known history of the rifle, and "his own knowledge and experience from performing failure analyses in approximately fifty other cases involving firearms, some of which also involved Remington rifles," he concluded that the Remington Model 700 had been defective, and that the defect caused the accident that killed Mr. O'Neal.[485]

Powell "testified that all Model 700 rifles manufactured at the time with the Walker fire control system [were] defective," because dirt corrosion or condensation could "build up between the trigger and the connector" and "lead to misfires," and "because the fire control components [were] enclosed in a riveted housing" which prevented uses from "easily inspect[ing] the connector's engagement with the sear."[486] While Powell "acknowledged that he could not testify with certainty that this alleged design defect caused the accident in this case," he was able to testify that "the specific rifle involved in this case was defective."[487]

Powell based this testimony on his knowledge that "many of the older Model 700 rifles fired inadvertently when the user toggled the safety from the 'on' to the 'off' position, and that Remington had "acknowledged by 1979 that about 1% of the approximately 2,000,000 Model 700 rifles manufactured prior to 1975 (*i.e.*, 20,000 rifles) were defectively made."[488] According to Powell, the manufacturing defect consisted of "'an insufficient clearance between the sear and the connector such that if the safety is on and you pull the

[482] *Id*., quoting *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012), quoting *Milward*, 639 F.3d at 15.

[483] *Id*. at 4.

[484] "The connector is an elongated U-shaped piece of metal located in front of the trigger. The sear is an independent piece of metal that interacts with the connector and the firing pin. When the rifle is not being fired, the bottom tip of the sear rests on and is supported by the top rear of the connector. The sear also restrains the firing pin. When the trigger is pulled, the connector is pushed forward and the bottom tip of the sear is allowed to fall behind the connector. This action releases the firing pin, which allows the rifle to fire a cartridge. When the safety is in the "safe" or "on" position, it physically lifts and restrains the sear away from its engagement point with the connector. When the safety is moved to the "fire" or "off" position, the sear is returned to its engagement point with the connector." *Id*. at 5.

[485] *Id*.

[486] *Id*.

[487] *Id*. at 6.

[488] *Id*.

trigger, the connector will get trapped in front of the sear and [be] allowed to drop.'"[489] He also based this opinion on the testimony of "Mark Ritter, the individual who [had] handled the gun at the time of the accident." Ritter testified that "the rifle discharged when he moved the safety from the 'on' to the 'off' position," which "supported" Powell's conclusion that "the rifle had the 1% defect because the defect allowed Model 700 rifles to discharge when the safety was toggled from the 'on' to the 'off' position."[490]

The greatest weakness in Powell's expert testimony was his admission that "he was unable to examine the rifle because it had been destroyed," and that therefore, he "could not determine definitively the amount of sear lift actually present in the rifle at the time of the accident."[491] Defendants also argued that Powell could not rule out other possible causes of the accident that did not support his theory. For example, since Powell could not inspect the destroyed rifle, he "could not be certain that the fire control system was improperly altered or adjusted."[492] And, because Powell could not examine the rifle, he also couldn't rule out whether the rifle's owner had improperly maintained, abused, or neglected it. Nevertheless, Powell testified that, although parts of the fire-control system, if broken, would have caused misfires, he was unaware of any evidence of improper maintenance, abuse or neglect of the rifle, or of broken fire-control system parts. "None of the officers noted the presence of broken parts or that the file showed signs of neglect."[493] Furthermore, because Powell could not examine the rifle, he could not "determine whether the original Walker fire-control system had ever been replaced" with an after-market trigger mechanism that could cause misfires.[494] In the absence of any evidence indicating that the Walker fire-control system had been replaced, Powell concluded that "Ritter's description of the accident was consistent with documented problems with the Walker fire control system."[495]

Although Powell was unable to definitively exclude other potential causes of the accident unrelated to a manufacturing defect, South Dakota law allows a plaintiff to "rely on circumstantial evidence to support a products liability cause of action." In other words, "the plaintiff need not 'eliminate all other possible explanations of causation that the ingenuity of counsel might suggest. It is sufficient that plaintiff negate his own and others' misuse of the product.'"[496] The district court then quoted *Kuhn*'s reference to *Milward*: "Thus, the '[p]roponents of expert testimony need not demonstrate that the assessments of their experts are correct, and trial courts are not empowered 'to determine which of several competing…theories has the best provenance.''"[497] "Rather, 'it is [O'Neal's] burden to show

[489] *Id*.
[490] *Id*.
[491] *Id*.
[492] *Id*. at 7.
[493] *Id*.
[494] *Id*.
[495] *Id*.
[496] *Id*. at 8, quoting *Crandell v. Larkin & Jones Appliance Co.*, 334 N.W.2d 31, 34 (S.D. 1983).
[497] *Id*., quoting *Kuhn*, 686 F.3d at 625 (quoting *Milward*, 639 F.3d at 15).

that [Powell] arrived at his…opinion in a scientifically sound and methodological fashion.'"[498]

The district court found that, "[a]lthough Powell agreed that he could not be absolutely certain about his conclusion, he also explained why he did not believe that any of the alternatives posed by defendants caused the accident." It also found that Powell "ha[d] offered sufficient justifications for his beliefs that those other conceivable causes are excludable."[499] Furthermore, the district court held that, although "Powell acknowledged that he could not pinpoint when the trigger was pulled [with Ritter having testified that he was sure he did not pull the trigger at any time while he was handling the rifle], … Powell believed that the trigger must have been pulled at some time after the rifle was loaded and that it was '*the best explanation* for what caused the fire-on-safe release.'"[500] The court apparently accepted Powell's explanations that "the trigger *could have been* pulled at any time after the rifle was loaded for the defect to manifest itself," and that "the trigger *could have been* pulled by accidental means, such as getting caught on an object or moved by an unaware individual," especially where it found that "the manner in which the rifle was kept inside the vehicle allowed for the possibility that someone, or some object depressed the trigger."[501] It would, therefore, seem that the district court had recognized Powell's use of abductive reasoning from which to derive an "inference to the best explanation," an approach that *Milward* had recognized as a reliable methodology in assessing the admissibility of expert testimony.[502]

Sioux Steel Co. v. KC Engineering, P.C. (D.S.D. 2018)[503] (Negligence)

Plaintiff Sioux Steel Company designed and manufactured an agricultural grain-storage bin (the "Hopper Bin") for Mexican company, Agropecuaria El Avion. Sioux Steel hired defendant engineering firm KC Engineering, P.C. to perform a design review of the structure prior to delivery. After Agropecuaria took possession of and installed the bin, its employees filled it with soybean meal. The bin collapsed, killing two employees. Plaintiff alleged that during its review, defendant negligently failed to identify a design defect made by Sioux Steel

[498] *Id*.

[499] *Id*. at 8.

[500] *Id*. at 9 (emphasis added).

[501] *Id*.

[502] *See id*. at 10. ("While the events leading up to the accident and the destruction of the rifle create several unknowns, expert opinions 'must be supported by appropriate validation-i.e., 'good grounds,' based on what *is* known.' *Daubert*, 509 U.S. at 590" (emphasis added)). What is known is that the subject rifle was manufactured during a time when approximately 1% of Model 700 rifles were constructed with a manufacturing defect and that the rifle discharged in a manner that could be indicative of that defect. The record contains at least some circumstantial evidence supporting Powell's theory. The Eighth Circuit has admonished district courts that the better practice in close cases is to give the jury the opportunity to pass on the proffered expert opinion evidence. *Lauzon*, 270 F.3d at 695. The court will follow that practice here. Based on the Rule 702 factors identified by the Eighth Circuit, the court finds that Powell is qualified to provide an expert opinion, and that his opinion would be relevant and reliable.").

[503] *Sioux Steel Co. v. KC Engineering, P.C.*, Civ. No. 4:15-CV-04136-KES (D.S.D. 2018).

engineer Chad Kramer, a failure that plaintiff argues led to the bin's collapse and the employees' deaths.

KC Engineering designated John Carson as its expert witness. Carson prepared two expert reports discussing the cause of the grain bin's structural failure and the role defendant's review of the grain bin had played in causing or contributing to its failure.[504] Carson concluded in his first report that the grain bin had failed "because a dynamic load formed due to either collapsing of an arch or rathole or firing of the air cannons."[505] Carson based his expert opinion on thirteen other opinions, court documents, photos and documents obtained during discovery, as well as three expert reports and one U.S. and two foreign (Australian and European) engineering standards. Carson's first expert report focused on the applicability of the engineering standards (U.S. – ANSI/ASAE EP 433 for loads exerted by free-flowing grains on bins; Australian – AS 3774 for loads on bulk solid containers; European – EN 1991-4, Eurocode 1 for actions on structures). [506]

Carson's second report focused on the firing of air cannons based on his review of Agropecuaria's surveillance video of the failure.[507] An air cannon is a high-pressure device that contains compressed gas that is quickly released into an agricultural bin or silo to rid it of "ratholing"—which occurs when materials stick to the sides of such structures to prevent material flow—or of "bridging"—which occurs when materials stick together across the width of the silo or bin to prevent material flow.[508] Ratholing and bridging will not occur if a product is "free flowing"—*i.e.*, "sand, provided that the particles are reasonably round and approximately the same size, and that the sand is not moist."[509] Carson concluded that defendant's expert's lack of review had no bearing on the structural failure, and that "the firing of the air cannons 'likely resulted in greatly increased (compared to gravity alone) pressure on the hopper wall,' considering that "the initial failure occurred almost directly below one of the air cannons."[510] Plaintiff moved to exclude Carson's testimony based on his lack of expert qualifications and because his testimony was not reliable.[511]

In evaluating the reliability of Carson's testimony under FRE 702, the district court noted that the party offering the testimony bears the burden of showing "by a preponderance of the evidence 'that the methodology underlying [the expert's] conclusions

[504] *Id*.
[505] *Id*.
[506] *Id*. at 2-3.
[507] *Id*. at 3.
[508] *See* Primasonics Acoustic Cleans, *Silo and Hopper Ratholing*, https://www.primasonics.com/silo-and-hopper-ratholing; Chicago Vibrator Products, *Air Cannons for Silos and Hoppers*, https://www.chicagovibrator.com/Store/c/air-cannon-systems; Martin Engineering, *Air Cannons*, https://www.martin-eng.com/content/product_subcategory/491/air-cannons-products.
[509] *See* SCE, *FAQ Overview: What is Bridging in a Silo?*, http://sce.be/en/faq/what-is-bridging-in-a-silo.
[510] *Sioux Steel Co. v. KC Engineering, P.C.*, slip op. at 3.
[511] *Id*.

is scientifically valid.'"[512] The district court also held that "when making the reliability inquiry, the court should focus on 'principles and methodology, not on the conclusions that they generate.'"[513] The district court quoted *Milward* for the following proposition: "At times, conclusions and methodology are not entirely distinct from one another, and the court 'need not completely pretermit judicial consideration of an expert's conclusions.'"[514]

The district court found Carson's expert testimony related to the agricultural industry grain-bin standard reliable[515] for the following reasons: 1) the evidence revealed that Carson's methodology consisted of reviewing and analyzing the parameters of an accepted U.S. standard/code (ANSI/ASAE EP 433, for loads exerted by free-flowing grains on bins) based on his experience, skill, education, and knowledge of storage structures, and then applying the standard to the facts of the matter, during which he had not relied on any new science for his opinions;[516] 2) there was no analytical gap between the data and Carson's opinions/statements that EPP 433 was "highly simplistic" because it "applies only to free-flowing agricultural whole grain," that soybean is not an agricultural whole grain, and that EPP 43 did not apply in this case because it does not address non-free-flowing grains;[517] and 3) although the methodology upon which Carson based his conclusion that EPP 433 was inapplicable to non-free-flowing grains had not been peer reviewed or tested, "Carson's plain reading and application [of the standard] to the facts [was] a reliable method."[518]

Moreover, the district court found Carson's testimony and report on air cannons reliable for the following reasons: 1) Carson found that, although the "Hopper Bin's upper portions had been under-designed to meet proper safety standards," it did not fail even though it had been filled for four days, thereby indicating that a "dynamic load" imposing a force greater than a "gravity-induced load" must have been present to cause the failure;[519] 2) Carson had based his explanation that "a dynamic load can develop in a bin from two possible means[, including]: by a collapse of an arch or rathole and by the firing of air cannons" upon his education, skill, experience and investigation;[520] 3) Carson had based his conclusion that the actual air cannon sequencing, based on their location (*i.e.*, where "the upper cannons fired before the lower ones") had been "contrary to 'good operating practice' (which caused the soymeal to "bec[o]me even more compacted than if the lower cannons were fired first," and "added even more pressure to the silo's walls") upon his own investigation and peer reviewed publications;[521] 4) Carson's examination of emails between

[512] *Id*. at 5, quoting *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010).
[513] *Id*. at 6, quoting *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (citing *Daubert*, 509 U.S. at 595).
[514] *Id*. at 6, quoting *Kuhn v. Wyeth, Inc.*, 686 F.3d at 625 (quoting *Milward*, 639 F.3d at 15).
[515] *Id*. at 11.
[516] *Id*. at 8-9.
[517] *Id*. at 10.
[518] *Id*. at 10-11.
[519] *Id*. at 13-14.
[520] *Id*. at 14.
[521] *Id*.

Sioux City and its contractor, Kramer, revealed Kramer's concern and "uncertainty about the 'kinds of loads the cannons would place on the hopper structure'";[522] and 5) Carson had drawn conclusions from his review and analysis of the Mexican company Agropecuaria's surveillance video of the failure and of plaintiff's expert reports based on his "extensive experience of investigating other silo failures";[523] and 6) although Carson's "opinions have not been tested nor subject to peer review," they were "based on his review of other peer reviewed material and his own publications."[524]

In sum, the district court concluded that Carson's report conclusions did "not amount to guesswork or speculation" because he "relied on facts in evidence and disclosed a reliable investigation to support his testimony," and consequently, his methodology "m[et] the *Daubert* standards."[525]

In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation (D. Minn. 2019)[526] (Products Liability)

In this MDL, the District of Minnesota acknowledged the acceptability of the weight-of-the-evidence methodology to determine the admissibility of expert testimony on general causation, but rejected as unacceptable the experts' specific application of this methodology to the facts of the case at bar.

"Plaintiffs alleged that Defendant's Bair Hugger Forced Air Warming Device ('the Bair Hugger') [, a device for keeping surgical patients warm, consist[i]ng of a portable heater or blower connected by a flexible hose to a disposable blanket that is placed over (or in some cases under) surgical patients,] caused their periprosthetic joint infection ('PJI') as a sequela to orthopedic-implant surgery."[527] Plaintiffs based their allegations on two theories. Pursuant to the "'airflow disruption' theory," "the Bair Hugger's warm air flow escapes the bottom edge of the surgical drape, creating turbulence in the operating room ('OR') which lifts squames (shed skin flakes that can carry bacteria) into the air and into the surgical site, and increased the risk of infection."[528] Plaintiff's engineering expert, "Dr. Elghobashi, a recognized expert in computational fluid dynamics ('CFD'), built a CFD simulation to model this theory," which "purports to show that the Bair Hugger generates extreme turbulence in the OR causing squames to reach the surgical site."[529] Pursuant to the "'dirty machine' theory," "the

[522] *Id*.
[523] *Id*. at 16.
[524] *Id*.
[525] *Id*. at 16-17.
[526] *In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation*, MDL No. 15-2666 (D. Minn. 2019). *See also* discussions re *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, Civ. No. 16-2247 (3d Cir. 2017) (precedential), and *Jones v. Novartis Pharmaceuticals Corporation*, 235 F. Supp. 3d 1244 (N.D. Ala. 2017) (11th Circuit).
[527] *Id.*, slip op. at 1.
[528] *Id*. at 2.
[529] *Id*.

device, which lacks an adequate filtration system, emits contaminants into the OR, and thus, increases the bacterial load reaching the surgical site."[530]

Having reviewed studies supporting both theories of causation, including Elgohashi's CFD simulation and "one epidemiological study that found a statistically significant association between the Bair Hugger and PJI," plaintiffs' three medical experts, Drs. Jarvis, Samet, and Stonnington, opined that the Bair Hugger causes PJI.[531] Defendants countered that "the scientific literature expressly disclaims causation," and, prior to trial, they moved "the Court to exclude these opinions for this reason," and for summary judgment.[532] The district court wrote that "[f]or purposes of general causation, the issue in this litigation [was] whether use of the Bair Hugger device increase[d] the risk of PJI compared to the risk of infection when the device is not used."[533]

In its December 13, 2017 order in one of eight selected bellwether cases, the district court denied defendants' *Daubert* motions to exclude such testimonies, finding Plaintiffs' engineering and medical experts' testimonies admissible. Specifically, the court found Elghobashi's simulation used "accepted physics principles to show how the Bair Hugger's warm air flow could cause squames to float upward toward the surgical wound." It also found the Jarvis, Samet, and Stonnington medical testimonies had relied on "Elgobashi's testimony as well as on the epidemiological study for reliable mechanistic and statistical evidence that the Bair Hugger causes PJI."[534]

During the April 2018 hearings on the parties' case-specific dispositive motions in the first bellwether case to make it to trial—*Gareis*—the court denied defendants' motions to exclude the testimonies of plaintiffs' engineering and medical experts.[535] However, the court granted defendants' May 2018 pretrial motions in *Gareis* to exclude evidence pertaining to plaintiffs' 'dirty machine' theory, having "determined that 'Plaintiffs [had] no evidence that however many *Staphylococcus epidermidis* might be in the Bair Hugger, that that number would have a meaningful impact on the bacterial load of that pathogen in the operating room.'"[536]

Although plaintiffs' experts Elghobashi, Jarvis, and Stonnington testified during the subsequent May 2018 trial, the jury ruled in favor of defendants. It concluded that plaintiffs had failed to "prove by a preponderance of the evidence that the Bair Hugger caused [their] infection," and that "[…] the Bair Hugger system was unreasonably dangerous and a safer

[530] *Id*.
[531] *Id*.
[532] *Id*. at 2, 3.
[533] *Id*. at 2.
[534] *Id*. at 3.
[535] *Id*.
[536] *Id*. at 4.

alternative design existed."[537] During August 2018, 3M requested leave to move for reconsideration of the court's earlier *Daubert* rulings on the basis that "new evidence [had] undermine[d] the scientific support proffered by plaintiffs' medical experts in their general causation opinions."[538]

In reviewing 3M's motion for reconsideration of its prior *Daubert* rulings, the district court ultimately excluded Elghobashi's testimony. It did so because Elghobashi's "conclusion relie[d] on an unproven and untested premise, … there [was] too great an analytical gap between the CFD results and [his] conclusion that the surgical team's movement would only increase the Bair Hugger's effect in the real world," and "the CFD simulation [had been] developed for litigation, which raise[d] concerns about its reliability and objectivity."[539] The district court also excluded as "unreliable" under *Daubert* the expert opinions/testimonies of plaintiffs' three medical experts. The court reasoned that "(1) there [was] too great an analytical gap between the literature and the experts' general causation opinions; (2) the experts failed to consider obvious alternative explanations; and (3) the causal inferences made by the experts [had] not been generally accepted by the scientific community."[540]

In explaining the reasoning behind its conclusion that there was too great an analytical gap between the literature and the medical experts' causation opinion, the court focused, in part, on the sole epidemiological observational (*i.e.*, not a blinded and controlled) study the medical experts had relied upon.[541] In so doing, it emphasized that, "'[i]n evaluating epidemiological evidence, the key questions […] are the extent to which a study's limitations compromise its findings and permit inferences about causation.'"[542] The court pointed out that the authors of the study, which "compared infection rates at Wansbeck Hospital in Northumbria, England, during a period when the Bair Hugger and […] when a conductive warming device were in use," had "warned against conflating correlation with causation: '[t]his study does not establish a causal basis…the data are observational and may be confounded by other infection control measures instituted at the hospital."[543] The court also emphasized that the study's authors had "expressly acknowledged that there was a period when different anti-thrombotic and different prophylactic antibiotic drugs were being used with the two groups of patients," and that the authors had been "unable to consider all factors that have been associated with [PJI], as the details of blood transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection, were not sufficiently detailed in the medical record.'"[544]

[537] *Id*.
[538] *Id*.
[539] *Id*. at 10.
[540] *Id*. at 22-23.
[541] *Id*. at 34.
[542] *Id*., quoting *Third Edition*, *supra* note 14, at 55-3.
[543] *Id.* at 34-35.
[544] *Id*. at 35, quoting the observational study (the McGovern (2011) Observational Study), at 8.

The court emphasized above all else how "it is unreliable for an expert to rely on studies to support conclusions that the study authors were themselves unwilling to reach."[545] As support for that proposition, the court noted how federal district courts had "analyzed whether an expert addresses a study's limitations as a way of determining if the study reliably supports a causation opinion."[546] The court next compared how plaintiffs' medical experts had "fail[ed] to address the McGovern researchers' caveats about confounders and alternative explanations" and had "inappropriately treat[ed] the association as affirmative evidence of causation." [547]According to the court, "[b]oth Drs. Jarvis and Stonnington cite[d] the Observational Study without discussing the study's limitations and possible confounders. And although Dr. Samet mentione[d] potential confounders acknowledged by the study's authors, his description of them [was] misleading."[548]

The court also primarily emphasized how Samet had "depart[ed] from his own description of reliable methodology when opining about causation."[549] The court specifically referred to Samet's application of "several criteria to determine if causation exists. With regard to 'strength of association'" (*i.e.*, his having reported that the Observational Study established a "'statistically significant association unlikely to be explained by confounding or other bias'").[550] It also specifically referred to Samet's application of the criteria of consistency: "Dr. Samet acknowledges, however, that this factor is not applicable to the Observational Study since this factor is generally related to the 'findings of multiple observational studies.' […] Instead, Dr. Samet points to the series of empirical studies which […] found that the Bair Hugger's convection currents increase the number of particles in the sterile field. But these studies do not establish – let alone consider – whether there was an association between the Bair Hugger and infection.").[551]

Indeed, the court found that, "[w]ithout further explanation of Dr. Samet's thought process and how he weighted these criteria, […] Dr. Samet's application of the factors [did] not reassure the Court that he ha[d] bridged the gap between the scientific literature and his causation opinion."[552] In support of this conclusion, the court compared Samet's failure to

[545] *Id*. at 36, quoting *Joiner*, 522 U.S. at 145-46, and citing *Huss v. Gayden*, 571 F.3d 442, 459 (5th Cir. 2009) ("It is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation had been proven.").

[546] *Id.* at 36, citing and quoting as an example, the U.S. District Court for the Southern District of New York's decision in *In re Mirena Ius Levonorgestrel-Related Prod. Liab. Litig*. (No. II), 341 F. Supp. 3d 213, 277 (S.D.N.Y. 2018), where the district court "found that an expert "'failed to consider the alternative, and benign, explanations that that study identified for the correlation it found between Mirena and IIH,' and consequently held that "the report inappropriately treated the correlation as 'affirmative evidence of causation' and excluded the expert's testimony because it did not meet the standards for reliability articulated in *Daubert*." *Id*. *See* discussion *supra* note 164 of *In re Mirena*.

[547] *Id*. at 37.

[548] *Id*.

[549] *Id*. at 37, quoting *Junk v. Terminix Int'l Co.*, 628 F.3d 439, 448 (8th Cir. 2010).

[550] *Id*. at 37.

[551] *Id*. at 37-38.

[552] *Id*. at 38.

follow his follow his own methodology with his failure "to employ 'the 'same level of intellectual rigor' that he employs in his academic work.'"[553] The district court also referred, once again, to *In re Mirena (No. II)* for the proposition that "courts have recognized [that] it is imperative that experts who apply multi-criteria methodologies such as Bradford Hill or the 'weight of the evidence' rigorously explain how they have weighted the criteria. Otherwise, such methodologies are virtually standardless and their applications to a particular problem can prove unacceptably manipulable. Rather than advancing the search for truth, these flexible methodologies may serve as vehicles to support a desired conclusion."[554]

Ninth Circuit

In re Roundup Products Liability Litigation (N.D. Cal. 2018)[555] (Toxic Tort)

In this recent toxic-tort MDL involving more than 400 cases, plaintiffs alleged that their exposure to glyphosate, which is the active ingredient in Roundup, a widely used herbicide, had caused them to contract Non-Hodgkin's Lymphoma ("NHL"), a form of cancer.[556] During the "general causation" phase of the action, Monsanto moved for summary judgment and the trial court evaluated "whether a reasonable jury could conclude […by a preponderance of the evidence…] that glyphosate, a commonly used herbicide, *can* cause [*i.e.*, "is capable of causing"] [NHL] at exposure levels people realistically may have experienced."[557] Although the district court concluded that it was a "close question" whether to admit the "shaky" opinions of three of plaintiffs' experts that glyphosate *can* cause NHL at human-relevant doses, it found those opinions admissible under Ninth Circuit caselaw.[558] According to the court, Ninth Circuit caselaw "emphasizes that a trial judge should not exclude an expert opinion merely because he thinks it's shaky, or because he thinks the jury will have cause to question the expert's credibility."[559] As "long as an opinion is premised on reliable scientific principles, it should not be excluded by the trial judge."[560]

The district court identified "two significant problems" with plaintiffs' expert opinions that made its *Daubert* determination on *reliability* such a "close call." The first was plaintiff's and their experts' heavy reliance on IARC's 2015 decision "to classify glyphosate as 'probably

[553] *Id*., quoting *Milward*, 639 F.3d at 26 (quoting *Kumho Tire Co.*, 526 U.S. at 152).

[554] *Id*., quoting *In re Mirena (No. II)*, 341 F. Supp. 3d at 247.

[555] *In re Roundup Products Liability Litigation*, MDL No. 2741, Civ. No. 16-md-02741-VC (N.D. Cal. 2018) (Pretrial Order No. 45: Summary Judgment and *Daubert* Motions).

[556] *Id*., slip op. at 4, 5.

[557] *Id*. at 1, 2, 5 (emphasis added).

[558] *Id*. at 3, 67-68. Indeed, in the next "specific causation" phase of this case, the trial judge noted that, "it was "again a close question, but *the plaintiffs have barely inched over the line*." (emphasis added). *See In re Roundup Products Liability Litigation*, MDL No. 2741, Civ. No. 16-md-02741-VC (N.D. CA 2018) (Pretrial Order No. 85: Denying Monsanto's Motion for Summary Judgment on Specific Causation).

[559] *Id*. at 3.

[560] *Id*.

carcinogenic to humans.'"[561] According to the court, this presented a significant problem because the IARC determination "'that a substance is 'probably carcinogenic to humans'" constituted only "a public health assessment" comprised of an identification of *hazards*," which "essentially asks whether a substance is cause for concern."[562] "IARC leaves the second step," an "evaluation of the *risk* that the hazard poses at particular exposure levels"—*i.e.*, "whether the substance currently presents a meaningful risk to human health,"—"to other public entities."[563] IARC admits that, "although it uses the word 'probably,' it does not intend for that word to have any quantitative significance."[564] Thus, the general public-health inquiry inherent in a hazard assessment "does not map nicely onto the inquiry required by civil litigation," which is whether the jury, at the general causation phase, "could conclude by a preponderance of the evidence that glyphosate can cause NHL at exposure levels people realistically could have experienced."[565]

The second problem was that plaintiffs' "evidence of a causal link between glyphosate exposure and NHL in the human population seems rather weak." The court found that "[s]ome epidemiological studies suggest that glyphosate exposure is slightly or moderately associated with increased odds of developing NHL. Other studies, including the largest and most recent, suggest there is no link at all."[566] In other words, "[a]ll the [relied upon] studies le[ft] certain questions unanswered, and every study ha[d] its flaws." Consequently, "[t]he evidence, viewed in its totality, seem[ed] too equivocal to support any firm conclusion that glyphosate causes NHL."[567]

The district court grounded its admission of plaintiffs' three experts' testimony relying upon the IARC assessment as "reliable" within the meaning of *Daubert* on its perception that these experts "went beyond the inquiry conducted by IARC, offering independent and relatively comprehensive opinions that the epidemiological and other evidence demonstrate[d] glyphosate causes NHL in some people who are exposed to it."[568] Thus, the court held that it could "not go so far as to say these experts ha[d] served up the kind of junk science that requires exclusion from trial."[569]

Expert testimony will be deemed reliable, the court concluded, if it "falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions,"[570] based *inter alia* on the following four factors: "(1) whether the expert's

[561] *Id*. at 1.
[562] *Id*. at 2 (emphasis added).
[563] *Id*. (emphasis in original).
[564] *Id*.
[565] *Id*.
[566] *Id*.
[567] *Id*.
[568] *Id*. at 3.
[569] *Id*.
[570] *Id*. at 7-8, quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (*Daubert II*), 43 F.3d 1311, 1317 (9th Cir. 1995).

theory or method is generally accepted in the scientific community; (2) whether the expert's methodology can be or has been tested; (3) the known or potential error rate of the technique; and (4) whether the methods has been subjected to peer review and publication."[571] The district court further held that courts must "consider whether the expert's testimony springs from research independent of the litigation."[572] The court noted that, if expert testimony does not spring from research independent of the litigation, then "the expert should point to other evidence that the testimony has a reliable basis, like peer-reviewed studies or a reputable source showing that the expert 'followed the scientific methods, as it is practiced by (at least) a recognized minority of scientists in their field.'"[573] The district court emphasized that the factors are "not a mandatory or inflexible checklist," and that courts have "broad discretion to determine which factors are most informative in assessing reliability in the context of a given case."[574] It also held that courts "must also consider whether, for a given conclusion, 'there is simply too great an analytical gap between the data and the opinion proffered.'"[575] In sum, "both unsound methods and unjustified extrapolations from existing data can require the Court to exclude an expert."[576]

Finally, the district court noted how the Ninth Circuit had narrowly interpreted the *Daubert* gatekeeping function as being intended only to "'screen the jury from unreliable nonsense opinions, but *not* to exclude opinions merely because they are impeachable.'" It also explained how the Ninth Circuit had granted more "deference to experts in close cases than might be appropriate in some other Circuits," where "the traditional and appropriate means of attacking shaky but admissible evidence" are available—*i.e.*, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof."[577]

The district court justified its decision to admit the testimonies of plaintiffs' three experts—Drs. Beate Ritz, Christopher Portier, and Dennis Weisenburger—in part on epidemiological research/studies. Unlike the First Circuit in *Milward*, the district court found that where epidemiological studies that "examine whether an association exists between an agent like glyphosate and an outcome like NHL" exist, they are "central to the general causation inquiry"[578] employing the Bradford Hill criteria.[579] Accepting that reasonable

[571] *Id*. at 8, citing *Daubert*, 509 U.S. at 593-94.

[572] *Id*. at 8, citing *Daubert II*, 43 F.3d at 1317.

[573] *Id*. at 8, citing *Daubert II*, 43 F.3d at 1317-19.

[574] *Id*. at 8, citing *Kumho Tire Co., Ltd.*, 526 U.S. at 141-42.

[575] *Id*. at 8, quoting *Joiner*, 522 U.S. at 146.

[576] *Id*. at 8.

[577] *Id*. at 8-9, contrasting a less deferential standard federal courts employ in the Third and Eleventh Circuits, citing *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, 858 F.3d 787, 800 (3d Cir. 2017), and *McClain v. Metabolife International, Inc.*, 401 F.3d 1233, 1244-45 (11th Cir. 2005).

[578] *Id*. at 13, contrasting the First Circuit's holding in *Milward* (that, "[e]pidemiological studies are not per se required as a condition of admissibility regardless of context"), citing *Milward*, 639 F. 3d at 24.

[579] *Id*. at 13-14. *See also id*. at 35, citing Michael D. Green, D. Michal Freedman, and Leon Gordis, *Reference Guide on Epidemiology*, in *Third Edition*, *supra* note 14, at 597 ("the Bradford Hill criteria are generally

scientists will have disagreements "about which evidence to emphasize in cases where the evidence does not point unequivocally toward a particular conclusion," the district court reasoned, consistent with the Third Edition of the *Scientific Reference Manual*[580] and *Milward*,[581] that, as long as "the plaintiffs' experts' analysis of [] studies 'falls within the *range* of accepted standards governing how scientists conduct their research and reach their conclusions," the testimony will be considered "reliable" for purposes of admissibility.[582]

According to the district court, application of the Bradford Hill criteria "requires an expert to consider more than the epidemiology literature." The "framework asks experts to survey all the available evidence that might support or disprove causation."[583] Consistent with *Milward*, the district court determined that a "broad survey of the available evidence is neither unusual in expert testimony nor necessarily inappropriate."[584] The court also recognized that "this feature of the Bradford Hill [weight-of-the-evidence] methodology is likely to be quite broad, the inquiry involves the exercise of subjective judgment, and an expert may opine on matters outside of her core area of expertise."[585] And, to the extent scientists "clearly disagree" "on questions that are currently the focus of extensive scientific research and debate," the court emphasized, citing *Milward* as support, that it "may not 'take sides.'"[586]

The court found the testimony of plaintiffs' most important expert, Portier, to be "reliable," and thus, admissible, for several reasons.

First, the court concluded that Portier was qualified to examine epidemiological literature to ascertain whether an association between glyphosate and NHL exists and if so, to engage in a Bradford Hill analysis, although epidemiology was *not* his core area of expertise.[587] It reasoned that he was a biostatistician whose graduate research focused on rodent studies design, and that he had been long employed by the National Institute of Health's Institute of Environmental Health Studies and the Center for Disease Controls'

associated with epidemiology, and a reliable assessment that an association between glyphosate and NHL exists in the epidemiological literature *is a prerequisite to application of the criteria*") (emphasis added).

[580] *See* Green, Freedman, and Gordis, *supra*, at 564, quoting *Marder v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1094 (D. Md. 1986), *aff'd sub nom. Wheelahan v. G.D. Searle & Co.*, 814 F.2d 655 (4th Cir. 1987) ("the court observed: 'There is a range of scientific methods for investigating questions of causation – for example, toxicology and animal studies, clinical research, and epidemiology – which all have distinct advantages and disadvantages.").

[581] In *Milward*, the First Circuit had determined that an evaluation of only six of nine Bradford Hill criteria was required, including the "consider[ation of] a *range* of plausible explanations for the association." *See Milward*, 639 F.3d at 17-18.

[582] *In re Roundup Products Liability Litigation*, MDL No. 2741, Civ. No. 16-md-02741-VC (N.D. Cal. 2018) (Pretrial Order No. 45: Summary Judgment and *Daubert* Motions) *supra*, slip op. at 34 (emphasis added).

[583] *Id*. at 35.

[584] *Id*. at 35 citing *Milward*, 639 F.3d at 19-20.

[585] *Id*.

[586] *Id*., citing and quoting *Milward*, 639 F.3d at 22.

[587] *Id*. at 36.

National Center for Environmental Health.[588]

Second, the court found most of Portier's "epidemiology-related conclusions – both his finding of an association between glyphosate exposure and NHL and his application of the Bradford Hill factors that turn[ed] on epidemiology studies" to be "sufficiently reliable to be admissible."[589]

Third, the court found reasonable and "reliable" Portier's heavier weighting of "the case-control studies than the AHS [Agricultural Health Study], a cohort study[590] […] of more than 57,000 licensed pesticide applicators from Iowa and North Carolina" who had been "surveyed between 1993 and 1997" and "asked about their use of 50 pesticides, including glyphosate."[591] The court reached this conclusion despite the potential flaws in the data from these respective studies and from the meta-analyses Portier had reviewed, reasoning that since such weighting by an expert fell "'within the range of accepted standards governing how scientists conduct their research and reach their conclusions,'" such weighting "cannot be excluded as categorically unreliable." [592]

Fourth, the court held that, "although IARC's overall conclusion that glyphosate is a 'probable human carcinogen' is not squarely relevant to the general causation question in this case, IARC's narrower conclusion about carcinogenicity in lab animals is quite relevant" and would support plaintiffs' case if there was "sufficient evidence [showing] glyphosate causes cancer in animals."[593] It reasoned that "[d]emonstrating that a chemical is carcinogenic in rodents would logically advance the plaintiff's argument that glyphosate is capable of causing NHL in humans, because it is pertinent to, at least, the biological plausibility criterion that is part of the Bradford Hill analysis."[594] The court then adjudged Portier's assessment of animal carcinogenicity data, and thus his biological plausibility conclusion as admissible, except for his pooled analysis.[595]

[588] *Id*.

[589] *Id*. at 39.

[590] *Id*.

[591] *Id*. at 24-25.

[592] *Id*. at 29. *See also id*. at 47 ("Dr. Portier explained that he weighted these studies heavily, as they demonstrate[d] DNA damage in living organisms with intact DNA repair mechanisms, making them more probative of potential DNA damage in humans than in vitro studies.").

[593] *Id*. at 30-31.

[594] *Id*. at 30.

[595] *Id*. at 46-48. *See also id*. at 17 ("In a pooled analysis, the study authors combine the raw, participant-level data from earlier studies and then analyze these data as one combined dataset. […] Pooling allows for uniform analysis of the data in the underlying studies and increases the statistical power of the earlier, smaller studies."). *See also id*. at 44 (The court noted further that, "[w]ithout pooling, the remainder of [Portier's] analysis evinces relatively minor disagreements with the other toxicology experts on how to interpret the studies, and his positions in these debates do not depart from the realm of reasonable science.").

Fifth, the court ruled that despite Portier's participation in the IARC Monograph process and his advocacy in favor of "increased regulatory attention to glyphosate," such participation and advocacy suggested "his position [was] not one he ha[d] taken solely for purposes of this litigation."[596]

Sixth and finally, although Portier's conclusions regarding glyphosate and NHL were not peer reviewed, "the studies underlying his opinion were in large part published in peer-reviewed journals."[597]

In sum, the court concluded that Portier had "adequately demonstrated that his opinion regarding general causation [was] sufficiently 'within the range of accepted standards governing how scientists conduct their research and reach their conclusions' to proceed to a jury." The court, in effect, endeavored to bring the weight-of-the-evidence approach experts employ to establish general causation closer to the preponderance of-the-evidence standard employed by finders-of-fact to evaluate claims of specific causation.

Tenth Circuit

Cattaneo v. Aquakleen Products, Inc. (D. Colo. 2012)[598] (Negligence/Wrongful Death)

Plaintiffs Nick and Roxanne Cattaneo alleged on their own and their minor child's behalf that the installer of defendant AquaKleen Products, Inc., from which they purchased an AcquaKleen water refinement system for their home in 2006, had improperly installed that system, "creating a 'cross-connection' between the AquaKleen system and a sewer pipe in the home."[599] Plaintiffs claimed that, as a result AquaKleen's negligent, incorrect installation of the system, they became severely ill, with the child contracting Hepatitis A and Mr. Cattaneo contracting Crohn's disease.[600]

The court found that AquaKleen exercised sufficient control and supervision over the installer, and that the local county water district representative had come to the Cattaneos' home and "discovered the cross-connection."[601] It then denied defendant's motion for summary judgment because it concluded there was insufficient evidence on whether AquaKleen had "knowingly or recklessly sent an unqualified person to inspect and investigate Plaintiffs' complaints, said person misrepresented the company had tested the water for the presence of contaminants, and the company had thereafter failed or otherwise refused to retest the water subjecting Plaintiffs to further sewage contaminated water."[602]

[596] *Id*. at 48.
[597] *Id*. at 47, citing *Daubert II*, 43 F.3d at 1318.
[598] *Cattaneo v. Aquakleen Products, Inc.*, Civ. No. 10-cv-02852-RBJ-MJW (D. Colo. 2012).
[599] *Id.*, slip op. at 1.
[600] *Id.* at 1, 5.
[601] *Id.* at 2, 4.
[602] *Id.* at 4-5.

After the court denied summary judgment, defendant moved to exclude the causation testimony of plaintiff's toxicology expert, Dr. Steven Pike, "primarily on the ground that it [was] not sufficiently reliable to pass muster under [FRE 702] and [*Daubert*]." Since neither party had requested a *Daubert* hearing, the court determined Defendant's *Daubert* motion based on the parties' briefs.[603] Noting that the "principle of Rule 702 and *Daubert* is that Rule 702, both before and after *Daubert*, […] mandates a liberal standard for the admissibility of expert testimony," the court found that Pike's opinion had been based on his review of "documents concerning the improper installation of the water refinement unit[,] various individuals' observations regarding the Cattaneos' water[,] medical records[,] and published literature, specifically including a publication by an epidemiologist concerning inferences of causality that was cited as an authoritative work in *Milward*."[604]

Moreover, the court held Pike's expert opinion that the Cattaneo's child had contracted Hepatitis A and Mr. Cattaneo had contracted Crohn's disease as the result of the improper installation, had not unreasonably been "based on *inferences* he [had drawn] from the facts […]", and that, "in his opinion, there [was] no plausible alternative explanation for the development of the illnesses."[605] The facts from which plaintiff's expert had apparently drawn inferences included the following: (1) the existence of a cross-connection; (2) "the water in the home had a foul odor"; (3) "allegedly coincident with the presence of the water refinement system"; (4) the water refinement system removed chlorine which had been added by the water district's treatment system as a disinfectant"; and (5) the timing of the development of the illnesses fits the timing of the alleged contamination of the water supply."[606]

Because neither party had "tested the water for the presence of contamination that would be caused by sewage," the court ruled that "[t]he combined failure to do the elementary testing that would presumably have answered the question one way or the other has caused both parties to have to approach causation differently."[607] The court noted that, while plaintiffs relied on their expert's toxicological opinion establishing "that sewage can cause these diseases and the absence of any alternative explanation for them," defendant relied on their expert's "engineering opinion that renders the ability of contaminants to get into the Catteneos' water, despite the cross-connection, unlikely." According to the court, since "[b]oth opinions [were] based on facts, data and inferences drawn from the facts and data," and neither party had "produced opinions of experts in the specialties of the other side," the court had "no basis to find that these opinions [were] not relevant and reliable within the meaning of Rule 702." Thus, the court ultimately held that "[t]he criticisms of Dr. Pike's opinions go to the weight to be given to them, and that [was] the province of the

[603] *Id.* at 5.
[604] *Id.*, citing *Milward*, 639 F.3d at 17-19.
[605] *Id.* at 5 (emphasis added).
[606] *Id*.
[607] *Id.* at 6.

jury."[608]

Walker v. Spina (D.N.M. 2019)[609] (Personal Injury)

Defendant Gregory Spina, who had been speeding in a commercial vehicle owned by Defendant Valley Express, Inc., ran through a red light in between two cars sitting side-by-side at an intersection, side-swiping and knocking both of them into the intersection. The collision caused causing Plaintiff Shirley Walker, the driver of one of the vehicles, physical and emotional injuries.[610]

Plaintiff indicated she would call, William Patterson, an economic consultant, as an expert on "'economic damages, including loss of household services, future medical expenses, and loss of value of enjoyment of life,'"[611] as an expert witness. After deposing Patterson, defendant moved to exclude his testimony, reasoning that "Patterson base[d] his opinions on 'speculation and generalities,' and not on facts, and that 'his methods [were] not supported by economic principles or literature.'"[612] Specifically, defendants "explain[ed] that courts and economic literature criticize[d] 'hedonic damages,' and the 'disparity of results reached in published value-of-life studies and trouble regarding their underlying methodology' ha[d] led courts to reject hedonic damages. […] The Defendants indicate[d] that 'the trend [was] away from allowing expert opinion testimony on valuation of hedonic damages.'"[613] Defendants also explained that Patterson's testimony "relie[d] on statistical-life values drawn 'from governmental studies, such as wage differential or willingness to pay studies,' which courts have recognized as 'based on assumptions that have not been, and cannot be, validated.' [Since] the statistical-life valuations are anonymous, hedonic damages valuations do not reflect the 'injured individuals' loss of enjoyment of life.'"[614] They also noted that "Patterson ha[d] not 'purport[ed] to give an opinion' on the value of S. Walker's loss of enjoyment of life or 'a specific value the jury should award,' but proffer[ed] only a 'benchmark for the jury to consider.'"[615]

Plaintiff Walker responded by noting how "New Mexico ha[d] rejected the federal rule for experts and that New Mexico does not apply 'the standard of scientific reliability' to experts testifying based on specialized knowledge."[616] Defendants replied that, because it was a federal diversity action, the FRE governed the admissibility of expert testimony on the subject of hedonic damages. They specifically argued that, "although the Tenth Circuit and

[608] *Id*.
[609] *Walker v. Spina*, Civ. No. 17-0991 JB\SCY (D.N.M. 2019).
[610] *Id*., slip op at 2.
[611] *Id.*
[612] *Id.* at 3.
[613] *Id.* at 4.
[614] *Id*.
[615] *Id*.
[616] *Id.* at 5.

New Mexico federal district courts 'have allowed economists to testify about the meaning of hedonic damages and how they differ from other damages,' the court should exclude computations of such damages."[617]

At a November 2018 hearing, plaintiff Walker informed defendants of "her decision not to seek 'loss of wages, cost of household services, future medical expenses, or medical care,' and to seek only hedonic, quality-of-life damages."[618] Defendants' replied that "federal law should govern whether Patterson may testify as an expert to hedonic damages, and argued both that federal law should apply and that, under federal law, the court should not permit Patterson to testify to such damages"[619] because "New Mexico federal district courts routinely exclude such testimony."[620]

The court indicated that, while "experts cannot quantify hedonic damages for the jury, […] experts can explain that methodologies for quantifying hedonic damages exist and can define hedonic damages."[621] Recognizing that FRE 702 governs the admissibility of expert testimony and that '*Daubert* require[d] the Court to 'scrutinize the proffered expert's reasoning to determine if that reasoning is sound,'"[622] the court concluded that expert testimony should be liberally admitted under FRE 702, and that it had "broad discretion in deciding whether to admit or exclude expert testimony."[623] In particular, the court noted its gatekeeper role under *Daubert*, pursuant to which it "must assess the reasoning and methodology underlying an expert's opinion, and determine whether it is both scientifically valid and relevant to the facts of the case, i.e., whether it is helpful to the trier of fact."[624] To this end, the court also recited the five non-exclusive factors "that weigh into a district court's first-step reliability determination,[625] and explained the court's inquiry related to adjudging reliability. "'[A] district court must […] determine if the expert's proffered testimony…has a reliable basis in the knowledge and experience of his [or her] discipline.' […] In making this determination, the district court must decide 'whether the reasoning or methodology underlying the testimony is scientifically valid.'"[626]

[617] *Id*.
[618] *Id*.
[619] *Id.* at 6.
[620] *Id*.
[621] *Id.* at 6-7.
[622] *Id.* at 7, quoting *United States v. Gutierrez-Castro*, 805 F. Supp. 2d 1218, 1224 (D.N.M. 2011).
[623] *Id.* at 8.
[624] *Id*., citing *Daubert*, 509 U.S. at 594-95.
[625] These include "(i) whether the method has been tested; (ii) whether the method has been published and subject to peer review; (iii) the error rate; (iv) the existence of standards and whether the witness applied them in the present case; and (v) whether the witness' method is generally accepted as reliable in the relevant medical and scientific community." *Id*.
[626] *Id.* at 9, quoting *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878 (10th Cir. 2005) (quoting *Daubert*, 509 U.S. at 589, 592).

The court noted in a footnote the difficulty of satisfying FRE 702's "sufficiency of basis" standard. According to the court, this difficulty has provoked a conflict in the decisions on "whether the questions of sufficiency of basis, and of application of principles and methods, are matters of weight or admissibility."[627] The court quoted, on the one hand, the Second Circuit's *Ruggiero v. Warner-Lambert Co.*, 424 F3d. 249 (2d Cir. 2005), as favoring the treatment of sufficiency of basis and application of principles and methods as a matter of admissibility, and the decision of the First Circuit's *Milward* as favoring the treatment of sufficiency of basis and application of principles and methods as a matter of weight.[628] *Ruggiero* held that "'when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony."[629] *Milward* held that "the soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact."[630]

Curiously, the *Spina* court concluded that such conflict "suggest[ed] that *Daubert* and Rule 702 are too academic," and that "*Daubert* and Rule 702 write better than they work in the courtroom and in practice."[631] The court further held in dicta that the basis of this conflict derives from the discomfort lower federal district courts have experienced excluding evidence on the basis of sufficiency, which they have "rightfully" equated with the usurpation of the jury's role at trial, the court's abuse of discretion, and ultimately, the violation of "the Sixth and Seventh Amendments to the Constitution protecting the right to jury trials in civil and criminal cases."[632] Consistent with this concern and based on Tenth Circuit law, the court admitted Patterson's testimony for the sole purpose of explaining hedonic damages and their calculation to the jury. The court, however, excluded his testimony for purposes of quantifying those damages, which the court noted had "'met considerable criticism in the [academic] literature of economics as well as in the federal court system.'"[633]

[627] *Id.* at 20, n. 4.

[628] *Id*.

[629] *Id*., quoting *Ruggiero*, 424 F.3d at 255.

[630] *Id*., quoting *Milward*, 639 F.3d at 22.

[631] *Id.* at 20, n. 4.

[632] *Id*., citing *Manpower, Inc. v. Ins. of Pa.*, 732 F.3d 796, 806 (7th Cir.) and Ronald J. Allen, Esfand Fafisi, Daubert *and its Discontents*, BROOKLYN L. REV., 131, 147 (2010) ("describing an argument for *Daubert*'s unconstitutionality under the Seventh Amendment").

[633] *Id.* at 18, quoting *Smith v. Ingersoll-Rand Co.*, 214 F.3d 1235, 1246 (10th Cir. 2000) holding ("'The district court also made an appropriate decision regarding reliability, excluding the quantification which has troubled both courts and academics, but allowing an explanation adequate to insure the jury did not ignore a component of damages allowable under state law.'").

Eleventh Circuit

In re Chantix (Varenicline) Products Liability Litigation (N.D. Ala. 2012)[634] (Products Liability)

In this MDL, plaintiffs alleged that Chantix, an FDA-approved smoking-cessation product/nicotine replacement therapy, "cause[d] depression and other psychiatric disorders, some so severe that reports of suicide and attempted suicide from Chantix use ha[d] been made." Plaintiffs also alleged that defendant Pfizer "either knew or should have known about such side effects, but for [D]efendant's intentional failure to design studies which were reflective of their targeted population."[635] Defendant "denie[d] there [was] any merit to such allegations, and assert[ed] that numerous studies show[ed] the side effects of Chantix to be in line with those of other nicotine replacement therapies (NRTs), such as nicotine patches."[636] Defendant moved to exclude certain general causation and liability opinions offered by plaintiffs' experts."[637]

In evaluating the admissibility of plaintiffs' experts' testimonies, the court recognized that FRE 702, as construed in *Daubert*, "'establishes a standard of evidentiary reliability' […] 'requir[ing] a valid…connection to the pertinent inquiry as a precondition to admissibility.'"[638] The court also recognized that, "[w]here such testimony's factual basis, data, principles, methods, or application is called sufficiently into question, the trial judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of [the relevant] discipline.' […] This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue."[639] The court also recognized that "the inquiry required by *Daubert* is meant to be a 'flexible one,' and that expert testimony that does not meet all or most of the *Daubert* factors[640] may still be admissible based on the specific facts of a particular case," since "[t]he correctness of an expert's conclusions is […] left to the trier of fact to determine" following "'vigorous cross-examination, presentation of contrary evidence, and careful instruction o the burden of proof.'"[641]

[634] *In re Chantix (Varenicline) Products Liability Litigation*, 889 F. Supp. 2d 1272 (N.D. Ala. 2012).

[635] *Id*. at 1277.

[636] *Id*.

[637] *Id*.

[638] *Id*. at 1279, quoting *Daubert*, 509 U.S. at 592.

[639] *Id*. at 1279, quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149, 119 (1999), and citing *Daubert*, 509 U.S. at 592-93.

[640] *See id*. at 1280 (reciting the *Daubert* factors and noting how they "do not exhaust the universe of considerations."). These factors include: "(1) testability; (2) error rate; (3) peer review and publication; and (4) general acceptance."

[641] *Id*. at 179-80, citing *United States v. Brown*, 415 F.3d 1257, 1267-68 (11th Cir. 2005), and quoting *Daubert*, 509 U.S. at 596.

Defendant's reliability challenge to the testimony of the plaintiff's first expert, Dr. Richard Olmstead, focused on the failure to "use all of the data available" and on the expert's methodology of "combining […] data from controlled and uncontrolled trials." The court ruled that "[n]othing inherent in the[D]efendant's objections to Dr. Olmstead's methodology addresses the reliability of his findings. The fact that no other researcher combined data in the manner Dr. Olmstead did [did] not make [his] data necessarily flawed. Rather, these and other objections […] are matters of credibility, not reliability, and are strictly within the province of the jury."[642]

Defendant's reliability challenge to the testimony of the second expert, Dr. Curt Furberg, focused on "his failure to discuss matters favorable to the [D]efendant in his expert report," especially "the analysis of the European Medicines Agency (EMA) … and its finding that the clinical trial data 'does not support a causal link' between Chantix use and serious neuropsychiatric events.'" Defendant also "asserted that '[t]o establish causation Dr. Furberg must demonstrate a valid statistical association between Chantix and serious neuropsychiatric events.'" [643] The court concluded that defendant "misse[d] the point of *Daubert*," holding that Plaintiffs had been required only to "establish that their experts opinions 'are based on sufficient facts or data' and will help the jury 'to understand the evidence.' […] What the [P]laintiffs do not have to do at this juncture is prove their case."[644]

In reaching this conclusion, the court referenced the U.S. Supreme Court's decision in *Mattrixx Initiatives, Inc. v. Siracusano*, as holding that "'[a] lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events … medical experts rely on other evidence to establish an inference of causation."[645] The court also cited to the Supreme Court's recognition of the Eleventh Circuit decision *Wells v. Ortho Pharmaceutical Corp.*, which held that "courts 'frequently permit expert testimony on causation based on evidence other than statistical significance."[646] The court declined to find Furberg's testimony inadmissible because he could not "'establish a valid statistical association between Chantix and serious neuropsychiatric events.'"[647]

Defendant's reliability challenge to the testimony of plaintiffs' third expert, Dr. Shira Kramer, focused on her basing her opinions on uncontrolled data, her inability to establish a

[642] *Id*. at 1282-83. *See also id*. at 1283-84 (the court reasoned that Olmstead had "considered the data used by defendant to reach his conclusion that 'the incidence of certain neuropsychiatric symptoms including depressed mood disorders and disturbances…should have merited additional scrutiny and concern by Pfizer…[…] In fact, Dr. Olmstead set[] forth the various methodologies he employed to calculate the increase in risk of various neuropsychiatric injuries from taking Chantix as compared to placebo. Thus, he accounted for background risk in the identical manner the defendant did.").

[643] *Id*. at 1285.

[644] *Id*.

[645] *Id*. at 1286, quoting *Mattrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1319 (2011).

[646] *Id*., quoting *Mattrix Initiatives, Inc*.(quoting *Wells*, 788 F.2d 741, 744-45 (11th Cir. 1986)).

[647] *Id*.at 1286.

statistical association, and her failure "consider the presence or absence of a dose-response relationship."[648] In addition, defendant objected to Kramer's consideration of "all evidence concerning Chantix, from whatever source, and whatever result, in performing a Weight of Evidence analysis,"[649] given how Kramer had "note[d] that determinations about the weight of evidence are 'subjective interpretations' based on 'various lines of scientific evidence' [and] a unique set of experiences training and expertise [and p]hilosophical differences […] between experts…"[650]

The court responded by highlighting Kramer's conclusions "[b]ased on her Weight of Evidence approach," namely that: "(1) defendant designed its trials inadequately to evaluate neuropsychiatric safety; that (2) varenicline is causally associated with increased risks of adverse neuropsychiatric events; and that (3) defendant had data which reflected safety concerns with Chantix as early as 2005, before the drug was placed on the market."[651] According to the court, "[t]he fact that Dr. Kramer did not credit certain studies with the same weight as [D]efendant is 'not necessarily evidence of flawed scientific reasoning or methodology, but rather differences in judgment between scientists,' especially since Kramer had "considered many of [D]efendant's clinical trials in reaching her conclusions." The court found that "[w]hy Dr. Kramer chose to include or exclude data from specific clinical trials is a matter for cross-examination, not exclusion under *Daubert*."[652] It held that "Dr. Kramer's weight of evidence methodology [was] persuasive," and that "[D]efendant's attempt to isolate individual pieces of evidence as a basis to exclude all of Dr. Kramer's testimony ha[d] been rejected by other courts."[653]

Defendant's reliability challenge to the testimony of the sixth expert, Dr. Antoine Bechara, "offered for the purpose of explaining why Chantix causes the alleged neuropsychiatric effects," focused on the animal studies that served as the basis of his "theory – that an increase in dopamine receptors reflects a decrease in overall dopamine ['dopamine depletion'] and that this is what Chantix does."[654] Defendant objected on the ground that animal-study "findings are not a basis to extrapolate to humans," especially since Bechara "cite[d] no support for his ascertain that an increase in dopamine receptors is evidence that dopamine is depleted, and because not all animal studies may be extrapolated to humans."[655] The court recognized the difference in opinion between Bechara and defendant's expert, Dr. Charles Dackis, over whether dopamine depletion can occur with

[648] *Id*. at 1287.
[649] *Id*. at 1288.
[650] *Id*.
[651] *Id*.
[652] *Id*. *See also id*. at 1292 (the court, furthermore found that Kramer did not "cherry pick" data as defendant had alleged, but instead had "reviewed all of the information, including the studies and trials [D]efendant chose not to publish. The fact that some of the studies Dr. Kramer considered may have weaknesses is not a basis to exclude her testimony.").
[653] *Id*. at 1292-93.
[654] *Id*. at 1298-99.
[655] *Id*.at 1299.

varenicline, which it attributed to the larger "debate in the scientific community as to whether Bechara's dopamine depletion theory for Chantix can explain major depression and other neuropsychiatric injuries."[656] The court, however, held that "debate is not a basis for exclusion, quoting the conclusion *Milward* reached, that, "'[w]hen the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony – a question to be resolved by the jury.'"[657] "Hence, the court is of the opinion that Dr. Bechara may testify as to his theory, Dr. Dackis may testify as to why Dr. Bechara's theory is mistaken, and the trier of fact may determine which of these dueling experts' conclusions is more correct."[658]

Jones v. Novartis Pharmaceuticals Corporation, (N.D. Ala. 2017)[659] (Products Liability)

Plaintiff Ernesteen Jones alleged that "she developed atypical femur fractures as a result of taking [defendant] Novartis' medication Reclast, which is a type of bisphosphonate […] Jones [had been] prescribed […] by Dr. Thomas Traylor, her treating physician, for her osteoporosis."[660] Defendant moved to exclude the testimonies of plaintiff's four medical experts, Drs. Parisian, Hinshaw, Taylor, and Worthen, as inconsistent with the *Daubert* standards for admissibility.[661]

The court's discussion of *Daubert's* gatekeeping standard in light of *Milward* focused on Hinshaw's testimony. His testimony consisted of an expert report and a supplemental expert report[662] which plaintiff had offered to establish general causation.[663]

The court recognized how Hinshaw had "primarily relie[d] on the Bradford Hill methodology to reach his conclusion that Reclast generally causes atypical femoral fractures. [AFF]"[664] Citing *Milward* for the proposition that "Sir Bradford Hill was a world-renowned epidemiologist who articulated a nine-factor set of guidelines in seminal methodological article on causality inferences,"[665] the court then noted how the Bradford Hill factors are "'widely used in the scientific community to assess general causation."[666] The court cited

[656] *Id*. at 1300.

[657] *Id*., quoting *Milward*, 639 F.3d at 22.

[658] *Id*. at 1301. In support of its ruling, the court cited *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625-626 (8th Cir. 2012), which in turn cited *Milward*, 639 F.3d at 15, and *Daubert,* 509 U.S. at 600-01.

[659] *Jones v. Novartis Pharmaceuticals Corporation*, 235 F. Supp. 3d 1244 (N.D. Ala. 2017). *See also* discussions on *In re Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, Civ. No. 16-2247 (3d Cir. 2017) (precedential), and *In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation*, MDL No. 15-2666 (D.C. MN 2019) (8th Circuit).

[660] *Jones*, 235 F. Supp. 3d at 1249.

[661] *Id*.

[662] *Id*. at 1265.

[663] *Id*. at 1266-67.

[664] *Id.* at 1267.

[665] *Id*. citing *Milward*, 639 F.3d at 17.

[666] *Id*. at 1267, quoting *In re Stand `N Seal Products Liab. Litig*., 623 F. Supp. 2d 1355, 1372 (N.D. Ga. 2009) (citing *Gannon v. United States*, 292 Fed. Appx. 170, 173 (3d Cir. 2008)).

Milward again in stating that "Sir Bradford Hill's article explains that 'one should not conclude that an observed association between a disease and a feature of the environment (e.g., a chemical) is causal without first considering a variety of [nine] 'viewpoints' on the issue.'"[667]

The district court, in addition, found that, while the Eleventh Circuit had "not yet directly commented on the Braford Hill criteria," numerous other circuit courts and district courts within the Eleventh Circuit had approved of an expert's use of the Bradford Hill criteria, thereby strengthening the reliability of such methodology.[668] It also noted how "the Third Restatement of Torts states that if an association is found between a substance and a disease, 'epidemiologists use a number of factors (commonly known as the 'Hill guidelines') for evaluating whether that association is causal or spurious.'"[669]

The court, furthermore, emphasized that, despite Hinshaw's application of all nine Bradford Hill criteria to reach his conclusion that Reclast causes AFF (as compared to the plaintiff's expert's testimony which used only three of those criteria when the Ninth Circuit excluded his testimony in *In re Nexium Esomeprazole*[670]),[671] Hinshaw's inability to "point to [an existing] study that establishes a casual association between Novartis' drug Reclast and AFFs" otherwise rendered such testimony inadmissible under *Daubert*. The court reasoned that both the *2011 Reference Guide on Epidemiology* and the *Restatement of Torts Third* conditioned the use of the Bradford Hill methodology to establish general causation on a preliminary finding that reliable existing medical studies establish an association between a substance and a disease.[672] "These resources explain that the Bradford Hill factors cannot be applied without first establishing a causal association,"[673] consistent with *Milward*.[674]

[667] *Id*. at 1267-68, quoting *Milward*, 639 F.3d at 17.

[668] *Id*. at 1268.

[669] *Id*., quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(3) (2010).

[670] *See In re Nexium Esomeprazole*, 662 Fed. Appx. 528, 530-31 (9th Cir. 2016) ("At best, Dr. Bal analyzed three of the nine Bradford Hill factors that guide scientists in drawing causal conclusions from epidemiological studies. *See Milward*, 639 F.3d at 17 (citing Arthur Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. ROYAL SOC'Y MED. 295 (1965)). We agree with the district court that Dr. Bal's analysis of the factors he did discuss was "extremely thin.").

[671] *Id*. at 1268-69.

[672] *Id*.

[673] *Id*. at 1267. *See also id*. at 1269, quoting *In re Lipitor*, 174 F. Supp. 3d 911, 925 (D S.C. 2016) ("'Courts exclude expert testimony that attempts to start at step two, applying the Bradford Hill criteria without adequate evidence of an association.'").

[674] *Id.* at 1269, citing *In re Lipitor*, 174 F. Supp. 3d at 925, and n. 12 ("[I]t is well established that the Bradford Hill method used by epidemiologists *does* require that an association through studies with statistically significant results. […] *Milward v. Acuity Specialty Products Grp., Inc.*, 639 F. 3d 11 (1st Cir. 2011) on which Plaintiffs rely is no exception. There the expert 'noted that *epidemiological studies have found a statistically significant increased incidence of AML in benzene-exposed workers* and have identified a dose-response relationship.'") (emphasis in original).

Moreover, the court emphasized how because Hinshaw had failed to identify any peer-reviewed study defining a "'statistically significant AFF association for Reclast specifically,'" his effort to overcome this hurdle by grounding "his general causation opinion on a causal association found between the entire class of BP drugs, of which Reclast is one type, and femoral fractures," was fatally flawed.[675] The court reasoned that since Hinshaw had "not substantiated his claim that a causal association between Reclast and AFFs may be extrapolated from a class-wide association between BPs and femoral fractures," "the court would have been required to 'make several scientifically unsupported 'leaps of faith' in the causal chain' in order to admit the plaintiff's evidence."[676] The court ultimately held that, given Hinshaw's failure to first establish that an association between Reclast and AFFs had existed, it would exclude his general causation opinion that relied on the Bradford Hill methodology as unreliable under *Daubert*.[677]

The court additionally held, citing *Milward*, that although the weight-of-the-evidence methodology "can be considered reliable," Dr. Hinshaw had "not described the process he used or the steps he took in applying this methodology, including whether he ranked plausible rival explanations."[678] The court concluded that since "both Dr. Hinshaw's 'weight of the evidence' and Bradford Hill methods were applied unreliably, his general causation opinion [was] due to be excluded."[679]

In re Abilify (Aripiprazole) Products Liability Litigation (N.D. Fla. 2018)[680] (Products Liability)

In this MDL, plaintiffs alleged that, as the result of taking Aripiprazole (Abilify), an antipsychotic drug, "they developed impulsive and irrepressible urges to engage in […] impulsive gambling, eating, shopping, and sex."[681] Defendant manufacturers and marketers (Otskuka Pharmaceutical Co., Ltd., Otsuka America Pharmaceutical, Inc., and Bristol-Myers Squibb Co.) moved for summary judgment on the issue of general causation.

Following an evidentiary hearing, the district court denied the motion because genuine issues of material fact remained concerning "whether Abilify can cause

[675] *Id*. at 1269-70.

[676] *Id*. at 1270-71, quoting *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002), citing *Joiner*, 522 U.S. at 152. *See also* 235 F. Supp. 3d at 1271 (quoting *Joiner*, 522 U.S. at 146 (where the court "elaborated that 'the studies in question [did] not directly address the relationship between [the specific drug] and [the alleged injury]' and critiqued the plaintiff for presenting 'no expert analysis as to how one might extrapolate' from the drug's effect on a group with one syndrome to another group who took the drug for a different purpose.").

[677] *Id*. at 1272.

[678] *Id.* at 1272-73.

[679] *Id.* at 1273.

[680] *In re Abilify (Aripiprazole) Products Liability Litigation*, 299 F. Supp. 3d 1291 (N.D. Fla. 2018).

[681] *Id.* at 1300-01.

uncontrollable impulsive behaviors in individuals taking the drug."[682] In particular, the court noted how, as early as 2010, "[t]he scientific community, the [US]FDA, Defendants and public health agencies worldwide took notice and began examining whether Abilify [was] linked to impulse control disorders."

Defendants challenged the reliability of the general-causation testimony of plaintiffs' five experts.[683] In the Eleventh Circuit, a plaintiff "must establish both general and specific causation through reliable expert testimony" in order "[t]o prevail in a pharmaceutical products liability case. […] General causation is established by demonstrating, often through a review of scientific or medical literature, that a drug or chemical can, in general, cause the type of harm alleged by the plaintiff."[684] In addition, the Eleventh Circuit has held "three 'primary' methodologies 'indispensable' for proving that a drug can cause a specific adverse effect: epidemiological studies,[685] dose-response relationship,[686] and background risk of disease."[687] Consequently, "[a] general causation opinion that is not supported by at least one of these primary methodologies is unreliable as a matter of law."[688] So long as an expert has reliably applied one of these primary methodologies, he/she "may bolster [his/her] general causation opinion with evidence from 'secondary' methodologies, such as: biological plausibility,[689] case studies and adverse event reports, extrapolations from [*in vivo*] animal[690] and *in vitro* studies,[691] and extrapolations from analogous drugs."[692]

[682] *Id*. at 1301.

[683] *Id*. at 1304.

[684] *Id.* at 1306.

[685] Epidemiology is "the branch of science that studies the incidence, distribution, and cause of disease in human populations." *Id*.

[686] Dose-response relationship "is a 'relationship in which a change in amount, intensity, or duration of exposure to [a drug] is associated with a change – either an increase or decrease – in risk of' adverse effects from that exposure." *Id.* at 1307.

[687] "Background risk is the risk that members of the general public would have of developing the disease without exposure to the drug. [] It encompasses all causes of the disease, whether known or unknown, except for the drug in question." *Id*. at 1308.

[688] *Id*. at 1306, citing *Chapman v. Procter & Gamble Distributing, LLC*, 766 F.3d 1296, 1308 (11th Cir. 2014).

[689] "Biological plausibility refers to a credible scientific explanation of the physiological processes or mechanisms by which a drug can cause a particular disease or adverse effect, based on the current biological and pharmacological knowledge." *Id.* at 1308. To the extent biological plausibility exists, it "'lends credence to an inference of causality' drawn from other, more substantial evidence." *Id*.

[690] In *in vivo* studies, "laboratory animals are exposed to a particular drug, with the outcomes monitored and compared to those for an unexposed control group." Although "they can be conducted as true experiments with exposure controlled and measured, […] are replicable […], usually follow a general accepted methodology, […] and […] present fewer ethical limitations than human experimentation," they "are almost always fraught with considerable, and currently unresolvable, uncertainty […] because biological 'differences in absorption, metabolism, and other factors may result in interspecies variation in responses," and "most animal studies involve significantly higher doses of a drug than would ever be present in humans," making it difficult to extrapolate from animals to humans. *Id.* at 1310.

[691] "*[I]n vitro* studies […] analyze the effects of drugs on human and animal cells, organs, or tissue cultures in a controlled laboratory setting," "but the chemical reactions that occur in the artificial environment

The district court considered epidemiological studies as providing the "'best evidence of causation in toxic tort actions.'"[693] It noted that [general] causation may be established through epidemiology, first, by demonstrating an association between a drug with a particular disease or adverse effect, and, second, by determining "whether that association represents a 'true cause-effect relationship' between exposure and the disease."[694] The district court emphasized that the "nine well-established" Bradford Hill factors, none of which is dispositive, serve to guide the causation inquiry."[695] It also cited *Milward* in emphasizing that the ultimate determination of "whether an association is causal is a matter of scientific judgment," and that "scientists reliably applying the Bradford Hill factors may reasonably come to different conclusions about whether a causal inference may be drawn."[696] According to the court, "[a]n epidemiological study identifying a statistically significant association between the use of a drug and a particular adverse effect, accompanied by a reliable expert opinion that the association is causal, is 'powerful' evidence of general causation."[697]

In addition, the Eleventh Circuit emphasized that, while any one or more of the individual categories of scientific evidence may support an expert opinion on general causation, many experts, in practice, "form a general causation opinion by weighing an entire body of scientific evidence."[698] To be considered "reliable," within the meaning of *Milward*, "[t]his 'weight of the evidence' approach to analyzing [general] causation" must "consider[] all available evidence carefully and explain[] how the relative weight of the various pieces of evidence led to [the expert's] conclusion."[699] Again citing *Milward*, the court emphasized that the expert also must show that he/she had applied the weight of evidence methodology reliably to derive an inference to the best explanation "with 'the same level of intellectual

of a test tube or petri dish may differ from how the drug will react in, and impact, the complex biological system that is the human body." *Id.* at 1310.

[692] *Id*. at 1306.

[693] *Id.* at 1306, quoting *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002),

[694] *Id.* at 1306-07.

[695] *Id.* at 1307.

[696] *Id*., citing *Milward*, 639 F.3d at 18. *See also id*. at 1352 (supporting the court's conclusion that "the fact that [plaintiffs' expert] Dr. Glenmullen [had] found that all of the Bradford Hill factors supported a causal inference does not, standing alone, render his methodology unreliable.").

[697] *Id*. at 1307, citing *Rider*, 295 F.3d at 1198. *See also id*. at 1352, citing *Milward*, 639 F.3d at 18 .

[698] *Id.* at 1311.

[699] *Id.* citing *Milward*, 639 F.3d at 17; *In re Zoloft (Sertraline Hydrochloride)*, 858 F.3d at 795-97; *Jones v. Novartis Pharmaceuticals Corporation*, 235 F. Supp. 3d at 1272-73. In other words, to demonstrate that weight-of-the-evidence methodology has been properly applied to derive an inference to the best explanation, the "scientist must: (1) identify an association between an exposure and a disease, (2) consider a range of plausible explanations for the association, (3) rank the rival explanations according to their plausibility, (4) seek additional evidence to separate the more plausible from the less plausible explanations, (5) consider all of the relevant available evidence, and (6) integrate the evidence using professional judgment to come to a conclusion about the best explanation." 299 F. Supp. 3d at 1311, quoting *Milward*, 639 F.3d at 17-18; J*ones*, 235 F. Supp. at 1273.

rigor' used by experts in the field."[700]

The district court evaluated the admissibility of an epidemiological case study ("Etminan Study") that three of plaintiffs' experts had relied upon, and it found that it had met Bradford Hill's statistical significance factor. The court reached this conclusion because the study had "described the existence and strength of the association found between Abilify, pathological gambling, and impulse disorder in the random sample of the entire LifeLink database," and since it "reported a relative risk of 5.23 for pathological gambling in individuals exposed to Abilify as compared to unexposed individuals" which the court found "statistically significant."[701] The court also considered the defendants' objections to the study's deficient design, failure to consider the risk of confounders,[702] and the presence of bias. It found that while these deficiencies may impact the weight afforded to the study's conclusions, they did not render the study unreliable, and thus, inadmissible under *Daubert*.[703] In addition, the court reviewed the defendants' objections to the statistical analysis of the Etminan study performed by one of plaintiffs' experts, Madigan, and to his published literature. It found that while they may impact the weight of the expert's opinion, they would not affect its admissibility.[704] The district court ultimately held that the Etminan Study was "a scientifically sound epidemiological study, and therefore, reliable evidence of general causation in this case."[705]

In addition, the court examined plaintiffs' experts' evidence of a dose-response relationship. It found that the experts' evidence of a dose-response relationship "lack[ed] the intrinsic reliability that is the hallmark of a primary methodology under the Eleventh Circuit's *Daubert* jurisprudence."[706] The court reasoned that the experts' failure to "present[] any controlled, experimentally derived evidence of a dose-response relationship between Abilify and impulse control disorders […] weaken[ed] the force and reliability of their conclusions as to dose-response."[707] Significantly, although the experts had presented published case studies and adverse event reports indicating "'a temporal relationship between the initiation of [Abilify] treatment and the onset of' impulse control problems," the court found that "the lack of meaningful scientific controls limit[ed] the weight that these case studies and adverse event reports may reliably bear on an expert's general causation opinion under Eleventh

[700] *Id.* at 1312, citing *Milward*, 639 F.3d at 17; *In re Zoloft (Sertraline Hydrochloride)*, 858 F.3d at 795-97; *Jones*, 235 F. Supp. 3d at 1272-73.

[701] *Id.* at 1313-14.

[702] *Id*. at 1322 ("When assessing the reliability of an epidemiological study, a court must consider whether the study adequately accounted for confounding factors, or confounders."). *See also id*. ("Counfounding occurs where an extraneous variable, or set of variables, may wholly or partially explain an apparent association between exposure to a drug and a disease, but that variable is not accounted for in the study.").

[703] *Id*. at 1315-21 (design); at 1321-25 (confounding); at 1325-27 (bias).

[704] *Id*. at 1327-29.

[705] *Id*. at 1330.

[706] *Id*.

[707] *Id*. at 1331.

Circuit standards." Consequently, the court held that such evidence was "relevant and admissible, but only as a *supplement* to the other, more substantial evidence of general causation (*i.e.,* the Etminan Study)."[708]

Furthermore, the court examined plaintiffs' experts' evidence "provid[i]ng] the background risk or prevalence of various impulse control disorders, including compulsive gambling, in the general population as reflected in the scientific literature." Although the experts had not offered "a more expansive background risk," the court found that such failure did "not present a 'serious methodological deficiency' or 'substantial weakness' in their general causation opinions" to prevent them from satisfying Rule 702 and *Daubert*.[709]

The district court, moreover, examined plaintiffs' experts' evidence of biological plausibility,[710] which it distinguished from "biological certainty."[711] The court found that [p]laintiffs' experts' biological plausibility opinions that Abilify can cause impulse control problems through its effects on dopamine neurotransmission in the brain to be scientifically reliable, based on current biochemistry and pharmacological knowledge," and to be "consistent with the FDA's assessment."[712] It also found that the experts had adequately supported "[e]ach element of this proposed mechanism of action" with "peer-reviewed, published scientific literature and sound scientific reasoning."[713] Citing *Milward*, the court ultimately held that such biological plausibility evidence could support "other, more substantial evidence" to establish general causation, by "'lend[ing] credence to an inference of causality' drawn from" such other evidence.[714]

CONCLUSION

The majority of civil litigation today—from toxic tort and products liability to even run-of-the-mill contract disputes—requires judges to rule on the admissibility of expert evidence. Judges' keeping of the evidentiary gate not only affects the parties in any given case, but also the judicial branch's broader role in our constitutional republic. The establishment of a lower evidentiary bar and the consequent narrowing of courts' gatekeeper role for evaluating the reliability, and hence, admissibility of expert evidence at trial can allow and, in fact, has allowed for the injection of a European-style, precautionary *regulatory* approach into the adjudication of legal disputes. This phenomenon has both rewarded plaintiffs whose claims are suspect and has set *ex ante*, restrictions on enterprises that were not before the court.

[708] *Id.* (italicized emphasis in original; underlined emphasis added.).
[709] *Id*. at 1332.
[710] *Id*. at 1332-44.
[711] *Id*. at 1344.
[712] *Id*.
[713] *Id*.
[714] *Id*., citing *Milward*, 639 F.3d at 25-26.

Arguably, these courts have become part of the U.S. administrative state, whose job is not to settle distinct disputes, but to protect the putative "public interest." Though administrative agencies' approach to science merits its own criticism,[715] federal regulators are at least nominally accountable to procedurally-focused laws such as the Information Quality Act and the Administrative Procedure Act, which, together, afford interested parties, respectively, the opportunity to judicially appeal final agency actions engendering Information Quality Act noncompliance[716] and to comment on regulatory proposals before they are finalized. The judiciary, by constitutional design, is not similarly accountable.

An approach to expert evidentiary gatekeeping embraced by the First Circuit in *Milward*, institutionalized by the Federal Judicial Center in its *Reference Manual on Scientific Evidence*, Third Edition, and spread by federal trial and appellate courts, undermines the scientific method. The scientific method is fundamentally a logical method of *deducing* conclusions and deriving enduring principles from rational hypotheses and validated assumptions with respect to single lines of evidence based on empirical observation and replication of cause-and-effect relationships.[717] A weight-of-the-evidence approach, by contrast, empowers scientific and technical experts to freely exercise their professional judgment and interpretation beyond the constraints of a defined methodological algorithm when employing the Bradford Hill guidelines to infer a general causal relationship between exposure to an agent and development of a disease after weighing different lines of evidence. It is highly problematic that the *Milward* court posited a presumption that scientists employing abductive reasoning to infer such causal relationships may come to different judgments about whether a causal inference is appropriate. This presumption, unfortunately, has since all but ensured that other federal courts applying the *Daubert* reliability test to an expert's subjective judgments will encounter difficulties confirming whether the expert's application of the methodologies undergirding those judgments can be deemed reliable by virtue of their having been scientifically validated or reproduced.

This WORKING PAPER documents a gradual drift, incited by *Milward* and the FJC's influential expert-evidence guidebook, away from an approach to judicial gatekeeping consistent with the Supreme Court's *Daubert* trilogy and Federal Rule of Evidence 702. Legal practitioners and policymakers should use the information presented here to carefully reconsider the legacy the FJC's support for the *Milward* decision has left on the rules of evidence, the rule of law overall, and the role of empirical science in regulating our daily affairs.

[715] *See* Lawrence A. Kogan, *Revitalizing the Information Quality Act as a Procedural Cure for Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study*, *supra* note 97, Secs. II-IV, 1-14

[716] *Id*. at Secs. VI-VII, 25-47.

[717] *See* A. Alan Moghissi, Betty R. Love, and Sorin R. Straja, *Peer Review and Scientific Assessment: A Handbook for Funding Organizations, Regulatory Agencies, and Editors* (Institute for Regulatory Science) (2013), at 39-40, https://nebula.wsimg.com/571cc7cacba816f0c69c60dea905cb36?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

The federal judiciary itself also must contemplate where this drift toward subjective, weight-of-evidence opinions is leading. Two options to address this drift are currently available. First, in drafting a *Fourth* Edition of its guidebook, the FJC could return to the principles embodied in its Second Edition. Second, the Judicial Conference's Advisory Committee on Evidence Rules could respond positively to stakeholders' requests that it amend FRE 702 in a manner that preserves the *Daubert* approach.

WEIGHT OF THE EVIDENCE:
A LOWER EXPERT EVIDENCE STANDARD
METASTASIZES IN FEDERAL COURTS

APPENDIX A

"HONORABLE MENTION" COURT DECISIONS

(**Editor's Note**: This appendix supplements the WLF WORKING PAPER *Weight of the Evidence: A Lower Standard for Expert Evidence Metastasizes in Federal Courts*. Appendix A compiles federal court decisions that make only brief reference of the First Circuit's *Milward* decision.

A. Traditional Tort Action Areas Receiving "Honorable Mention" (Toxic Torts, Products Liability, Negligence/Wrongful Death, Medical Malpractice)

Other tort cases that fall within the traditional tort areas, but which make only a brief reference ("honorable mention") of the *Milward* decision, are identified below by federal circuit and traditional tort area.

First Circuit (Where *Milward* Is Binding Precedent)

Products Liability

Bertrand v. General Electric Co. (D. Mass. 2011)[1]

> "'Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky, but admissible evidence.'"[2]

Pukt v. Nexgrill Industries, Inc. (D.N.H. 2016)[3]

> "Generally, disputes about the factual bases of an expert's opinion affect the weight and credibility of the opinion but not its admissibility."[4] "Any weakness in the factual bases of the experts' opinions can be addressed through cross-examination."[5]

Short v. Amerada Hess Corp. et al. (D.N.H. 2019)[6]

> "A plaintiff in a personal-injury action of this variety generally must demonstrate two forms of causation: general and specific. ''General causation' exists when a substance is capable of causing a disease' and ''[s]pecific causation' exists when

[1] Civil No. 09-11948-RGS.

[2] *Id*., slip op. at 4, quoting *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 596 (1993), and citing *Milward v. Acuity Specialty Prods. Group, Inc.*, 639 F.3d 11, 15 (1st Cir. 2011).

[3] Civil No. 14-cv-215-JD (D.N.H. 2016).

[4] *Id*., slip op. at 3, citing *inter alia Milward*, 639 F.3d at 22.

[5] *Id*. at 7, citing *Milward*, 639 F.3d at 22.

[6] Civ. No. 16-cv-204-JL (D.N.H. 2019).

exposure to an agent caused a particular plaintiff's disease.'"[7]

Medical Malpractice

Bradley v. Sugarbaker (1st Cir. 2015)[8]

> "A district court['s…] decision to admit or exclude testimony is reviewed for an abuse of discretion […] But, '[t]he [abuse of discretion] standard is not monolithic: within it, embedded findings of fact are reviewed for clear effort, [and] questions of law are reviewed de novo.'"[9]
>
> "[…] Bradley's reliance on *Milward* is unavailing. There, this Court determined that, '[w]hen the factual underpinning of an expert's opinion is weak it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the jury.' But *Milward* concerned the district court's extensive evaluation of the reliability of the scientific theories underscoring the expert's testimony, and not the threshold issue of factual relevance."[10]

Guzman-Fonalledas v. Hospital Expanol Auxilio (D.P.R. 2018)[11]

> "In *Daubert*, the Supreme Court listed four factors to determine an expert's testimony's reliability, but 'd[id] not presume to set out a definitive checklist or test.'[12] The First Circuit has held that the proponent of expert testimony does not need to prove that the expert is correct, but 'must show only that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.'"[13]

Arrieta v. Hospital Del Maestro (D.P.R. 2018)[14] (expert testimony not admitted)

> "In *Daubert*, the Supreme Court 'vested in trial judges a gatekeeper function, requiring that they assess proffered expert scientific testimony for reliability before admitting it.'[15] Moreover, the Supreme Court later 'clarified that courts have this function with respect to all expert testimony, not just scientific.'"[16]

[7] *Id*., slip op. at 15, quoting *Milward*, 639 F.3d at 13 (quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmts. c(3), c(4) (2010)).

[8] 809 F.3d 8 (1st Cir. 2015).

[9] *Id*. at 17, quoting *Milward*, 639 F.3d at 13-14 (quoting *Ungar v. Palestine Liberation Org.*, 599 F.3d 79, 83 (1st Cir. 2010)).

[10] *Id*. at 20, n. 10, quoting *Milward*, 639 F.3d at 22.

[11] 308 F. Supp. 3d 604 (D.P.R. 2018).

[12] *Id*. at 609, quoting *Daubert*, 509 U.S. at 593.

[13] *Id*., quoting *Milward*, 639 F.3d at 15.

[14] Civil No. 15-3114 (MEL).

[15] *Id*., slip op. at 4, quoting *Milward*, 639 F.3d at 14.

[16] *Id*., quoting *Milward*, 639 F.3d at 14 n.1, (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999)).

Negligence

Situ v. O'Neill (D.P.R. 2016)[17]

> "The *Daubert* Court identified four factors that may assist the trial court in determining whether or not scientific expert testimony was reliable: '(1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; and (4) the level of the theory or technique's acceptance within the relevant discipline.'[18] The factors are not a checklist for the trial judge to follow, but rather the inquiry is a flexible one, allowing the trial judge to determine and adapt these factors to fit the particular case at bar."[19]

Second Circuit

Products Liability

In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (MDL No. II) (S.D.N.Y. 2018)[20]

> "As the Third Circuit has put the point: 'To ensure that the Bradford Hill/weight of the evidence criteria is truly a methodology, rather than a mere conclusion-oriented selection process … there must be a scientific method of weighting that is used and explained.'[21] And as the First Circuit has required, while the expert's bottom-line conclusion need not be independently supported by each of the nine Bradford Hill factors, in analyzing the factors, separately and together, the expert must employ 'the same level of intellectual rigor' that he employs in his academic work.'"[22]

Fourth Circuit

Products Liability

In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation (D.S.C. 2016)[23]

[17] Civil No. 11-1225 (GAG) (D.P.R. 2016).

[18] *Id*., slip op. at 5, n. 1, quoting *U.S. v. Mooney*, 315 F.3d 54, 62 (1st Cir. 2002) (citing *Daubert*, 509 U.S. at 593-94).

[19] *Id*. at 5, n. 1, citing *Kumho Tire Co., Ltd.*, 526 U.S. at 150; *Milward*, 639 F.3d at 15-16.

[20] 341 F. Supp. 3d 213 (S.D.N.Y. 2018).

[21] *Id*. at 247, quoting *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.,* 858 F.3d 787, 796 (3d Cir. 2017); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 607 (D.N.J. 2002) (same), *aff'd*, 68 F. App'x 356 (3d Cir. 2003).

[22] *Id*. at 247-48, quoting *Milward*, 639 F.3d at 26 (quoting *Kumho Tire*, 526 U.S. at 152).

[23] 174 F. Supp. 3d 911 (D.S.C. 2016).

"Whether an established association is causal is a matter of scientific judgment, and scientists appropriately employing this method 'may come to different judgments' about whether a causal inference is appropriate."[24]

"While a causation opinion need not be based on epidemiological studies, [], it is well established that the Bradford Hill method used by epidemiologists does require that an association be established through studies with statistically significant results.[12]" […] [12] *Milward v. Acuity Specialty Products Grp., Inc.*, 639 F.3d 11 (1st Cir. 2011), on which Plaintiffs rely, is no exception. There, the expert 'noted that *epidemiological studies have found a statistically significant increased incidence of AML in benzene-exposed workers* and have identified a dose-response relationship.' *Id*. at 19 (emphasis added)."[25]

Fifth Circuit

Toxic Tort

Yarbrough v. Hunt Southern Group, LLC (S.D. Miss. 2019)[26]

"Dr. Goldstein states that he applied the Bradford Hill Criteria of Causation to determine 'that the residents in the Yarbrough household were exposed to, and suffered from, toxins released by the presence of Aspergillus and Penicillium in their home.' (Goldstein Report 5, ECF No. 216-1.)

'Sir Bradford Hill was a world-renowned epidemiologist who articulated a nine-factor set of guidelines in his seminal methodological article on causality inferences.[27] […] Sir Bradford Hill's article explains that 'one should not conclude that an observed association between a disease and a feature of the environment (e.g., a chemical) is causal without first considering a variety of 'viewpoints' on the issue.'"[28]

[24] *Id*. at 916, citing *Milward,* 639 F.3d at 18.

[25] *Id*. at 936 and n. 12, citing *Milward*, 639 F.3d at 19.

[26] Cause No. 1:18cv51-LG-RHW (S.D. Miss. 2019).

[27] *Id*., slip op. at 4, quoting *Jones v. Novartis Pharm. Corp.*, 235 F. Supp. 3d 1244, 1267 (N.D. Ala. 2017), aff'd, 720 F. App' 1006 (11th Cir. 2018), quoting *Milward*, 639 F.3d at 17 (citing Arthur Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. ROYAL SOC'Y MED. 295 (1965)).

[28] *Id*. at 4, quoting *Jones*, 235 F. Supp. 3d at 1267, aff'd, 720 F. App'x 1006 (11th Cir. 2018), quoting *Milward*, 639 F.3d at 17.

Seventh Circuit

Wrongful Death

Ashley v. Schneider National Carriers, Inc. (N.D. Ill. 2016)[29]

> "Defendants also uncovered that Mr. Hess lacked any factual basis supporting his assertion other than his own personal knowledge. That being said, '[w]hen the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the jury.'"[30]

Eighth Circuit

Products Liability

Clinton v. Mentor Worldwide, LLC (E.D. Mo. 2016)[31]

> "Plaintiff also points out that Dr. Skinner could not rule out necrotizing fasciitis as the cause of plaintiff's pain prior to her diagnosis. However, '[p]roponents of expert testimony need not demonstrate that the assessments of their experts are correct, and trial courts are not empowered to determine which of several competing scientific theories has the best provenance.'"[32]

Personal Injury/Wrongful Death

Crawford v. Safeway, Inc. (D. Neb. 2016)[33]

> "'Proponents of expert testimony need not demonstrate that the assessments of their experts are correct, and trial courts are not empowered 'to determine which of several competing scientific theories has the best provenance.'"[34]

Ninth Circuit

Products Liability

In Re Nexium Esomeprazole (9th Cir. 2016)[35]

[29] Case Nos. 12-cv-8309, 13-cv-3042 (N.D. Ill. 2016).
[30] *Id*., slip op. at 10, quoting *Milward*, 639 F.3d at 22.
[31] Civ. No. 4:16-CV-00319 (CEJ) (E.D. Mo. 2016).
[32] *Id*., slip op. at 8, quoting *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (quoting *Milward*, 639 F.3d at 15.
[33] Civ. No. 7:14CV5001 (D. Neb. 2016).
[34] *Id*., slip op. at 4, quoting *Kuhn*, 686 F.3d at 625 (quoting *Milward*, 639 F.3d at 15).
[35] 662 F. App'x 528 (9th Cir. 2016).

> "At best, Dr. Bal analyzed three of the nine Bradford Hill factors that guide scientists in drawing causal conclusions from epidemiological studies.[36] We agree with the district court that Dr. Bal's analysis of the factors he did discuss was 'extremely thin.'"[37]

Negligence/Strict Liability

Wendall v. GlaxoSmithKline, LLC (9th Cir. 2017)[38]

> "However, expert testimony may still be reliable and admissible without peer review and publication.[39] That is especially true when dealing with rare diseases that do not impel published studies."[40]

B. Non-Traditional Tort and Other Cases Receiving "Honorable Mention" (Environment/Discrimination/Business/Criminal)

Milward's has had such a broad influence that courts have also referenced it in federal cases implicating non-traditional torts and other areas. Those areas include environmental, discrimination (employment and enrollment-related age and racial), business (tort and contract), and criminal law. The cases below are identified by nontraditional tort or other area and sub-area, and by federal circuit.

Environmental Cases

Third Circuit

McMunn v. Babcock & Wilcox Power Generation Group, Inc. (W.D. Pa. 2014)[41]

> "Moreover, as the Court of Appeals for the First Circuit recognized, '[t]here is an important difference between what is unreliable support and what a trier of fact may conclude is insufficient support for an expert's conclusion.'"[42]

[36] *Id*. at 530, citing *Milward*, 639 F.3d at 17 (citing Arthur Bradford Hill, *supra* note 27).
[37] *Id*.
[38] 858 F.3d 1227 (9th Cir. 2017).
[39] *Id*. at 236, quoting *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1056 (9th Cir. 2003).
[40] *Id*., citing *Milward*, 639 F.3d at 24 ("recognizing that the 'rarity' of a particular form of leukemia was one reason that it would be 'very difficult to perform an epidemiological study of the causes of [the disease] that would yield statistically significant results.'").
[41] Civ. No. 2:10cv143 (W.D. Pa. 2014).
[42] *Id*., slip op. at 7, quoting *Milward*, 639 F.3d at 22.

Discrimination Cases

First Circuit

EEOC v. Texas Roadhouse, Inc., (D. Mass. 2016)[43] (Employment/Age)

> "As long as the expert's testimony is found to rest upon reliable grounds, 'the traditional and appropriate means of attacking shaky but admissible evidence' is through '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'"[44]
>
> "[…] In addition, the parties' differing opinions as to which party the corrected PUMS data supports, D. 594 at 16; D. 621 at 8-10, can again be addressed in the course of direct and cross-examinations of both Saad and Crawford and, ultimately, will be resolved by the jury."[45]
>
> "[…] While the *Frye* standard of general acceptability is no longer the touchstone of admissibility of expert opinion under Fed. R. Evid. 702 post-*Daubert*, whether a methodology has been peer reviewed remains one factor for the Court to consider when addressing challenges to the admissibility of expert testimony."[46]
>
> "[…] any such limitations of his analysis are concerns to be raised on cross-examination and are a matter for the jury to consider and weigh."[47]

Riley v. Massachusetts Department of State Police (D. Mass. 2018)[48] (Employment/Racial)

> "If the Court determines that the expert's testimony is reliable and relevant, 'the traditional and appropriate means of attacking shaky but admissible evidence' is through '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" [49]

Students for Fair Admissions, Inc. v. Harvard (D. Mass. 2018)[50] (Enrollment/Racial)

> "'Even assuming, arguendo, that this Court were to conclude that 'the factual

[43] *EEOC v. Texas Roadhouse, Inc.*, Civ. No. 1-11732-DJC (D. Mass. 2016).
[44] *Id*., slip op. at 2, citing *Milward*, 639 F.3d at 15 (quoting *Daubert*, 590 U.S. at 590).
[45] *Id*. at 13, citing *Milward*, 639 F.3d at 15.
[46] *Id*. at 15, citing *Milward*, 639 F.3d at 14, 22.
[47] *Id*. at 16, citing and quoting *Milward*, 639 F.3d at 22 (explaining that '[w]hen the factual underpinning of an Expert's opinion is weak, [that] is a matter affecting the weight and credibility' of that expert's opinion), (quoting *United States v. Vargas*, 471 F.3d 255, 264 (1st Cir. 2006)).
[48] Civ. No. 15-14137 (D. Mass. 2018).
[49] *Id*., slip op. at 2, quoting *Milward*, 639 F.3d at 15 (quoting *Daubert*, 509 U.S. at 590).
[50] 346 F. Supp. 3d 174 (D. Mass. 2018).

> underpinning of [either party's] expert's opinion [was] weak,'' the challenges by SFFA and Harvard affect 'the weight and credibility of the testimony' to be evaluated at trial when the Court assumes its fact-finding role."[51]

Fourth Circuit

Brown v. Nucor Corp. (4th Cir. 2015)[52] (Employment/Racial)

> "'[T]rial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable.'"[53]

Equal Employment Opportunity Commission v. Freeman (4th Cir. 2015)[54] (Employment/Racial)

> "Rather, courts widely agree that 'trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable.'"[55]

General Business Cases

First Circuit

In re Neurontin Marketing and Sales Practices Litigation (1st Cir. 2013)[56] (Tort—Fraudulent Marketing)

> "Admissibility does not turn on a determination by the trial court of 'which of several competing scientific theories has the best provenance,' nor does it turn on convincing the trial court that the proffered expert is correct."[57]

Keppler v. RBS Citizens N.A. (D. Mass. 2014)[58] (Tort—Consumer Bank Fraud)

> "However, that is no reason to exclude her testimony. 'Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof [would be] the traditional and appropriate means of attacking'

[51] *Id*. at 193-94, quoting *Pac. Indem. Co. v. Dalla Pola*, 65 F. Supp. 3d 296, 304 (D. Mass. 2014) (quoting *Milward,* 639 F.3d at 22).

[52] 785 F. 3d 895 (4th Cir. 2015).

[53] *Id*. at 936, quoting *Milward*, 639 F.3d at 15.

[54] 778 F.3d 463 (4th Cir. 2015).

[55] *Id*. at 472, quoting *Milward*, 639 F.3d at 15.

[56] 712 F.3d 21 (1st Cir. 2013).

[57] *Id*. at 42, quoting *Milward*, 639 F.3d at 15 (quoting *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)).

[58] *Keppler v. RBS Citizens N.A.*, Civ. No. 12-10768-FDS (D. Mass. 2014).

Kerr's opinion in those circumstances."[59]

Pacific Indemnity Co. v. Dalla Pola (D. Mass. 2014)[60] (Contract—Homeowner Insurance Subrogation)

> "Even assuming, arguendo, that this court were to conclude that 'the factual underpinning of [the] expert's opinion [was] weak,' the challenges by the defendant at most affect 'the weight and credibility of the testimony—a question to be resolved by the jury.'"[61]

> "[…] To the extent Dalla Pola wishes to expose any alleged flaws in Klem's expert analysis, he will have an ample opportunity to do so through cross-examination and the presentation of evidence at trial." (""Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'"[62]

Noveletsky v. Metropolitan Life Ins. Co., Inc. (D. Me. 2014)[63] (Contract—Life Insurance Policy)

> "With regard to the sufficiency of the facts and data in particular, 'trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support.'"[64]

Mass. Mutual Life Ins. Co. v. DB Structured Products, Inc. (D. Mass. 2015)[65] (Tort—Securities Fraud & Misrepresentation)

> "The *Daubert* Court identified four factors which might assist a trial court in determining the admissibility of an expert's testimony: (1) whether the theory or technique can be and has been tested; (2) whether the technique has been subject to peer review and publication; (3) the technique's known or potential rate of error; and (4) the level of the theory's or technique's acceptance within the relevant discipline."[66]

> "'These factors, however, 'do not constitute a definitive checklist or test.'"[67] "'Given that 'there are many different kinds of experts, and many different kinds

[59] *Id*., slip op. at 8, quoting *Milward*, 639 F.3d at 15.
[60] *Pacific Indemnity Co. v. Dalla Pola*, 65 F. Supp. 3d 296 (D. Mass. 2014).
[61] *Id*., quoting *Milward*, 639 F.3d at 22.
[62] *Id*., citing and quoting *Milward*, 639 F.3d at 15.
[63] Civil No. 2:12-cv-00021-NT (D. Me. 2014).
[64] *Id*., slip op. at 11, quoting *Milward*, 639 F.3d at 15 (quoting *Ruiz-Troche*, 161 F.3d at 81).
[65] *Mass. Mutual Life Ins. Co. v. DB Structured Products, Inc.*, Civ. No. 11-30039-MGM (D. Mass. 2015).
[66] *Id*., slip op. at 7-8, citing *Milward*, 639 F.3d at 14.
[67] *Id*. at 8, quoting *Milward*, 639 F.3d at 14 (quoting *Kumho Tire Co.*, 526 U.S. at 150).

of expertise,' these factors 'may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'"[68]

"While expert testimony may be excluded if there is 'too great an analytical gap between the data and the opinion proffered,'[69] '[t]his does not mean that trial courts are empowered 'to determine which of several competing scientific theories has the best provenance.'"[70]

"'*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct.'"[71]

"Rather, '[t]he proponent of the evidence must show only that 'the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.''"[72]

"As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,'[73] 'it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities.'"[74]

"[…] First, contrary to Defendants' assertion, Dr. Kilpatrick does provide support for his 31 questions and the weight assigned to each. He points to the USPAP standards, commonly used appraisal forms, and his own knowledge and experience in the field."[75] "('In concluding that the weight of the evidence supported the conclusion that benzene can cause APL, Dr. Smith relied on his knowledge and experience in the field of toxicology and molecular epidemiology and considered five bodies of evidence drawn from the peer-reviewed scientific literature on benzene and leukemia.')."

"[…] Ultimately, the trier of fact will have to make that determination. But it is not a reason to exclude Mr. Butler's opinion."[76]

[68] *Id*. quoting *Milward*, 639 F.3d at 14 (quoting *Kumho Tire Co.*, 526 U.S. at 150).
[69] *Id*. quoting *Milward*, 639 F.3d at 15 (quoting *Joiner*, 522 U.S. at 146).
[70] *Id.*, quoting *Milward*, 639 F.3d at 15 (quoting *Ruiz-Troche*, 161 F.3d at 85).
[71] *Id*.
[72] *Id*.
[73] *Id*., quoting *Milward*, 639 F.3d at 15 (quoting *Daubert*, 509 U.S. at 590).
[74] *Id*., quoting *Milward*, 639 F.3d at 15.
[75] *Id*. at 10-11, citing *Milward* 639 F.3d at 19.
[76] *Id*. at 13, citing *Milward*, 639 F.3d at 22 (quoting *U.S. v. Vargas*, 471 F.3d 255, 264 (1st Cir. 2006) ("'When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the jury.'")).

> "[…] FN [17] Defendants' other arguments for exclusion, namely, the inconsistencies between some of the CAM questions, while no doubt bearing on the persuasiveness, or weight, of the analysis, do not render it inadmissible." ("'(There is an important difference between what is *unreliable* support and what a trier of fact may conclude is insufficient support for an expert's conclusion.'"). (emphasis in original).[77]

Ferring Pharms., Inc. v. Braintree Labs, Inc. (D. Mass. 2016)[78] (Tort—False Advertising/Unfair Trade Practices)

> "If expert testimony 'rests upon good grounds, based on what is known, it should be tested by the adversarial process.'"[79]

Lawes v. Q.B. Construction (D.P.R. 2016)[80] (Tort—Defective Construction-Related Traffic Management Plan)

> "Courts may exclude theories and conclusions when their sole connections to the data are the expert's own dogmatic statements."[81] ("'conclusions and methodology are not entirely distinct from one another' and 'nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.')."
>
> "[…] Thus, the categorical assertion that a monitoring plan, which Aronberg admitted did not require nightly inspections under Section 6B of the MUTCD,23 would have detected a midblock crossing problem has little support in light of the random crossing and skirting patterns that the merchant marines testified to." ("'Expert testimony may be excluded if there is 'too great an analytical gap between the data and the opinion proffered.'")[82]
>
> "[…] Traditionally, '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the . . . appropriate means of attacking shaky but admissible evidence.'"[83]

[77] *Id*. at 15-16, n. 17, citing and quoting *Milward*, 639 F.3d at 22.
[78] *Ferring Pharms., Inc. v. Braintree Labs, Inc.*, 210 F. Supp. 3d 252 (D. Mass. 2016).
[79] *Id*. at 257, quoting *Milward*, 639 F.3d at 15.
[80] *Lawes v. Q.B. Construction*, Civ. No. 12-1473 (DRD) (D.P.R. 2016).
[81] *Id*., slip op. at 23, citing and quoting *Milward*, 639 F.3d at 15.
[82] *Id*. at 29, citing and quoting *Milward*, 639 3d. at 15
[83] *Id*. at 40, quoting *Milward*, 639 F.3d at 15 (quoting *Daubert*).

Packgen v. Berry Plastics Corporation (1st Cir. 2017)[84] (Tort—Breach of Implied Warranties/Negligence)

> "'Exactly what is involved in 'reliability'. . . must be tied to the facts of a particular case.'"[85] "'So long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities.'"[86]

Iconics, Inc. v. Massaro (D. Mass. 2017)[87] (Tort—Software Copyright and Trade Secret Infringement)

> "Once it is established that an expert's testimony 'rests upon good grounds based on what is known,' however, I should allow the evidence to be presented to the jury and 'be tested by the adversarial process.'"[88]

> "[…] Ultimately, however, it is the factfinder's role to evaluate the credibility of an expert's testimony, which may include a consideration of the data underlying the testimony." ("'When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the jury.'").[89]

> "[…] As discussed above, the strength of the factual underpinning of an expert's opinion is a matter of weight and credibility."[90]

In re Asacol Antitrust Litigation (D. Mass. 2017)[91] (Tort—Antitrust)

> "The standard for admissibility is not whether Clark's methodology is the best; only whether it is 'methodologically reliable' and rests on 'good grounds,' which the Court concludes it does."[92]

In re: Dial Complete Marketing and Sales Practices Litigation (D.N.H. 2017)[93] (Tort—Consumer Fraud, False and Misrepresentative Marketing)

[84] Civ. No. No. 16-1348 (1st Cir. 2017).

[85] *Id*., slip op. at 3, quoting *Milward*, 639 F.3d at 14-15 (quoting *Beaudette v. Louisville Ladder, Inc.*, 462 F.3d 22, 25-26 (1st Cir. 2006)).

[86] *Id*. at 3, quoting *Milward*, 639 F.3d at 15 (quoting *Daubert*, 509 U.S. at 590).

[87] 266 F. Supp. 3d 461 (D. Mass. 2017).

[88] *Id*. at 466, citing and quoting *Milward*, 639 F.3d at 15.

[89] *Id*. at 470, citing and quoting *Milward*, 639 F.3d at 22.

[90] *Id*. at 475, citing *Milward*, 639 F.3d at 22.

[91] Civil Action No. 15-cv-12730-DJC (D. Mass. 2017).

[92] *Id*., slip op. at 16, citing and quoting *Milward*, 639 F.3d at 15.

[93] *In re: Dial Complete Marketing and Sales Practices Litigation*, MDL Case No. 11-md-2263-SM (D.N.H. 2017).

> "As our court of appeals noted in *Milward v. Acuity Specialty Prod. Grp., Inc.*:
>
> '*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct.'[94] 'The proponent of the evidence must show only that 'the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.''[95] The object of *Daubert* is 'to make certain that an expert, whether basing testimony on professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.'"[96]
> "[…] However, '[t]here is an important difference between what is unreliable support and what a trier of fact may conclude is insufficient support for an expert's conclusion.'"[97]

Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd. (D. Mass. 2017)[98] (Tort—Patent Infringement)

> "The parties shall particularly be prepared to discuss whether Dr. Wurm's test results provide Dr. Butler and him with a reliable basis from which to conclude that the ingredients of the accused powders, in their allegedly equivalent concentrations, perform substantially the same function in the accused powders as they do in the patented invention."[99] […] More specifically, they shall be prepared to address whether Drs. Wurm and Butler employed scientifically sound and methodologically reliable methods in reaching their conclusions that the 29 ingredients that Dr. Wurm added to the claimed powders did not mask[] large differences in Dr. Wurm's comparisons by performing overlapping functions with the 12 allegedly equivalent ingredients."[100]

<u>Fifth Circuit</u>

Gil Ramirez Grp., LLC v. Houston Indep. Sch. Dist. (S.D. Tex. 2016)[101] (Civil RICO)

> "The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact. … When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the

[94] *Id*., slip op. at 12, quoting *Milward*, 639 F.3d at 15 (quoting *Ruiz–Troche*, 161 F.3d at 81).
[95] *Id*., quoting *Milward*, 639 F.3d at 15 (citing *United States v. Vargas*, 471 F.3d 255, 265 (1st Cir. 2006)).
[96] *Id*. at 12, quoting *Milward*, 639 F.3d at 15 (quoting *Kumho Tire Co.*, 526 U.S. at 152).
[97] *Id*. at 17, quoting *Milward*, 639 F.3d at 22.
[98] Civil Action No. 15-10698-MLW (D. Mass. 2017).
[99] *Id*., slip op. at 3, n. 1, citing *Milward*, 639 F.3d at 15.
[100] *Id*.
[101] Civ. No. 4:10-CV-04872 (S.D. Tex. 2016).

testimony—a question to be resolved by the jury.'"[102]

Ninth Circuit

Johns v. Bayer Corporation (S.D. Cal. 2013)[103] (Tort—False and Deceptive Advertising (Class Action))

> "Taking all the evidence into consideration, the Court finds Plaintiffs' arguments go to the weight rather than the admissibility of Dr. Blumberg's testimony." ("'There is an important difference between what is unreliable support and what a trier of fact may conclude is insufficient support for an expert's conclusion.'").[104] […] "Thus, Plaintiffs' request for piecemeal exclusion of selected studies based solely on their allegations that such studies, taken in isolation, are unreliable, is an inappropriate ground for exclusion and exceeds the court's gatekeeping function under Rule 702." […] "('In this, the court overstepped the authorized bounds of its role as gatekeeper.')."[105]

Townsend v. Monster Beverage Corp. (C.D. Cal. 2018)[106] (Tort—Antitrust/Anti-competition/Unfair Competition (Class Action))

> "('There is an important difference between what is *unreliable* support and what a trier of fact may conclude is insufficient support for an expert's conclusion.')."[107]

Tenth Circuit

White v. Town of Hurley (D.N.M. 2019)[108] (Tort—Discrimination (Employment/Age))

> "'[T]he soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact.'"[109]

[102] *Id*., slip op. at 6, quoting *Milward*, 639 F.3d at 22.
[103] Civ. No. 09cv1935 AJB (DHB) (S.D. Cal. 2013).
[104] *Id*., slip op. at 20, citing and quoting *Milward*, 639 F.3d at 22.
[105] *Id.*
[106] 303 F. Supp. 3d 1010 (C.D. Cal. 2018).
[107] *Id*, quoting *Milward*, 639 F.3d at 22 (emphasis in original).
[108] Civ. No. 17-0983JB\KRS (D.N.M. 2019).
[109] *Id*., slip op. at 54, n. 54, quoting *Milward*, 639 F.3d at 22 (quoted in David E. Bernstein & Eric G. Lasker, *Defending Daubert: It's Time to Amend Federal Rule of Evidence* 702, 57 WM. & MARY L. REV. 1, 33 (2015)).

Criminal Cases

First Circuit

United States v. Candelario-Santana (D.P.R. 2013)[110]

> "To the contrary, Dr. Greenspan's testimony before *this* court failed to meet the high standards of scientific reliability and evidence demanded in his field."[111]

US v. Tavares (1st Cir. 2016)[112]

> "To say more on this point would be to paint the lily. In the circumstances here, we think that any question about the factual underpinnings of Auclair's opinion goes to its weight, not to its admissibility."[113]

[110] Crim. No. 09-427 (JAF) (D.P.R. 2013).
[111] *Id*., slip at 10-11, citing *Milward*, 639 F.3d at 26 (emphasis in original).
[112] 843 F.3d 1 (1st Cir. 2016).
[113] *Id*., citing *Milward*, 639 F.3d at 22.

WEIGHT OF THE EVIDENCE:
A LOWER EXPERT EVIDENCE STANDARD
METASTASIZES IN FEDERAL COURTS

APPENDIX B

TABLE OF CASES

WORKING PAPER TEXT
TRADITIONAL FEDERAL TORT ACTION AREAS

Toxic Torts	Products Liability	Negligence/ Wrongful Death	Medical Malpractice	Federal Circuit
Campos v. Safety-Kleen Systems, Inc. (D.P.R. 2015)				1st Circuit
	Jenks v. New Hampshire Motor Speedway (D.N.H. 2012)			1st Circuit
	West v. Bell Helicopter Textron, Inc. (D.N.H. 2013)			1st Circuit
	Calisi v. Abbott Laboratories, (D. Mass. 2013)			1st Circuit
		Zagklara v. Sprague Energy Corp. (Zagklara II) (D. Me. 2013)		1st Circuit
			Torres v. Mennonite General Hospital, Inc. (D.P.R. 2013)	1st Circuit
	Quilez-Velar v. Ox Bodies, Inc. (1st Cir. 2016)			1st Circuit
		Drake v. Allergan, Inc. (D. Vt. 2015)		2nd Circuit
Sullivan et al. v. Saint-Gobain Performance Plastics (D. Vt. 2019)				2nd Circuit
	In re Fosamax (D.N.J. 2013)			3rd Circuit
	In re Zoloft (Sertraline Hydrochloride) (3d Cir. 2017)			3rd Circuit
	Levitt v. Merck Sharp & Dohme Corp. (In re Vioxx Prods.) (E.D. La. 2016)			5th Circuit
	Sparling ex rel. Sparling v. Doyle (W.D. Tex. 2016)			5th Circuit
	In re Heparin Products Liability Litigation (N.D. Ohio 2011)			6th Circuit

	DeGidio v. Centocor Ortho Biotech, Inc. (N.D. Ohio 2014)			6th Circuit
Kuhn v. Wyeth, Inc. (8th Cir. 2012)				8th Circuit
	O'Neal v. Remington Arms Co. (D.S.D. 2016)			8th Circuit
		Sioux Steel Co. v. KC Engineering, P.C. (D.S.D. 2018)		8th Circuit
	In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation (D. Minn. 2019)			8th Circuit
In re Roundup Products Liability Litigation (N.D. Cal. 2018)				9th Circuit
		Cattaneo v. Aquakleen Products, Inc. (D. Colo. 2012)		10th Circuit
		Walker v. Spina (D.N.M. 2019)		10th Circuit
	In re Chantix (Varenicline) Products Liability Litigation (N.D. Ala. 2012)			11th Circuit
	Jones v. Novartis Pharmaceuticals Corporation (N.D. Ala. 2017)			11th Circuit
	In e Abilify (Aripiprazole) Products Liability Litigation (N.D. Fla. 2018)			11th Circuit
4 cases	**15 cases**	**5 cases**	**1 case**	**25 cases**

TABLE OF CASES HONORABLE MENTION TRADITIONAL FEDERAL TORT ACTION AREAS				
Toxic Torts	**Products Liability**	**Negligence/ Wrongful Death**	**Medical Malpractice**	**Federal Circuit**
	Bertrand v. General Electric Co. (D. Mass. 2011)			1st Circuit
			Bradley v. Sugarbaker (1st Cir. 2015)	1st Circuit
		Situ v. O'Neill (D.P.R. 2016)		1st Circuit
	Pukt v. Nexgrill Industries, Inc. (D.N.H. 2016)			1st Circuit
			Guzman-Fonalledas v. Hospital Expanol Auxilio (D.P.R. 2018)	1st Circuit
			Arrieta v. Hospital Del Maestro (D.P.R. 2018)	1st Circuit
	Short v. Amerada Hess Corp. et al. (D.N.H. 2019)			1st Circuit
	In re Mirena IUS Levonorgestrel-Related Products Liability Litigation (MDL No. II) (S.D.N.Y. 2018)			2nd Circuit
	In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices and Products Liability Litigation (D.S.C. 2016)			4th Circuit
Yarbrough v. Hunt Southern Group, LLC (D. Miss. 2019)				5th Circuit
		Ashley v. Schneider National Carriers, Inc. (N.D. Ill. 2016)		7th Circuit
	Clinton v. Mentor Worldwide, LLC (E.D. Mo. 2016)			8th Circuit

		Crawford v. Safeway, Inc. (D. Neb. 2016)		8th Circuit
	In Re Nexium Esomeprazole (9th Cir. 2016)			9th Circuit
		Wendall v. GlaxoSmithKline, LLC (9th Cir. 2017)		9th Circuit
1 case	**7 cases**	**4 cases**	**3 cases**	**15 cases** ========

TABLE OF CASES				
"HONORABLE MENTION" NON-TRADITIONAL FEDERAL TORT ACTION AREAS				
Environmental	**Employment / Civil Rights Discrimination**	**Business**	**Criminal**	**Federal Circuit**
	EEOC v. Texas Roadhouse, Inc. (D. Mass. 2016)			1st Circuit
	Riley v. Massachusetts Department of State Police (D. Mass. 2018)			1st Circuit
	Students for Fair Admissions, Inc. v. Harvard (D. Mass. 2018)			1st Circuit
		In re Neurontin Marketing and Sales Practices Litigation (1st Cir. 2013)		1st Circuit
		Keppler v. RBS Citizens N.A. (D. Mass. 2014)		1st Circuit
		Pacific Indemnity Co. v. Dalla Pola (D. Mass. 2014)		1st Circuit
		Noveletsky v. Metropolitan Life Ins. Co., Inc. (D. Me. 2014)		1st Circuit
		Mass. Mutual Life Ins. Co. v. DB Structured Products, Inc. (D. Mass. 2015)		1st Circuit
		Ferring Pharms., Inc. v. Braintree Labs, Inc. (D. Mass. 2016)		1st Circuit
		Lawes v. Q.B. Construction (D.P.R. 2016)		1st Circuit

		Packgen v. Berry Plastics Corporation (1st Cir. 2017)		1st Circuit
		Iconics, Inc. v. Massaro (D. Mass. 2017)		1st Circuit
		In re Asacol Antitrust Litigation (D. Mass. 2017)		1st Circuit
		In re: Dial Complete Marketing and Sales Practices Litigation (D.N.H. 2017)		1st Circuit
		Janssen Biotech, Inc. v. Celltrion Healthcare Co., Ltd. (D. Mass. 2017)		1st Circuit
		In re Asacol Antitrust Litig. (D. Mass. 2017)		1st Circuit
			United States v. Candelario-Santana (D.P.R. 2013)	1st Circuit
			US v. Tavares, (1st Cir. 2016)	1st Circuit
McMunn v. Babcock & Wilcox Power Generation Group, Inc. (W.D. Pa. 2014)				3rd Circuit
	Brown v. Nucor Corp. (4th Cir. 2015)			4th Circuit
	Equal Employment Opportunity Commission v. Freeman (4th Cir. 2015)			4th Circuit
		Gil Ramirez Grp., LLC v. Houston Indep. Sch. Dist. (S.D. Tex. 2016)		5th Circuit
		Johns v. Bayer Corporation (S.D. Cal. 2013)		9th Circuit
		Townsend v. Monster Beverage Corp. (C.D. Cal. 2018)		9th Circuit
		White v. Town of Hurley (D.N.M. 2019)		10th Circuit
1 case	**5 cases**	**17 cases**	**2 cases**	**25 cases**

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
(b)(6) per EOUSA

Critical Legal Issues: WORKING PAPER SERIES

INCONSISTENT GATEKEEPING UNDERCUTS THE CONTINUING PROMISE OF *DAUBERT*

By

Joe G. Hollingsworth
Mark A. Miller
Hollingsworth LLP

Washington Legal Foundation
Critical Legal Issues WORKING PAPER Series

Number 213
July 2019

TABLE OF CONTENTS

ABOUT OUR LEGAL STUDIES DIVISION

Since 1986, WLF's Legal Studies Division has served as the preeminent publisher of persuasive, expertly researched, and highly respected legal publications that explore cutting-edge and timely legal issues. These articles do more than inform the legal community and the public about issues vital to the fundamental rights of Americans—they are the very substance that tips the scales in favor of those rights. Legal Studies publications are marketed to an expansive audience, which includes judges, policymakers, government officials, the media, and other key legal audiences.

The Legal Studies Division focuses on matters related to the protection and advancement of economic liberty. Our publications tackle legal and policy questions implicating principles of free enterprise, individual and business civil liberties, limited government, and the rule of law.

WLF's publications target a select legal policy-making audience, with thousands of decision makers and top legal minds relying on our publications for analysis of timely issues. Our authors include the nation's most versed legal professionals, such as expert attorneys at major law firms, judges, law professors, business executives, and senior government officials who contribute on a strictly *pro bono* basis.

Our eight publication formats include the concise COUNSEL'S ADVISORY, succinct LEGAL OPINION LETTER, provocative LEGAL BACKGROUNDER, in-depth WORKING PAPER, topical CIRCULATING OPINION, informal CONVERSATIONS WITH, balanced ON THE MERITS, and comprehensive MONOGRAPH. Each format presents single-issue advocacy on discrete legal topics.

In addition to WLF's own distribution network, full texts of LEGAL OPINION LETTERS and LEGAL BACKGROUNDERS appear on the LEXIS/NEXIS® online information service under the filename "*WLF*," and every WLF publication since 2002 appears on our website at www.wlf.org. You can also subscribe to receive select publications at www.wlf.org/subscribe.asp.

To receive information about WLF publications, or to obtain permission to republish this publication, please contact Glenn Lammi, Chief Counsel, Legal Studies Division, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, DC 20036, (b)(6) per EOUSA, (b)(6) per EOUSA.

ABOUT THE AUTHORS

Joe G. Hollingsworth is a nationally renowned courtroom advocate. He specializes in trials and appeals on behalf of corporate defendants and leads a practice group of eighty-five attorneys at Hollingsworth LLP in Washington, DC. He has conducted more than twenty-five jury trials, and more than one hundred opinions arising from his cases are published in the federal and state reporters. *The National Law Journal* has honored him three times in its annual recognition of the year's Top Ten Defense Wins.

Mr. Hollingsworth and his firm have pioneered and advanced developments in the law critical to corporate tort defendants, including securing four leading U.S. Circuit Court *Daubert* decisions, which have been cited thousands of times and are taught and broadly discussed in legal scholarship. He argued the 6th Circuit's first post-*Daubert* case while *Daubert* itself was still pending before the Supreme Court, and he first published on *Daubert* in 1993. He appears frequently as a lecturer and is consulted by media interests about the importance of sound science in the courtroom.

Mr. Hollingsworth represents major manufacturers in the defense of serial products liability claims involving tens of thousands of litigants and an array of pharmaceutical, medical device, chemical, and consumer products. These matters include MDLs, serial litigations, and mass torts, such as the Roundup® herbicide litigation (Monsanto/Bayer), the Omniscan™ contrast dye litigation (General Electric), and the Zometa®/Aredia® bisphosphonate litigation (Novartis). He has relied on science in the successful defense of atypical tort suits as well, such as the defense of claims brought by thousands of Ecuadorians in connection with the joint U.S-Colombia war-on-drugs initiatives (DynCorp International) and the defense of catastrophic loss following a major train derailment and chlorine release in South Carolina (Norfolk Southern).

Mr. Hollingsworth serves on the Georgetown University Law Center Board of Visitors, the board of Atlantic Legal Foundation, and the board of Chesapeake Legal Alliance (a non-profit using the law to improve the quality of the Chesapeake Bay). He is named annually to *Super Lawyers, Best Lawyers*, and as an AV Preeminent® Lawyer by Martindale-Hubbell™. He is a graduate of the Georgetown University Law Center and DePauw University.

Mark A. Miller is a partner at the Washington, D.C. law firm Hollingsworth LLP. Mr. Miller's complex litigation practice emphasizes the defenses of pharmaceutical

products, toxic torts, products liability, and environmental claims. He has defended corporate clients in serial mass tort and class action litigation, including both state and federal multidistrict litigation. In 2014, he was part of a trial team that successfully tried a case on remand from one of the most active federal MDLs for a large pharmaceutical company, achieving the first defense verdict in Florida after the jury deliberated for less than 45 minutes following a three week trial. In that same litigation, he has also obtained summary judgment on various grounds including adequacy of the drug's warning, secured *Daubert* rulings excluding plaintiffs' expert testimony, and won a motion to preclude punitive damages under preemption principles.

In the environmental context, Mr. Miller has successfully defended clients in mass toxic tort cases in state and federal courts in which the plaintiffs alleged personal injuries and property damages from exposures to chemicals including PCBs, dioxins, nuclear by-products, lead, arsenic, and TCE. He successfully represented a Fortune 500 public utility in a CERCLA cost recovery mediation against the United States in a "war plants" case. He has represented an aluminum manufacturer in a remediation cost-recovery action, defended a power plant in a citizen suit alleging violations of the PSD and NNSR provisions of the Clean Air Act, represented a pesticide manufacturer in litigation related to a cancellation proceeding under FIFRA, and represented a Fortune 500 chemical manufacturer in a NEPA case concerning genetically-modified alfalfa. Mr. Miller has also advised large chemical companies, manufacturers, public utilities, and other corporations on litigation risk assessment and compliance with statutory and regulatory schemes including CERCLA, the PSD and NNSR provisions of the Clean Air Act, FIFRA, and NEPA.

Mr. Miller's product liability experience includes successfully defending a Fortune 500 automobile parts manufacturer in a federal consumer class action alleging defective product design, false advertising, and consumer fraud by defeating class certification through a preemptive motion to strike the class allegations and obtaining summary judgment on all counts. In addition, he has defended large corporations in the context of serial and multidistrict litigation against personal injury allegations stemming from the use of prescription pharmaceuticals.

INCONSISTENT GATEKEEPING UNDERCUTS THE CONTINUING PROMISE OF *DAUBERT*

More than 25 years have now elapsed since the Supreme Court decided *Daubert v. Merrell-Dow Pharmaceuticals*, 509 U.S. 579 (1993), its seminal decision interpreting Federal Rule of Evidence 702 as a mandate instructing courts to act as gatekeepers to prevent junk science from reaching juries. At the time, *Daubert* was a "revolution in the criteria for the admissibility of scientific testimony" and "evolutionary in scope."[1] Some predicted *Daubert* would "substantially reduce[] the likelihood that the sellers of expert opinion will be able to take control of the process by which their own testimony is admitted."[2]

Daubert remains the law in federal (and in the majority of state) courts. But in the time since *Daubert* was first issued, courts have taken different approaches to how it is applied. Some courts have embraced the *Daubert* view of Rule 702, rejecting junk science and forestalling the burden on the judicial system caused by protracted litigation of claims with little if any scientific merit. Other courts interpret *Daubert* in a way that has regressed from the Supreme Court's mandates on gatekeeping. A recent decision from the *In re Roundup Products Liability Litigation* multidistrict litigation ("MDL") highlights an example of the implications when a court, more

[1] William J. Blanton, *Reducing the Value of Plaintiff's Litigation Option in Federal Court: Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 2 GEO. MASON U. L. REV. 159, 159 (1995).

[2] *Id.* at 190.

specifically the U.S. Court of Appeals for the Ninth Circuit, lowers the Supreme Court's bar for what is considered admissible scientific evidence.

In *In re Roundup*, the defendant challenged the plaintiffs' experts' specific causation evidence for a variety of reasons, including that the experts failed to rule out idiopathic causes in a differential diagnosis that concluded the defendant's glyphosate product allegedly caused non-Hodgkins lymphoma ("NHL").[3] The experts even admitted there is no scientific way to prove that "NHL presents differently when caused by exposure to glyphosate."[4] The trial court recognized that, "[u]nder a strict interpretation of *Daubert*, perhaps that would be the end of the line for the plaintiffs and their experts (at least without much stronger epidemiological evidence). But in the Ninth Circuit, that is clearly not the case."[5] The court continued that "the Ninth Circuit's recent decisions reflect a view that district courts should typically admit specific causation opinions that lean strongly toward the 'art' side of the spectrum" and the Ninth Circuit's "opinions are impossible to read without concluding that district courts in the Ninth Circuit must be more tolerant of borderline expert opinions than in other circuits."[6] Thus, the trial court was compelled to admit expert evidence

[3] *In re Roundup Prod. Liab. Litig.*, No. 16-MD-02741-VC, 2019 WL 917058, at *2 (N.D. Cal. Feb. 24, 2019).

[4] *Id.*

[5] *Id.* (citing *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1233–37 (9th Cir. 2017); *Messick v. Novartis Pharms. Corp.*, 747 F.3d 1193, 1198–99 (9th Cir. 2014)).

[6] *Id.*

that, in its view, "barely inched over the line" of the lower admissibility bar for expert testimony in the Ninth Circuit.[7]

I. *DAUBERT* BACKGROUND

Daubert has been the subject of much scholarly writing since it was first announced.[8] To summarize, *Daubert* rejected the "general acceptance" test, established in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). Under *Daubert*, courts now evaluate the scientific reliability of an expert's theory or technique, including whether it (1) can be and has been tested; (2) has been subjected to peer-review and publication; (3) has a known or potential error rate; and (4) has general acceptance within a relevant scientific community. The Supreme Court gave ample further guidance on the application of its evidentiary test in two other cases,[9] and in

[7] *Id.* at *1; *see also In re Roundup Prod. Liab. Litig.*, No. 16-MD-02741-VC, 2018 WL 3368534, at *2 (N.D. Cal. July 10, 2018) (declining to exclude questionable general causation evidence from plaintiffs' experts, because "the case law—particularly Ninth Circuit case law—emphasizes that a trial judge should not exclude an expert opinion merely because he thinks it's shaky, or because he thinks the jury will have cause to question the expert's credibility.").

[8] *See*, *e.g.*, Joe Hollingsworth & Eric Lasker, *Daubert in Toxic Tort Litigation*, https://www.hollingsworthllp.com/uploads/23/doc/media.379.pdf (part 1), https://www.hollingsworthllp.com/uploads/23/doc/media.376.pdf (part 2), and https://www.hollingsworthllp.com/uploads/23/doc/media.777.pdf (part 3); Eric G. Lasker, *It is Time to Amend Federal Rule of Evidence 702*, IADC Civil Justice Response & Toxic & Hazardous Substances Litig. Joint Newsletter (Apr. 2016), https://www.hollingsworthllp.com/uploads/1353/doc/EGL&Bernstein_Time_to_Amend_Fed_Rule_Evidence_702_IADC_Newsletter_April2016.pdf.

[9] *General Electric Co. v. Joiner*, 522 U.S. 136 (1997) (courts may exclude expert testimony when the evidence relied on by the evidence does not support the expert's conclusion); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999) (the gatekeeping obligation applies to "non-scientific" and "scientific" experts alike).

December 2000, the Federal Judicial Conference amended Rule 702 to incorporate *Daubert*'s standards, mandating "a rigorous exercise requiring the trial court to scrutinize, in detail, the expert's basis, methods, and application."[10]

Following *Daubert* and Rule 702's amendment, courts began to exclude "junk science." In a string of cases known as the "Parlodel® Trilogy,"[11] *Daubert* was used to end what would have been massive serial litigation. Parlodel® is an FDA-approved drug that doctors still prescribe today for a variety of uses. But in 1995 the FDA withdrew its approval for the prevention of postpartum lactation based on the conclusion that the possible risks outweighed the drug's utility. Numerous lawsuits followed in which the plaintiffs' experts claimed that Parlodel® caused a narrowing of blood vessels, which can result in stroke, seizures, myocardial infarction, and death. District judges nationwide excluded this expert testimony and instead required affirmative and reliable scientific support for the hypotheses expressed. These decisions closely examined the testimony of the proffered experts, holding, among other things, that reliance on regulatory standards as proof of causation was not sound science and hence inadmissible, and focusing on the importance of

[10] Mem. from Dan Capra, Reporter to Advisory Comm. on Evidence Rules at 47 (Mar. 1, 1999), www.uscourts.gov/sites/default/files/fr_import/EV1999-04.pdf.

[11] The Parlodel® Trilogy, cited more than 2,500 times in cases, articles and other court documents, consists of *Glastetter v. Novartis Pharmaceuticals Corp.*, 252 F.3d 986 (8th Cir. 2001), *Hollander v. Sandoz Pharmaceutical Corp.*, 289 F.3d 1193 (10th Cir. 2002), and *Rider v. Sandoz Pharmaceutical Corp.*, 295 F.3d 1194 (11th Cir. 2002).

epidemiology.[12]

Daubert continues to be an important tool in challenging questionable expert evidence, at least in some courts, and the decision in *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016), is such an outcome. *In re Mirena* was a products liability MDL litigation filed against the manufacturers of intrauterine devices ("IUDs") alleging that, after implantation, the IUDs caused patients to develop uterine perforation. The defendants moved to exclude the plaintiffs' general causation experts under *Daubert*, and the court granted the motion. The court held that the plaintiffs' experts, among other things, (1) were first given the preferred conclusion by the plaintiffs' lawyers, and worked backwards to find support for that conclusion, a process lacking any scientific methodology; (2) reached speculative conclusions from studies exceeding the limitations the study authors placed on the studies; and (3) relied upon admittedly flawed studies without explaining how those studies could be used to support the experts' opinions.[13] The plaintiffs' lack of reliable general causation evidence, "doom[ed] hundreds of cases," and the court then granted the

[12] *Glastetter* held that regulatory decisions are based on lesser, prophylactic causation standards than required in courts, 252 F.3d at 991, and differential diagnoses are flawed if they fail to rule out other known potential causes, *id.* at 989–91. *Rider* held that epidemiological evidence is highly persuasive to causation questions, 295 F.3d at 1198, and causation evidence for one drug in a class is not evidence of causation for another drug, *id.* at 1201–02. *Hollander* opined that merely criticizing another expert's scientific evidence does not meet the burden to show reliability. 289 F.3d at 1213.

[13] 169 F.3d at 429–34.

defendants summary judgment, ending the MDL.[14]

There are more examples of courts exercising proper gatekeeping duties as well. In 2018, the Eleventh Circuit affirmed the exclusion of the plaintiff's general causation expert in the bisphosphonate litigation, finding that he had no epidemiological evidence regarding the drug at issue but instead improperly relied on evidence pertaining to the drug class to extrapolate causation.[15] The Fourth Circuit also has continued to apply *Daubert* strictly to causation evidence. In affirming an MDL-ending summary judgment motion, the court held in 2018 that "[t]o hand to the jury the [expert] evidence here and ask it to reach a conclusion as to causation with any amount of certainty would be farcical and would likely result in a verdict steeped in speculation."[16] Other recent decisions have also excluded unreliable science and noted the continued importance of a court's gatekeeper role.[17]

II. THE REGRESSION OF *DAUBERT*'S PRINCIPLES

Ninth Circuit courts are unfortunately not the only federal courts that do not meet the standard the Supreme Court set for admission of expert evidence in

[14] *In re Mirena IUD Prod. Liab. Litig.*, 202 F. Supp. 3d 304, 328 (S.D.N.Y. 2016), *aff'd*, 713 F. App'x 11 (2d Cir. 2017).

[15] *Jones v. Novartis Pharms. Corp.*, 720 F. App'x 1006, 1008 (11th Cir. 2018).

[16] *In re Lipitor Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 647 (4th Cir. 2018).

[17] *See, e.g.*, *Glenn v. B & R Plastics, Inc.*, No. 1:16-CV-00508-MWB, 2018 WL 3448212, at *9 (D. Idaho July 16, 2018) (courts have an "active role as a gatekeeper to prevent[ ] shoddy expert testimony and junk science from reaching the jury" (quotations omitted; alteration in original)).

Daubert. In *Canary v. Medtronic, Inc.*, No. 16-11742, 2018 WL 5921327 (E.D. Mich. Nov. 13, 2018), the plaintiff alleged that she suffered severe allergic reactions after being implanted with the defendant's spinal cord stimulator. The plaintiff did not retain any general or specific causation experts, and instead chose to rely on the causation opinion of her treating physician.[18] The physician testified that it was possible and plausible that the implant could have caused the allergic reaction, but did not otherwise conduct a differential diagnosis or testify to a reasonable degree of medical certainty.[19] The court allowed the physician's testimony, and did not consider the defendant's *Daubert* challenge because, in the Sixth Circuit, the "general rule . . . is that 'a treating physician may provide expert testimony regarding a patient's illness, the appropriate diagnosis for that illness, and the cause of that illness.'"[20] While true that a treating physician is permitted to opine on causation, "a treating physician's testimony remains subject to the requirement set forth in *Daubert* that an expert's opinion testimony must have a reliable basis in the knowledge and experience of his discipline."[21] Had the *Canary* court conducted a proper *Daubert* analysis, it should

[18] 2018 WL 5921327, at *2.

[19] *Id.* at *2–3.

[20] *Id.* at *5 (quoting *Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009)).

[21] *In re Aredia & Zometa Prod. Liab. Litig.*, No. 3:06-MD-1760, 2009 WL 2496921, at *1 (M.D. Tenn. Aug. 13, 2009) (citing *Gass*, 558 F.3d at 426).

have excluded the treating physician's expert testimony, because, at the very least, it was not stated to a reasonable degree of medical certainty.[22]

The decision in *In re Abilify (Aripiprazole) Products Liability Litigation*, 299 F. Supp. 3d 1291 (N.D. Fla. 2018), is another instance of a court ignoring the Supreme Court's *Daubert* gatekeeping mandate. In this MDL litigation, the plaintiffs allege that the defendant's atypical antipsychotic drug caused them to develop "impulsive and irrepressible urges to engage in certain harmful behaviors, including impulsive gambling, eating, shopping, and sex."[23] The defendants challenged the opinions of the plaintiffs' general causation experts because, among other things, the experts "failed to provide *reliable* scientific evidence demonstrating a statistically significant association between Abilify and impulsive behaviors," but the court nonetheless admitted the evidence.[24]

The court's analysis began by identifying the types of general causation evidence typically deemed valid under Eleventh Circuit precedent: "epidemiological studies, dose-response relationship, and background risk of disease."[25] The plaintiffs

[22] *See id.* at *3–4 ("Plaintiff has not carried her burden of showing that [the treating physician] is qualified to offer expert causation testimony," because he could not testify to a reasonable degree of medical certainty that the defendant's medications caused the alleged injury).

[23] *In re Abilify (Aripiprazole) Products Liability Litigation*, 299 F. Supp. 3d 1291, 1300 (N.D. Fla. 2018).

[24] *Id.* at 1304 (emphasis in original).

[25] *Id.* at 1306 (citing *Chapman v. Procter & Gamble Distributing, LLC*, 766 F.3d 1296, 1308 (11th Cir. 2014)).

did not have—as the court should have determined—valid epidemiological evidence, because the "epidemiological" study the experts relied upon was prepared by an ophthalmologist who had contacted plaintiffs' counsel for their input *before* he developed the research protocol for his study and considered as "adverse events" conditions the drug was designed to treat. The ophthalmologist further failed to obtain the study patients' medical records to determine how much of the defendant's drug they ingested, if any.[26]

The court allowed the plaintiffs to rely on such questionable evidence under a "weight of the evidence" approach.[27] While the court cited the Supreme Court's *Joiner* opinion,[28] had the court faithfully applied *Joiner* and *Daubert*, it would have come to a different conclusion. In *Joiner*, the Supreme Court affirmed a trial court opinion rejecting a "weight of the evidence" analysis as scientifically unacceptable. Like the experts in *In re Abilify*, the plaintiffs' expert in *Joiner* could not show "that any one study provided adequate support for their conclusions."[29] Instead, the plaintiffs' "weight of the evidence" was based upon the "substantial judgment on the part of the expert."[30] While exercising "substantial judgment" may be appropriate for a scientist

[26] *Id.* at 1317–25.

[27] *Id.* at 1311–12.

[28] *See, e.g.*, *id.* at 1310.

[29] 522 U.S. at 152–53.

[30] *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, 299 F. Supp. 3d at 1311.

postulating new theories or a regulatory agency setting exposure limits, establishing legal causation requires more.[31]

Certain courts have also taken a more relaxed view on the importance of statistical significance. Statistical significance eliminates chance results by measuring how likely it is that repeated data sets of similar size would yield similar outcomes. Statistical significance is inherent in the "known or potential rate of error" *Daubert* factor, and *Joiner* held that, without it, a "court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."[32] In 2017, however, the Third Circuit refused to establish a bright-line rule requiring statistical significance to prove causation in an MDL alleging that a prescription antidepressant caused birth defects.[33] The plaintiffs' experts did not rely upon statistically significant studies showing a causal association. Despite *Joiner*, the Third Circuit viewed statistical significance as not required in the *Daubert* reliability analysis and indicated that causation can be proven through a variety of means, including "weight of the evidence" (rejected in *Joiner*), the "Bradford Hill criteria," or a "differential diagnosis."[34] The court's *Daubert* inquiry thus focused not on the reliability of the

[31] *See, e.g.*, *Glastetter*, 252 F.3d at 991 (regulatory decisions are based on lesser, prophylactic causation standards than required in courts).

[32] 522 U.S. at 145–46.

[33] *In re Zoloft Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017).

[34] *Id.* at 795.

expert's opinion, but rather on whether the expert consistently applied the methodology he chose. Ultimately the court excluded the expert's methods as inconsistently applied under any of these approaches, but the opinion provides ways in which otherwise questionable expert evidence could be admitted despite the mandates in *Daubert* and its progeny.

Courts even have split on whether it is permissible under *Daubert* for an expert to rely on favorable data while ignoring contrary data, a process called "cherry-picking," even though the need for exclusion of such testimony should be obvious.[35] There are numerous other recent opinions highlighting how some courts and appellate circuits have not strictly applied *Daubert*, in favor of letting a jury decide whether an expert's testimony is credible.[36]

The Ninth Circuit provides the best illustration of the departure from *Daubert*'s gatekeeping requirements, constraining the courts within the Circuit on what evidence can be excluded. In *In re Roundup*, Ninth Circuit precedent compelled the trial court was required to admit a differential diagnosis that failed to rule out

[35] *Compare, e.g.*, *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 634 (4th Cir. 2018) ("Result-driven analysis, or *cherry-picking, undermines principles of the scientific method* and is a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion." (emphasis added)), *with, e.g.*, *Kim v. Crocs, Inc.*, No. CV 16-00460 JAO-KJM, 2019 WL 923879, at *8 (D. Haw. Feb. 25, 2019) ("any questions about the weight of this [expert] opinion [based on cherry-picked data] should be resolved by a jury").

[36] *E.g.*, *Adams v. Toyota Motor Corp.*, 867 F.3d 903, 916 (8th Cir. 2017) (affirming admission of expert testimony, reiterating the flexibility of the *Daubert* inquiry and emphasizing that defendant's concerns could all be addressed with "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof").

idiopathic causes of the alleged NHL.[37] In other words, the expert was permitted to say the defendant's product caused the injury, even though the expert could not exclude the fact that some people get cancer and there is no known cause of their cancer. The *In re Roundup* court had to admit this evidence because of Ninth Circuit precedent allowing "shaky" expert testimony that falls on the "'art' side of the spectrum."[38] In other circuits more closely following *Daubert*, an expert's failure to rule-out idiopathic causes in rendering a specific causation opinion would require the exclusion of that opinion.[39]

III. POTENTIAL SOLUTIONS TO BRING BACK STRICTER *DAUBERT* ANALYSES

Several reasons may explain the growing split within the federal judiciary's approach to *Daubert* and Rule 702. Less rigorous *Daubert* opinions could be the result of an improper understanding of the gatekeeping function. To that extent, the issue can be rectified through better advocacy. Defendants favoring sound science in the courtroom should encourage counsel to take the time to learn the science, to develop

[37] *In re Roundup Prod. Liab. Litig.*, 2019 WL 917058, at *2.

[38] *Id.*; *In re Roundup Prod. Liab. Litig.*, 2018 WL 3368534, at *2 ("the case law—particularly Ninth Circuit case law—emphasizes that a trial judge should not exclude an expert opinion merely because he thinks it's shaky . . . .").

[39] *Hall v. ConocoPhillips*, 248 F. Supp. 3d 1177, 1190–91 (W.D. Okla. 2017) (Excluding specific causation opinion, because the expert "did not consider 'idiopathic causes [for plaintiff's AML], additionally rendering his differential diagnosis unreliable. Although idiopathic or de novo is not a cause, per se, courts have repeatedly faulted experts for their failure to consider idiopathic or unknown causes for diseases when rendering their differential diagnoses." (citing *Milward v. Rust–Oleum Corp.*, 820 F.3d 469, 475–76 (1st Cir. 2016); *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1311 (11th Cir. 2014))), *aff'd sub nom. Hall v. Conoco Inc.*, 886 F.3d 1308 (10th Cir. 2018).

a detailed record exposing an expert's methodological flaws, and then to educate the judge about what a proper *Daubert* analysis entails.

Less strict views on *Daubert* may also reflect philosophical leanings against gatekeeping. If so, advocating not just in courts, but in a jurisdiction's legislative arena may be required. There are current discussions on amending Rule 702 to clarify the courts' obligations when conducting *Daubert* inquiries.[40] The Advisory Committee on the Federal Rules of Evidence can consider amendments to make clear how courts should conduct the required assessment of reliability, instead of courts viewing disputes over expert testimony as a question of weight rather than admissibility.[41]

Altering *Daubert* views at the state level may be more complicated. Progress has occurred, with a number of state legislatures adopting *Daubert*'s standards. *Daubert* has been adopted to varying degrees by 43 of the states, most recently by the District of Columbia in October 2016, Missouri in March 2017, New Jersey (to a degree) in August 2018, and Florida on May 23, 2019 following several battles between the state's legislature and supreme court.[42] Some of the remaining *Frye*

[40] *See* Lasker, *supra* n.3, *It is Time to Amend Federal Rule of Evidence 702*. Perhaps the more difficult question is why, at the federal level, amending Rule 702 is necessary. The existing Rule incorporates *Daubert*'s standards, as it has for almost 20 years. Pursuant to Federal Rule of Evidence 101, federal courts are supposed to follow that rule as well as the decisions of the Supreme Court interpreting the Rules of Evidence. As discussed above, however, that is not always the case.

[41] *See, e.g.*, *Liquid Dynamics Corp. v. Vaughan Corp.*, 449 F.3d 1209, 1221 (Fed. Cir. 2006) ("The identification of such flaws in generally reliable scientific evidence is precisely the role of cross-examination." (quotations omitted)).

[42] *See In re Amendments to Fla. Evidence Code*, No. SC19-107, 2019 WL 2219714, at *3 (Fla.

states, which have a historically "liberal" bent like California, may not be receptive to *Daubert*, which critics may view as part of the "conservative" agenda.

Sound science is neither conservative nor liberal. Advocates of *Daubert* and the admissibility of appropriate scientific evidence should thus continue to pursue requirements for such evidence in the appropriate legislative or judicial arenas.

May 23, 2019) ("in accordance with this Court's exclusive rule-making authority and longstanding practice of adopting provisions of the Florida Evidence Code as they are enacted or amended by the Legislature, we adopt the [*Daubert*] amendments"); *In re Accutane Litig.*, 234 N.J. 340, 399 (2018) ("In adopting use of the *Daubert* factors, we stop short of declaring ourselves a '*Daubert* jurisdiction.' Like several other states, we find the factors useful, but hesitate to embrace the full body of *Daubert* case law as applied by state and federal courts."); Michael Morgenstern, *Daubert v. Frye – A State-by-State Comparison*, The Expert Inst. (Apr. 3, 2017), https://www.theexpertinstitute.com/daubert-v-frye-a-state-by-state-comparison/.

Washington Legal Foundation
2009 Massachusetts Avenue, NW
Washington, DC 20036

May 6, 2020

Rebecca A. Womeldorf
Secretary
Committee on Rules of Practice and Procedure
Administrative Office of the United States Courts
One Columbus Circle, NE
Washington, D.C. 20544

Re: Amending Federal Rule of Evidence 702 to Clarify Courts' "Gatekeeping" Obligation

Dear Ms. Womeldorf:

Washington Legal Foundation (WLF) writes to share with you a just-published WLF Legal Studies Division publication that is relevant to the work of the Advisory Committee on Evidence Rules.

Gatekeeping Reorientation: A Rule 702 Amendment Can Correct Judicial Misunderstandings about Expert Evidence was written for WLF by Lee Mickus of Evans Fears & Schuttert LLP. The paper provides examples of court decisions in which the presiding judge or panel of judges misapplied Rule 702 in such a way that the decision reversed the burden of proof or allowed the jury to weigh the reliability and relevance of the expert evidence, a task that Rule 702 clearly assigns to the court. Mr. Mickus concludes that judicial intervention, in the form of circuit-court rulings or a U.S. Supreme Court decision, is unlikely, leaving the task of clarifying the requirements of Rule 702 in the hands of the Advisory Committee.

We encourage the Advisory Committee on Evidence Rules to take the information and analysis in this educational paper into consideration when weighing whether to formally amend Rule 702.

Thank you for your consideration.

Sincerely,

(b)(6) per EOUSA

Glenn G. Lammi
Chief Counsel, Legal Studies Division

Attachment

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
(b)(6) per EOUSA

Critical Legal Issues: WORKING PAPER SERIES

GATEKEEPING REORIENTATION:
AMEND RULE 702 TO CORRECT JUDICIAL MISUNDERSTANDING ABOUT EXPERT EVIDENCE

By

Lee Mickus
Evans Fears & Schuttert LLP

Washington Legal Foundation
Critical Legal Issues WORKING PAPER Series

Number 217
May 2020

TABLE OF CONTENTS

ABOUT OUR LEGAL STUDIES DIVISION

Since 1986, WLF's Legal Studies Division has served as the preeminent publisher of persuasive, expertly researched, and highly respected legal publications that explore cutting-edge and timely legal issues. These articles do more than inform the legal community and the public about issues vital to the fundamental rights of Americans—they are the very substance that tips the scales in favor of those rights. Legal Studies publications are marketed to an expansive audience, which includes judges, policymakers, government officials, the media, and other key legal audiences.

The Legal Studies Division focuses on matters related to the protection and advancement of economic liberty. Our publications tackle legal and policy questions implicating principles of free enterprise, individual and business civil liberties, limited government, and the rule of law.

WLF's publications target a select legal policy-making audience, with thousands of decision makers and top legal minds relying on our publications for analysis of timely issues. Our authors include the nation's most versed legal professionals, such as expert attorneys at major law firms, judges, law professors, business executives, and senior government officials who contribute on a strictly *pro bono* basis.

To receive information about WLF publications, or to obtain permission to republish this publication, please contact Glenn Lammi, Chief Counsel, Legal Studies Division, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, DC 20036, (b)(6) per EOUSA, (b)(6) per EOUSA.

ABOUT THE AUTHOR

Lee Mickus is a Partner in the Denver, CO office of Evans Fears & Schuttert LLP. He defends manufacturers and other business interests nationally in product liability and tort lawsuits. He has successfully tried cases to juries in jurisdictions across the country. Mr. Mickus works with a wide range of products and industries, including automobiles, pharmaceuticals, medical devices and recreational equipment. In his practice, Mr. Mickus often develops strategies for addressing expert testimony, including challenging the admissibility of expert opinions that fall short of the Rule 702 standard. Mr. Mickus is also active in rulemaking and legislative reform efforts. He has given presentations and submitted comments to the Advisory Committee on Civil Rules and has testified before several state legislatures on bills affecting a wide range of civil justice issues.

GATEKEEPING REORIENTATION:
A RULE 702 AMENDMENT CAN CORRECT JUDICIAL MISUNDERSTANDINGS ABOUT EXPERT EVIDENCE

Federal Rule of Evidence 702 needs attention. The language of the rule articulates courts' gatekeeping responsibilities and the extensive Committee Note explains the rule's elements and proper application, but courts nonetheless fail to carry out Rule 702's requirements.[1] Some courts discard the burden of production that Rule 702 places on an expert's proponent in favor of a "presumption of admissibility"[2] or an understanding that exclusion is "the exception rather than the rule."[3] Despite Rule 702's direction that the judge must determine if an expert's factual basis and application of methodology are reliable, some courts see such

[1] *See* Memorandum from Daniel J. Capra, Reporter, Advisory Comm. on Evidence Rules, to Advisory Comm. on Evidence Rules, *Forensic Evidence, Daubert and Rule 702* (Apr. 1, 2018) at 50 *in* ADVISORY COMMITTEE ON EVIDENCE RULES APRIL 2018 AGENDA BOOK 49 (2018), https://www.uscourts.gov/rules-policies/archives/agenda-books/advisory-committee-rules-evidence-april-2018:

> It does not appear to be a matter of vague language. The wayward courts simply don't follow the rule. They have a different, less stringent view of the gatekeeper function.

[2] *See*, *e.g.*, *Powell v. Schindler Elevator Corp.*, No. 3:14cv579 (WIG), 2015 WL 7720460, at *2 (D. Conn. Nov. 30, 2015)("The Second Circuit has made clear that *Daubert* contemplates liberal admissibility standards, and reinforces the idea that there should be a presumption of admissibility of evidence."); *Advanced Fiber Technologies (AFT) Trust v. J&L Fiber Services, Inc.*, No. 1:07-CV-1191, 2015 WL 1472015, at *20 (N.D.N.Y. Mar. 31, 2015)("In assuming this [gatekeeper] role, the Court applies a presumption of admissibility.").

[3] *See*, *e.g.*, *Wright v. Stern*, 450 F. Supp. 2d 335, 359–60 (S.D.N.Y. 2006)("Rejection of expert testimony, however, is still 'the exception rather than the rule,' Fed.R.Evid. 702 advisory committee's note (2000 Amendments)[.] . . . Thus, in a close case the testimony should be allowed for the jury's consideration.")(quotation omitted).

questions addressing merely the weight and not the admissibility of opinion testimony.[4] Some courts even go so far as to state that the Rule 702 gatekeeping responsibility exists to achieve a mission of only minimal significance:

- "The aim is to exclude expert testimony based merely on subjective belief or unsupported speculation."[5]
- "[T]he gatekeeping function is meant to 'screen the jury from unreliable nonsense opinions[.]'"[6]
- "Ultimately, a trial judge should exclude expert testimony if it is speculative or conjectural or based on assumptions that are so unrealistic and contradictory as to suggest bad faith or to be in essence an apples and oranges comparison."[7]
- "The expert's opinion thus should be excluded only when it is so fundamentally unreliable that it can offer no assistance to the jury."[8]

Rule 702 would hardly be necessary if it were intended to preclude only such deeply flawed and problematic testimony as these courts describe.

[4] *See*, *e.g.*, *Alvarez v. State Farm Lloyds*, No. SA-18-CV-01191-XR, 2020 WL 734482, at *3 (W.D. Tex. Feb. 13, 2020)("To the extent State Farm wishes to attack the 'bases and sources' of Dr. Hall's opinion, such questions affect the weight to be assigned to that opinion rather than its admissibility and should also be left for the jury's consideration.")(quotation omitted).

[5] *Imperial Trading Co. v. Travelers Prop. Cas. Co. of Am.*, No. CIV.A. 06-4262, 2009 WL 2356292, at *2 (E.D. La. July 28, 2009).

[6] *In re Viagra (Sildenafil Citrate) and Cialis (Tadalafil) Products Liability Litigation*, 424 F. Supp. 3d 781, 790 (N.D. Cal. 2020)(quoting *Alaska Rent-A-Car, Inc. v. Avis Budget Group, Inc.*, 738 F.3d 960, 969 (9th Cir. 2013)).

[7] *Hulett v. City of Syracuse*, 253 F. Supp. 3d 462, 507 (N.D.N.Y. 2017)(quotations omitted). *See also Berman v. Mobil Shipping & Trans. Co*., No. 14 CIV. 10025 (GBD), 2019 WL 1510941, at *9 (S.D.N.Y. Mar. 27, 2019)(similar statement).

[8] *Paul Beverage Co. v. American Bottling Co*., No. 4:17CV2672 JCH, 2019 WL 1044057, at *2 (E.D. Mo. Mar. 5, 2019). *See also Sandoe v. Boston Sci. Corp.*, 333 F.R.D. 4, 10 (D. Mass. 2019)("Expert testimony should be excluded only if it is so 'fundamentally unsupported that it can offer no assistance to the jury.'")(quotation omitted).

The 2000 amendments to Rule 702 sought to establish a uniform approach to scrutinizing the admissibility of proffered opinion testimony: "The trial judge in *all* cases of proffered expert testimony *must find* that it is properly grounded, well-reasoned, and not speculative *before* it can be admitted."[9] This critical goal of uniformity has gotten lost, and now courts operating in different circuits apply quite divergent standards. As one court recently recognized, for example, district judges in the Ninth Circuit "must account for the fact that a wider range of expert opinions (arguably much wider) will be admissible in this circuit."[10]

This WORKING PAPER will address how Rule 702 was intended to function, the misunderstandings courts have embraced that produce striking departures from this intent, and available avenues for clarifying the rule's requirements to restore substance and consistency to court applications of Rule 702. Section I discusses the Advisory Committee's proceedings in the period leading up to adoption of the 2000 amendments to Rule 702 and its recent activities considering possible amendments. Review of the Advisory Committee's work reveals that Rule 702 was intended to incorporate three key elements: (1) rigorous judicial scrutiny of the expert's methodology, factual basis, and application to the issues of the case undertaken before determining that the opinion testimony may be admitted; (2) a burden of

[9] Advisory Committee Note to 2000 Amendments to Rule 702 (emphasis added).

[10] *In re Roundup Products Liability Litigation*, 358 F. Supp. 2d 956, 960 (N.D. Cal. 2019).

production placed on the sponsor to establish admissibility of the opinion testimony; and (3) uniformity of approach in analyzing the admissibility of opinion testimony.[11]

Considering the intent motivating the 2000 amendment, Section II reviews current court practices to find that failures to comprehend Rule 702 have effectively re-written the rule in ways that significantly change the nature and rigor of the gatekeeping function. First, courts rely on outcome-oriented characterizations of the admissibility standard. These conceptions tilt the admissibility analysis and displace the sponsor's burden of establishing by a preponderance of the evidence that the opinion testimony is admissible. Also, courts misunderstand the rule's requirement that the court must assess an expert's factual basis and application of the methodology to the issues at hand. Instead, they hold that the rule makes those steps pertinent only to the weight of the opinion testimony which the jury alone must determine. Courts that include these common missteps in their admissibility analysis simply fail to understand the requirements of Rule 702.

With these patterns of Rule 702 departures in mind, Section III examines the need for reform to clarify its requirements in order to address these recognized

[11] The full name of the "Advisory Committee" is the Judicial Conference Advisory Committee on Evidence Rules. Its agenda books contain minutes of previous meetings, as well as memoranda prepared by the Reporter on topics of concern and other references and materials considered by the members. Additionally, the Advisory Committee has conducted conferences and symposia to address questions and issues about current practice and contemplated amendments. These materials provide considerable insight regarding the intent of Rule 702 and the extent to which courts have departed from the course charted by the Advisory Committee.

deviations from Rule 702 as the Advisory Committee intended the rule to be applied. The WORKING PAPER concludes that rulemaking is needed to overcome the influence of previous court mischaracterizations and ongoing misapprehensions of the expert admissibility standard.

I. THE ADVISORY COMMITTEE INTENDED RULE 702 TO ESTABLISH A UNIFORM STANDARD COURTS WOULD USE TO SCRUTINIZE AN EXPERT'S BASIS, METHODOLOGY, AND APPLICATION

The Advisory Committee intended Rule 702 in its current form to bring a consistent thoroughness to courts' assessment of opinion testimony. The Supreme Court's 1993 ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[12] had produced waves of disruption among the lower courts. Courts were initially unclear if the gatekeeping function applied broadly to all opinion testimony, or only to the narrow category of experts offering opinions about "scientific" knowledge.[13] More fundamentally, they disagreed about the depth of analysis that a court must undertake before concluding that opinion testimony could be admitted.[14]

[12] 509 U.S. 579 (1993).

[13] The Supreme Court in *Kumho Tire Co. v. Carmichael* resolved this issue, recognizing the incompatibility of decisions finding that *Daubert* does not reach "technical" or "other specialized" knowledge, such as *Compton v. Subaru of America, Inc.,* 82 F.3d 1513, 1518–19 (10th Cir.), *cert. denied*, 519 U.S. 1042 (1996), with cases holding that *Daubert* applies broadly to all expert testimony, as held by *Watkins v. Telsmith, Inc.,* 121 F.3d 984, 990–91 (5th Cir. 1997). *See Kumho Tire*, 526 U.S. 137, 147 (1999).

[14] *See* Draft Minutes of the Meeting of April 12-13, 1999, Advisory Comm. on Evidence Rules at 6, *in* ADVISORY COMMITTEE ON EVIDENCE RULES OCTOBER 1999 AGENDA BOOK 10 (1999), https://www.uscourts.gov/rules-policies/archives/agenda-books/advisory-committee-rules-evidence-october-1999 ("[T]here are a number of *Daubert* questions on which the courts disagree, including

The Advisory Committee on Evidence Rules recognized that courts had widely differing perspectives on *Daubert*'s requirements:

> Some courts approach *Daubert* as a rigorous exercise requiring the trial court to scrutinize in detail the expert's basis, methods, and application. Other courts hold that *Daubert* requires only that the trial court assure itself that the expert's opinion is something more than unfounded speculation.[15]

Confronting this cacophony, the Advisory Committee sought to reform Rule 702 so that it would both provide "a uniform structure for assessing expert testimony"[16] and establish a standard mandating courts to assess, as a matter of admissibility, opinion testimony's factual foundation, methodological underpinnings, and application to the issues in dispute.[17]

The Advisory Committee started from the position that the analytical

the appropriate standard of proof and the rigor with which expert testimony should be scrutinized."). *See also* May 1, 1998 Report of the Advisory Committee on Evidence Rules, *in* Preliminary Draft of Proposed Amendments to the Federal Rules of Civil Procedure and Evidence: Request for Comment, 181 F.R.D. 18, 132 (1998)(indicating that the proposed amendment to Rule 702 "attempts to address the conflict in the courts about the meaning of *Daubert*.").

[15] Hon. Fern M. Smith, Report of the Advisory Committee on Evidence Rules (May 1, 1999) at 7, *in* ADVISORY COMMITTEE ON EVIDENCE RULES OCTOBER 1999 AGENDA BOOK 52 (1999), https://www.uscourts.gov/rules-policies/archives/agenda-books/advisory-committee-rules-evidence-october-1999.

[16] Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 44 n.6.

[17] *See* May 1, 1998 Report of the Advisory Committee on Evidence Rules, *supra* n. 14, 181 F.R.D. at 131 ("The proposed amendment specifically extends the trial court's *Daubert* gatekeeping function to all expert testimony; requires a showing of reliable methodology and sufficient basis; and provides that the expert's methodology must be applied properly to the facts of the case.").

framework set forth by the U.S. Supreme Court should define the standard.[18] The complexity of the *Daubert* holding, however, posed difficulties for rulemaking. The Advisory Committee's Reporter, Professor Daniel J. Capra, has colorfully observed that the *Daubert* ruling can be seen as "a schizophrenic opinion."[19] On the one hand, *Daubert* directs trial courts to evaluate proffered expert opinions to ensure that they arise from a reliable methodology that is properly applied to the facts at issue.[20] On the other hand, the opinion stresses the value of cross-examination and the

[18] The Advisory Committee understood that it was empowered to alter the admissibility standard, but determined that it should not change from the direction taken in *Daubert* and clarified by the *Kumho Tire* ruling:

> Judge Shadur opened the discussion on Rule 702 by noting that in deciding how to amend the Rule, the Committee was not technically bound by the Supreme Court's interpretation of the existing Rule 702 in *Daubert* and in the recent case of *Kumho Tire v. Carmichael*. However, all members of the Committee were in agreement that the approach taken by the Supreme Court – an approach that is followed in the proposal issued for public comment – provided an excellent and definitive means of regulating unreliable expert testimony. There was unanimous agreement that if the Rule is to be amended, it should stick as closely as possible to the Supreme Court's teachings in *Daubert* and *Kumho*.

Draft Minutes of the Meeting of April 12-13, 1999, Advisory Comm. on Evidence Rules, *supra* n. 14, at 2.

[19] Daniel J. Capra, *Symposium on Forensic Expert Testimony,* Daubert*, and Rule 702*, 86 FORDHAM L. REV. 1463, 1528 (2018). *See also United States v. McCluskey*, 954 F. Supp. 2d 1224, 1254 (D.N.M. 2013)(observing that "the extent of the trial judge's gatekeeping function" is '[p]erhaps *Daubert's* most serious ambiguity.'")(quoting 29 Charles Alan Wright & Victor James Gold, *Federal Practice and Procedure* § 6266, at 287 (1997 & Supp.2012)).

[20] *See Daubert*, 509 at 592-93 (indicating that trial judges must make "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.").

adversarial process to drive the appropriate outcome of a trial.[21]

The key to reconciling these divergent strands of the *Daubert* holding is the recognition that cross-examination simply is not capable of safeguarding the trial process against the misleading influence of unreliable expert testimony.[22] Because the foundations of expert testimony lay beyond the experience and instincts of jurors, courts cannot expect them to recognize when opinions are formed from flawed methodological analysis or inadequate facts.[23] Accordingly, the judge must protect the integrity of trials by policing opinion testimony to ensure that unreliable analyses do not reach the jury. The Advisory Committee sought to produce a rule that

[21] *Id*. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

[22] *See* Minutes of the Meeting of May 3, 2019, Advisory Comm. on Evidence Rules at 23, *in* ADVISORY COMMITTEE ON EVIDENCE RULES OCTOBER 2019 AGENDA BOOK 73 (2019), https://www.uscourts.gov/rules-policies/archives/agenda-books/advisory-committee-rules-evidence-october-2019**:**

> The key to *Daubert* is that cross-examination alone is ineffective in revealing nuanced defects in expert opinion testimony and that the trial judge must act as a gatekeeper to ensure that unreliable opinions don't get to the jury in the first place.

[23] *See* Memorandum from Daniel J. Capra, Reporter, Advisory Comm. on Evidence Rules, to Advisory Comm. on Evidence Rules, *Possible Amendment to Rule 702* (Oct. 1, 2019) at 11 *in* ADVISORY COMMITTEE ON EVIDENCE RULES OCTOBER 2019 AGENDA BOOK 131 (2019), https://www.uscourts.gov/rules-policies/archives/agenda-books/advisory-committee-rules-evidence-october-2019:

> The premise [in *Daubert*] is that cross-examination cannot undo the damage that has been done by the expert who has power over the jury. This is because, for the very reason that an expert is needed (because lay jurors need assistance) the jury may well be unable to figure out whether the expert is providing real information or junk.

remained true to the expert admissibility standard the Supreme Court had articulated, and so it incorporated this distillation of the *Daubert* holding into Rule 702.[24]

The Advisory Committee understood that the expert admissibility standard it set forth in amended Rule 702 "clearly envision[s] a more rigorous and structured approach than some courts are currently employing."[25] Displacing softer interpretations of the admissibility standard that depend on jurors to identify and reject unreliable opinion testimony was an intended result of amending Rule 702, as the Advisory Committee sought to produce "uniformity in the *approach* to *Daubert* questions."[26] The pre-amendment perspectives and practices of some courts would therefore need to change in order to meet the directives of amended Rule 702.

The Advisory Committee used the Committee Note as well as the language of the rule itself to convey to courts that they must scrutinize expert opinions in a manner consistent with the amended rule's scope before allowing presentation of the

[24] Draft Minutes of the Meeting of April 12-13, 1999, Advisory Comm. on Evidence Rules, *supra* n. 14, at 2. ("There was unanimous agreement that [the amendment to Rule 702] should stick as closely as possible to the Supreme Court's teachings in *Daubert* and *Kumho*."). *See also* Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 42 n.5 ("the amendment was intended to codify and expand upon, not depart from, *Daubert*."). After the Advisory Committee had begun its rulemaking efforts, the Supreme Court issued its *Kumho Tire* holding. The Advisory Committee found that ruling to be in line with the Committee's understanding of the standard previously articulated by the Court and the approach taken in the Committee's existing proposals for modifying the rule. *See* Draft Minutes of the Meeting of April 12-13, 1999, Advisory Comm. on Evidence Rules, *supra* n. 14, at 8 ("The sense of the Committee was that the analysis in *Kumho* is completely consistent with and supportive of, the approach taken in the proposed amendment and Committee Note[.]").

[25] May 1, 1999 Report of the Advisory Committee on Evidence Rules, *supra* n. 15, at 7 (emphasis original).

[26] *Id*.

testimony to a jury.[27] Issuing the lengthy Committee Note itself has been described as a "goal" of the rulemaking process.[28] The extensive Note was meant to be a resource that would

> provide substantial and detailed guidance into the meaning of *Daubert* and its progeny; that would instruct on how to use the *Daubert* factors; and that would assist courts and litigants in determining which questions about experts would go to weight and which to admissibility.[29]

Considering the weight that the Advisory Committee attached to the Committee Note as an authority articulating the proper understanding of Rule 702, its contents warrant considerable attention.

The Committee Note discusses the critical elements of Rule 702. First, the proponent of the opinion testimony "has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence."[30] That burden specifically includes showing that the expert employed a reliable methodology, based each opinion on sufficient facts or data, and applied the

[27] *Id.* (identifying the Committee Note along with the amended rule as collectively signaling "a more rigorous and structured approach than some courts are currently employing" and that were expected "to provide uniformity" in the manner in which courts approached admissibility challenges). *See also* May 1, 1998 Report of the Advisory Committee on Evidence Rules, *supra* n. 14, 181 F.R.D. at 131 ("The Committee has prepared an extensive Committee Note that will provide guidance for courts and litigants in determining whether expert testimony is sufficiently reliable to be admissible.").

[28] Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 42 n.5. Professor Capra has explained that "[b]ecause a Committee Note cannot be freestanding, an amendment was necessary[.]"

[29] *Id*.

[30] Advisory Committee Note to 2000 Amendments to Rule 702.

methodology to the facts of the case in a reliable way.[31] Put another way, the sponsor must satisfy the court that *all steps* employed in the development of the expert's opinions are sound.[32] In evaluating these underpinnings of the opinion testimony, the reviewing court must apply "exacting"[33] scrutiny. As Justice Scalia observed in his *Kumho Tire* concurring opinion, trial courts do not have the discretion "to perform the [gatekeeping] function inadequately."[34] Notably, the barometer initially suggested in the Advisory Committee's 1998 draft Committee Note—that in testifying an expert must adhere to the same standards of intellectual rigor demanded in the expert's

[31] *See* May 1, 1999 Report of the Advisory Committee on Evidence Rules, *supra* n. 15, at 5 ("The proposed amendment to Evidence Rule 702 . . . requires a showing of reliable methodology and sufficient basis, and provides that the expert's methodology must be applied properly to the facts of the case."). *See also* Memorandum from Daniel J. Capra, Reporter, Advisory Comm. on Evidence Rules, to Advisory Comm. on Evidence Rules, *Possible Amendments to Rule 702* (Apr. 1, 2019) at 23 *in* ADVISORY COMMITTEE ON EVIDENCE RULES MAY 2019 AGENDA BOOK 95 (2019), https://www.uscourts.gov/rules-policies/archives/meeting-minutes/advisory-committee-rules-evidence-may-2019 ("The Rule provides that the requirements of sufficient basis and reliable application must be treated as questions of admissibility, and so must be established by a preponderance of the evidence under Rule 104(a)."); Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 43 ("In sum, the 2000 amendment specifies that sufficient basis and application of method are admissibility requirements – the judge must be satisfied by a preponderance of the evidence that the expert has relied on sufficient facts or data, and that the expert has reliably applied the methods.").

[32] *See* Advisory Committee Note to 2000 Amendments ("As the court noted in *In re Paoli R.R. Yard PCB Litig*., 35 F.3d 717, 745 (3d Cir. 1994), '*any* step that renders the analysis unreliable . . . renders the expert's testimony inadmissible. *This is true whether the step completely changes a reliable methodology or merely misapplies that methodology*.'")(emphasis original).

[33] *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000)("Since *Daubert,* moreover, parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet."). *See also* Advisory Committee Note to 2000 Amendments to Rule 702 ("The amendment specifically provides that the trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case."). Of course, the content of Rule 702 itself also directs that each of these three requirements must be established. *See* Fed. R. Evid. 702(b)-(d).

[34] *Kumho Tire*, 526 U.S. at 159 (Scalia, J., concurring).

professional field—was adopted in the Supreme Court's *Kumho Tire* holding.[35]

Critically, these reliability components are admissibility questions that the court must decide, not credibility issues for the jury to weigh:[36]

> It is not the case that the judge can say, 'I see the problems, but they go to the weight of the evidence.' After a *preponderance* is found, then any slight defect in either of these factors becomes a question of weight. But not before.[37]

Thus, only *after* the sponsor has demonstrated that the expert satisfies all Rule 702 requirements may the court defer to the jury regarding the expert's basis, application, or method.

Finally, *all* opinion testimony must receive scrutiny. Rule 702 "specifically extends the trial court's *Daubert* gatekeeping function to all expert testimony[.]"[38] The jury should only hear opinions that have been fully considered and determined meet Rule 702's admissibility requirements.

[35] May 1, 1999 Report of the Advisory Committee on Evidence Rules, *supra* n.15, at 6 ("The Court in *Kumho* emphasized the same overriding standard as that set forth in the Committee Note to the proposed amendment, i.e., that an expert must employ the same degree of intellectual rigor in testifying as he would be expected to employ in his professional life"). *See also Kumho Tire*, 526 U.S. at 152 ("The objective of [the gatekeeping] requirement . . . is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."); Preliminary Draft of Proposed Amendments to the Federal Rules of Civil Procedure and Evidence: Request for Comment, 181 F.R.D. at 147.

[36] *Id*. *See also* Oct. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.23, at 1 (Rule 702 "already establishes that the reliability requirements are questions for the court, to be decided by a preponderance of the evidence.").

[37] Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 43 (emphasis original).

[38] May 1, 1999 Report of the Advisory Committee on Evidence Rules, *supra* n. 15, at 7.

II. COURTS HAVE RE-WRITTEN THE EXPERT ADMISSIBILITY STANDARD IN WAYS THAT EVADE THE INTENT OF RULE 702

During the twenty years that have passed since the 2000 amendment, courts have departed so substantially from Rule 702's intended approach for evaluating the admissibility of opinion testimony that today's court assessments often bear little resemblance to the analytical process described by the Committee Note. Patterns have emerged in which trial courts consider proffered expert testimony in ways that negate critical aspects of Rule 702. These include ignoring the sponsor's burden of establishing admissibility and deferring to the jury determinations that the court must make. These departures from the analytical approach directed by Rule 702 and the Committee Note create confusion about the admissibility standard, undermine the goal of uniformity, and expose juries to the misleading influence of unreliable opinion testimony that should not have been admitted.

A. Many Courts Read Rule 702 to Presume Admissibility Rather than to Require the Proponent to Satisfy the Burden of Production

Some courts overlay the Rule 702 analysis with outcome-focused characterizations that turn the standard upside-down. Although the Committee Note declares that an expert's proponent bears the burden of demonstrating that the

admissibility requirements are met,[39] courts have decided that the rule includes a "presumption of admissibility."[40] In certain instances, this mistaken presumption has even been juxtaposed against a recitation of Rule 702's burden of production, with no apparent recognition of these statements' incompatibility. For example:

> The party seeking to introduce the expert testimony bears the burden of establishing by a preponderance of the evidence that the proffered testimony is admissible. There is a presumption that expert testimony is admissible[.][41]

This notion that courts should place a thumb on the scale in favor of admitting expert testimony seems to stem from a misinterpretation of the *Daubert* holding that pre-dates the 2000 amendment to Rule 702, but which courts continue to cite.[42]

[39] In addition to the Committee Note, *see supra* n. 30, the Supreme Court has indicated that the proponent of evidence bears the burden of establishing its admissibility under Rule 104(a). *See Bourjaily v. United States*, 483 U.S. 171, 175-76 (1987).

[40] *See*, *e.g.*, *Price v. General Motors, LLC*, No. CIV-17-156-R, 2018 WL 8333415, at *1 (W.D. Okla. Oct. 3, 2018)("[T]here is a presumption under the Rules that expert testimony is admissible.")(quotation omitted); *Powell*, 2015 WL 7720460, at *2 ("The Second Circuit has made clear that *Daubert* contemplates liberal admissibility standards, and reinforces the idea that there should be a presumption of admissibility of evidence that there should be a presumption of admissibility of evidence."); *AFT Trust*, 2015 WL 1472015, at *20 ("In assuming this [gatekeeper] role, the Court applies a presumption of admissibility."); *Crawford v. Franklin Credit Mgt. Corp.,* 08-CV-6293 (KMW), 2015 WL 13703301, at *2 (S.D.N.Y. Jan. 22, 2015)("[T]he court should apply 'a presumption of admissibility' of evidence" in carrying out the gatekeeper function.); *Martinez v. Porta*, 598 F. Supp. 2d 807, 812 (N.D. Tex. 2009)("Expert testimony is presumed admissible").

[41] *S.E.C. v. Yorkville Advisors, LLC*, 305 F. Supp. 3d 486, 503-04 (S.D.N.Y. 2018). *See also Cates v. Trustees of Columbia Univ. in City of New York*, No. 16CIV6524GBDSDA, 2020 WL 1528124, at *6 (S.D.N.Y. Mar. 30, 2020)(similar statement).

[42] The source usually identified as the origin for this problematic characterization is a decision from the Second Circuit, *Borawick v. Shay*, 68 F.3d 597, 610 (2d Cir. 1995), *cert. denied*, 517 U.S. 1229 (1996). *See*, *e.g.*, *Yorkville Advisors, LLC*, 305 F. Supp. 3d at 503-04; *Powell*, 2015 WL 7720460, at *2. The *Borawick* decision explicitly states it did not address a challenge to the reliability of expert testimony offered. *Borawick*, 68 F.3d at 610 ("We do not believe that *Daubert* is directly applicable to the issue here"). Nonetheless, the opinion in *dicta* offered the view that, "by loosening the strictures

A second misunderstanding that courts frequently raise to tip the balance in the direction of admitting opinion testimony arises from a line in the Committee Note stating that "the rejection of expert testimony is the exception rather than the rule."[43] Some courts imagine this statement to indicate that admission of opinion testimony is Rule 702's preferred outcome:

> Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility. Fed. R. Evid. 702 Advisory Committee's Notes ('[A] review of the case law ... shows that rejection of the expert testimony is the exception rather than the rule.')[.][44]

When read in context, however, this statement in the Committee Note is simply an empirical observation that, during the first few years following publication of the *Daubert* ruling, courts did not exclude opinion testimony with great regularity.[45] The Committee Note's statement is descriptive, not normative, and does not authorize or encourage courts to admit opinion testimony without confirming that the evidence

on scientific evidence set by *Frye* [*v. United States*, 293 F. 1013 (D.C.Cir.1923)], *Daubert* reinforces the idea that there should be a presumption of admissibility of evidence." *Id*.

[43] Advisory Committee Note to 2000 Amendments to Rule 702.

[44] *In re E. I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, No. 2:18-CV-00136, 2019 WL 6894069, at *2 (S.D. Ohio Dec. 18, 2019). *See also*, *e.g.*, *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 530 (6th Cir. 2008)("'[R]ejection of expert testimony is the exception, rather than the rule,' and we will generally permit testimony based on allegedly erroneous facts when there is some support for those facts in the record.")(quoting Advisory Committee Note to 2000 Amendments to Rule 702); *Wright*, 450 F. Supp. 2d at 359–60 ("Rejection of expert testimony, however, is still 'the exception rather than the rule,' Fed.R.Evid. 702 advisory committee's note (2000 Amendments)[.] . . . Thus, in a close case the testimony should be allowed for the jury's consideration.")(quotation omitted).

[45] The complete sentence reads as follows: "A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule." Advisory Committee Note to 2000 Amendments to Rule 702.

satisfies the requirements of Rule 702.

Another outcome-oriented characterization is based on the impression that Rule 702 embodies a "liberal standard," at least in comparison to the *Frye* test discarded by the *Daubert* Court. Some courts bootstrap this perspective of the rule into a policy favoring admissibility: "Since Rule 702 embodies a liberal standard of admissibility for expert opinions, the assumption the court starts with is that a well-qualified expert's testimony is admissible."[46] Similarly, in an approach akin to sandlot baseball's rule that a "tie goes to the runner," some courts read the rule to favor admission when a court's evaluation of opinion testimony seemingly presents a "close call" under Rule 702.[47]

Rulings that view Rule 702 as preferring admission of opinion testimony over exclusion present several serious inconsistencies with the rule's intended application.

[46] *In re Zyprexa Prod. Liab. Litig.*, 489 F. Supp. 2d 230, 282 (E.D.N.Y. 2007). *See also In re ResCap Liquidating Tr. Litig.*, No. 13-CV-3451 (SRN/HB), 2020 WL 209790, at *3 (D. Minn. Jan. 14, 2020)("Courts generally support an attempt to liberalize the rules governing the admission of expert testimony, and favor admissibility over exclusion.")(quotation omitted); *Collie v. Wal-Mart Stores E., L.P.*, No. 1:16-CV-227, 2017 WL 2264351, at *1 (M.D. Pa. May 24, 2017)("Rule 702 embraces a 'liberal policy of admissibility,' under which it is preferable to admit any evidence that may assist the factfinder[.]"); *Billone v. Sulzer Orthopedics, Inc.*, No. 99-CV-6132, 2005 WL 2044554, at *3 (W.D.N.Y. Aug. 25, 2005)("[T]he Supreme Court has emphasized the 'liberal thrust' of Rule 702, favoring the admissibility of expert testimony.").

[47] *See*, *e.g.*, *United States v. Ameren Missouri*, No. 4:11 CV 77 RWS, 2019 WL 1384580, at *3 (E.D. Mo. Mar. 27, 2019); *Holloway v. Winkler, Inc.*, No. 4:17CV2208 RLW, 2019 WL 330872, at *3 (E.D. Mo. Jan. 25, 2019); *Conner v. W W Indus. Corp.*, No. 4:16-CV-1539 RLW, 2018 WL 2744978, at *4 (E.D. Mo. June 7, 2018). Rulings that apply this "close case" presumption of admissibility usually cite to *Lauzon v. Senco Prod., Inc.*, 270 F.3d 681, 695 (8th Cir. 2001), in which the court declared that "[i]t is far better where, in the mind of the district court, there exists a close case on relevancy of the expert testimony in light of the plaintiff's testimony to allow the expert opinion and if the court remains unconvinced, allow the jury to pass on the evidence."

First, these cases invert the burden of production that Rule 702 places on the sponsor of the opinion testimony.[48] Decisions applying the view that "exclusion is disfavored" fail to hold the proponent responsible for establishing by a preponderance of the evidence that the expert's analysis meets all the Rule 702 requirements.[49] Courts reading Rule 702 to presume admissibility thus misunderstand the very essence of Rule 702: unless an expert's analysis is shown to relay actual scientific or other knowledge, the court must exclude it.[50] Next, courts that presume the admissibility of

[48] *See*, *e.g.*, *Frankenmuth Mut. Ins. Co. v. Ohio Edison Co.*, No. 5:17CV2013, 2018 WL 9870044, at *2 (N.D. Ohio Oct. 9, 2018)(quoting Advisory Committee Note to 2000 Amendments to Rule 702 that "rejection of expert testimony is the exception, rather than the rule" and concluding "[a]lthough it is a very close call, the Court declines to exclude Churchwell's expert opinions under Rule 702."); *Crawford*, 2015 WL 13703301, at *6 ("In light of the 'presumption of admissibility of evidence,' that opportunity [for cross-examination] is sufficient to ensure that the jury receives testimony that is both relevant and reliable.")(quoting *Borawick*, 68 F.3d at 610).

[49] *See*, *e.g.*, *Orion Drilling Co., LLC v. EQT Prod. Co.,* No. CV 16-1516, 2019 WL 4273861, at *34 (W.D. Pa. Sept. 10, 2019)(after declaring that "[e]xclusion is disfavored" under Rule 702, the court flipped the burden of production and declared the opinion testimony admissible, stating "Orion has not established that incorporation of the data renders Ray's opinion unreliable."). *See also Citizens State Bank v. Leslie*, No. 6-18-CV-00237-ADA, 2020 WL 1065723, at *4 (W.D. Tex. Mar. 5, 2020)(rejecting challenge that opinion was "not based on sufficient facts" without assessing the expert's factual basis after stating "the rejection of expert testimony is the exception rather than the rule."); *Mason v. CVS Health*, 384 F. Supp. 3d 882, 891 (S.D. Ohio 2019)("Any doubts regarding the admissibility of an expert's testimony should be resolved in favor of admissibility.").

[50] For example, in *Rovid v. Graco Children's Prod. Inc.*, No. 17-CV-01506-PJH, 2018 WL 5906075, at *13 (N.D. Cal. Nov. 9, 2018), *appeal dismissed*, No. 19-15033, 2019 WL 1522786 (9th Cir. Mar. 7, 2019), the court demonstrated how the burden of establishing admissibility should operate to exclude opinion testimony when the court cannot ascertain if the expert's methodology, basis and application are reliable:

> Because Tres' report is devoid of, *inter alia*, his findings and his methodology, the court cannot determine whether his testimony reflects scientific knowledge or whether it is the product of 'good science.' Similarly, because Tres makes no attempt to tie his general background to the facts of this action or to any relevant issue in this action, the court cannot determine whether his testimony is 'relevant

expert testimony rely too heavily on the power of cross-examination to convince jurors of the defects present in unreliable testimony.[51] As discussed above, *Daubert* and Rule 702 direct trial judges to scrutinize proffered opinion testimony for reliability precisely *because* "cross-examination alone is ineffective in revealing nuanced defects in expert opinion testimony" and the jury needs protection against the misleading influence of dubious opinion evidence addressing complicated or unfamiliar subjects.[52] Finally, use of an outcome-oriented Rule 702 characterization inaccurately suggests that courts can reach a proper assessment of a particular expert's testimony without undertaking the analysis Rule 702 directs. Rule 702 allows no short cuts.[53]

> to the task at hand,' as required by the second part of the *Daubert* analysis. *Id*. at 597. Accordingly, Tres must be excluded under Rule 702 and *Daubert*.

[51] *See*, *e.g*., *Powell*, 2015 WL 7720460, at *2 ("To the extent Defendant argues that Mr. McPartland's conclusions are unreliable, it may attack his report through cross examination."); *Wright*, 450 F. Supp. 2d at 360 ("In a close case, a court should permit the testimony to be presented at trial, where it can be tested by cross-examination and measured against the other evidence in the case.")(quotation omitted).

[52] Minutes of the Meeting of May 3, 2019, Advisory Comm. on Evidence Rules, *supra* n. 22, at 23.

[53] *See* Advisory Committee Note to 2000 Amendments to Rule 702:

> Under the amendment, as under *Daubert*, when an expert purports to apply principles and methods in accordance with professional standards, and yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied. The amendment specifically provides that the trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case. (citation omitted).

B. Treating an Expert's Basis and Application as Credibility Considerations for the Jury, rather than Admissibility Questions for the Court, Shows Deep Confusion about the Requirements of Rule 702

Despite the explicit directives of Rule 702(b)[54] and Rule 702(d)[55] that the court must rule on the sufficiency of the expert's basis and the reliability with which the expert has applied the methodology to the matters at issue, many courts misunderstand such challenges as bearing only on the weight of the testimony.[56] These rulings fail to fulfill the courts' Rule 702 gatekeeping responsibilities and place demands on jurors that they are ill-equipped to manage.[57]

The recent case law is full of courts' incorrect statements that questions concerning the sufficiency of an expert's factual basis bear only on the weight to be afforded the testimony.[58] Examples of such misreadings of the rule include:

[54] Rule 702(b) requires consideration of whether "the testimony is based on sufficient facts or data[.]"

[55] Rule 702(d) directs determination if "the expert has reliably applied the principles and methods to the facts of the case."

[56] *See*, *e.g.*, *United States v. Hodge*, 933 F.3d 468, 478 (5th Cir. 2019)("As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration."); *Katzenmeier v. Blackpowder Prods., Inc.*, 628 F.3d 948, 952 (8th Cir. 2010)("As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination.").

[57] *See* Minutes of the Meeting of May 3, 2019, Advisory Comm. on Evidence Rules, *supra* n. 22, at 23. *See also United States v. Glynn*, 578 F. Supp. 2d 567, 574 (S.D.N.Y. 2008)("[T]he explicit premise of *Daubert* and *Kumho Tire* is that, when it comes to expert testimony, cross-examination is inherently handicapped by the jury's own lack of background knowledge."), quoted in Oct. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.23, at 11.

[58] *See* Apr. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.31, at 23 (indicating that broad statements such as such as "challenges to the sufficiency of an expert's basis raise

- "As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility."[59]

- "More fundamentally, each of these arguments goes to the factual basis of the report, . . . , and it is well settled that the factual basis for an expert opinion generally goes to weight, not admissibility."[60]

- "[T]he court will not exclude expert testimony merely because the factual bases for an expert's opinion are weak."[61]

- "[W]hen the adequacy of the foundation for the expert testimony is at issue, the law favors vigorous cross-examination over exclusion."[62]

Courts have similarly dismissed challenges to the reliability of an expert's application of his or her methodology to the issues at hand:

- "[O]bjections [that the expert could not link her experienced-based methodology to her conclusions] are better left for cross examination, not a basis for exclusion."[63]

questions of weight and not admissibility" are "misstatement[s] made by circuit courts in a disturbing number of cases[.]").

[59] *Puga v. RCX Sols., Inc.*, 922 F.3d 285, 294 (5th Cir. 2019).

[60] *Patenaude v. Dick's Sporting Goods, Inc.*, No. 9:18-CV-3151-RMG, 2019 WL 5288077, at *2 (D.S.C. Oct. 18, 2019).

[61] *Wischermann Partners, Inc. v. Nashville Hosp. Capital LLC*, No. 3:17-CV-00849, 2019 WL 3802121, at *1 (M.D. Tenn. Aug. 13, 2019)(quotation omitted). *See also id*. at *3 ("[A]rguments that Pinkowski's opinions are unreliable because he failed to review other relevant information and ignored certain facts bear on the factual basis for Pinkowski's opinions, and, therefore, go to the weight, rather than the admissibility, of Pinkowski's testimony.").

[62] *Carmichael v. Verso Paper, LLC*, 679 F. Supp. 2d 109, 119 (D. Me. 2010). Numerous additional examples of courts dismissing Rule 702(b) challenges as fodder only for cross-examination are described in the Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 44-45.

[63] *AmGuard Ins. Co. v. Lone Star Legal Aid*, No. CV H-18-2139, 2020 WL 60247, at *8 (S.D. Tex. Jan. 6, 2020).

- "Concerns surrounding the proper application of the methodology typically go to the weight and not admissibility[.]"[64]

Broad assertions such as these do not simply reject the particular challenges to a specific expert, but rather project a deep misunderstanding of Rule 702 and the primary role it intends for the court to play in evaluating an expert's factual basis and application. The fact that some courts "routinely state the misguided notion that arguments about sufficiency of basis and reliability of application almost always go to weight and not admissibility"[65] indicates a failure in the content of the rule to communicate the judge's intended role.

Under Rule 702, criticisms of an expert's basis and application may eventually become credibility considerations for the jury to weigh, but only *after* the court first concludes that the proponent of the testimony has established by a preponderance of the evidence that the Rule 702(b) and 702(d) standards are met.[66] Courts that dismiss attacks on an expert's factual basis and application as addressing only the weight of

[64] *Murphy-Sims v. Owners Ins. Co.*, No. 16-CV-0759-CMA-MLC, 2018 WL 8838811, at *7 (D. Colo. Feb. 27, 2018). Additional cases taking a similar view are discussed in the Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 45-46. Such rulings present a sharp contrast to the instruction set forth in the Advisory Committee Note to 2000 Amendments to Rule 702: "*any* step that renders the analysis unreliable . . . renders the expert's testimony inadmissible. *This is true whether the step completely changes a reliable methodology or merely misapplies that methodology*.")(quoting *In re Paoli R.R. Yard PCB Litig*., 35 F.3d 717, 745 (3d Cir. 1994))(emphasis original).

[65] Oct. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.23, at 30.

[66] *See supra* n.38. *See also* Apr. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.31, at 23 (noting that the expert's factual basis and application of methodology can be credibility considerations, but only after the court has found that the opinion testimony meets the Rule 702 burden of establishing admissibility by a preponderance of the evidence.).

the testimony therefore leave out a necessary step in the analysis. Rule 702 directs that the court must *first* decide whether the expert has been shown by a preponderance of the evidence to have employed a sufficient factual basis, used a reliable methodology, and reliably applied that methodology to the issues in dispute.[67]

Rejecting challenges to an expert's basis and application as bearing only on the weight of the evidence effectively casts the jury in the role of gatekeeper. Once the court determines it will not assess the factual basis and application underlying the opinions before they are presented at trial,[68] the jury must consider the testimony and decide whether to accept or reject the expert's conclusion.[69] Doing so ignores the central premise of Rule 702, namely that jurors are not capable of adequately performing that function:

> The whole point of Rule 702 – and the *Daubert*-Rule 104(a) gatekeeping function – is that these issues *cannot* be left to cross-examination. The underpinning of *Daubert* is that an expert's opinion could be unreliable and the jury could not figure that out, even given cross-examination and

[67] *See*, *e.g.*, *Alsadi v. Intel Corp.*, No. CV-16-03738-PHX-DGC, 2019 WL 4849482, at *4 -*5 (D. Ariz. Sept. 30, 2019)(Excluding opinion testimony because "Plaintiffs have not shown by a preponderance of the evidence that Dr. Garcia's causation opinions are based on sufficient facts or data to which reliable principles and methods have been applied reliably" and noting that these issues reflect "conditions for admissibility" and not credibility considerations). Judge David G. Campbell, author of the *Alsadi* ruling, chairs the Standing Committee on Rules of Practice and Procedure and has participated in the Advisory Committee's discussions of Rule 702 and the intent for its operation. *See*, *e.g.*, 86 FORDHAM L. REV., *supra* n.19, at 1464.

[68] *See*, *e.g.*, *Citizens State Bank*, 2020 WL 1065723, at *4.

[69] *See Nease v. Ford Motor Co*., 848 F.3d 219, 231 (4th Cir. 2017)("For the district court to conclude that Ford's reliability arguments simply 'go to the weight the jury should afford Mr. Sero's testimony' is to delegate the court's gatekeeping responsibility to the jury.").

> argument, because the jurors are deferent to a qualified expert (i.e., the white lab coat effect).[70]

Based on this conclusion that jurors lack the capability to recognize inadequate expert practices, Rule 702 extends courts' gatekeeping responsibility to all aspects of the expert's analysis and directs courts to assess the expert's factual basis and application to the issues in the case, as well as the expert's methodology.[71] This position is not an Advisory Committee invention, but stems directly from the Supreme Court's holdings.[72] In fact, the opinion testimony at issue in *Kumho Tire* was excluded because of insufficiencies in that expert's factual basis and the application of his methodology to the specific issues in that case.[73]

[70] Oct. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.23, at 11 (emphasis original).

[71] Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 50 ("The same 'white lab coat' problem – that the jury will not be able to figure out the expert's missteps – would seem to apply equally to basis, methodology and application.").

[72] *See* Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 49:

> [T]here are a number of lower court decisions that do not comply with Rule 702(b) or (d). . . . [S]ome courts have defied the Rule's requirements – which stem from *Daubert* – that the sufficiency of an expert's basis and the application of methodology are both admissibility questions requiring a showing to the court by a preponderance of the evidence.

[73] *See Kumho Tire*, 526 U.S. at 153-54:

> [T]he specific issue before the court was not the reasonableness *in general* of a tire expert's use of a visual and tactile inspection to determine whether overdeflection had caused the tire's tread to separate from its steel-belted carcass. Rather, it was the reasonableness of using such an approach, along with Carlson's particular method of analyzing the data thereby obtained, to draw a

Courts that mistakenly believe Rule 702 identifies an expert's factual basis or the application of methodology as matters of weight, not admissibility, are carrying forward pre-*Daubert* approaches to opinion testimony that amended Rule 702 should have displaced. To take just one example, courts frequently reiterate the following statement as consistent with Rule 702: "As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration."[74] This passage actually originates in a case decided in 1987, six years before *Daubert* was handed down, and so cannot possibly reflect the Rule 702 admissibility standard.[75] Citations to such anachronisms show that at least some courts fail to appreciate that Rule 702 has expanded the courts' gatekeeping considerations beyond what many courts employed before *Daubert*.[76] Courts that rely on these outdated statements of

> conclusion regarding *the particular matter to which the expert testimony was directly relevant.* That matter concerned the likelihood that a defect in the tire at issue caused its tread to separate from its carcass. The tire in question, the expert conceded, had traveled far enough so that some of the tread had been worn bald; it should have been taken out of service; it had been repaired (inadequately) for punctures; and it bore some of the very marks that the expert said indicated, not a defect, but abuse through overdeflection. The relevant issue was whether the expert could reliably determine the cause of *this* tire's separation. (emphasis original; citation omitted).

[74] *See*, *e.g., MCI Communications Service Inc. v. KC Trucking & Equip. LLC*, 403 F. Supp. 3d 548, 556 (W.D. La. 2019); *Coleman v. United States*, No. SA-16-CA-00817-DAE, 2017 WL 9360840, at *4 (W.D. Tex. Aug. 16, 2017).

[75] *Viterbo v. Dow Chem. Co*., 826 F.2d 420, 422 (5th Cir. 1987).

[76] The statement in the Committee Note that "*Daubert* did not work a seachange over federal

law have thus trapped themselves in a loop that repeats a discarded approach to opinion testimony, and they have not allowed the language of amended Rule 702 to interrupt this pattern.[77] At bottom, archaic conceptions of the admissibility standard recycled for more than two decades in some circuits have produced confusion about what the rule requires, with the result that some courts fail to recognize that Rule 702 now directs a "more rigorous and structured approach" than these pre-*Daubert* cases were willing to accept.[78] As members of the Advisory Committee have suggested, breaking this pattern will require action demonstrating to courts that "it is incorrect to make broad statements that sufficiency of basis and reliable application are questions of weight and not admissibility."[79]

evidence law" may unwittingly suggest to some courts that pre-*Daubert* interpretations of the court's gatekeeping role remain in force after adoption of the 2000 amendments to Rule 702. *See*, *e.g.*, *More, JC, Inc. v. Nutone Inc.*, No. A-05-CA-338 LY, 2007 WL 4754173, at *7 (W.D. Tex. Mar. 21, 2007)(quoting referenced passage from the Committee Note and proceeding to ignore Rule 702(b) and instead draw upon the Fifth Circuit's 1987 decision in *Viterbo*, 826 F.2d at 422, for the proposition that "[q]uestions relating to the bases and sources of an expert's opinion, rather than its admissibility, should be left for the jury's consideration.").

[77] Pronouncements that challenges to an expert's factual basis or application of the methodology bear only on the weight of the testimony, not its admissibility, consistently stem from pre-*Daubert* decisions. *Katzenmeier*, 628 F.3d at 952, discussed *supra* n. 56, cites to *Hose v. Chicago Nw. Transp. Co.,* 70 F.3d 968, 974 (8th Cir. 1995), which in turn quotes *Loudermill v. Dow Chem. Co.,* 863 F.2d 566, 570 (8th Cir. 1988)("As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination."). *Carmichael*, 679 F. Supp. 2d at 119, discussed *supra* n. 62, likewise quotes *Loudermill* and also *Viterbo*, 826 F.2d at 422. *Wischermann Partners*, 2019 WL 3802121, at *1, discussed *supra* n. 61, references *McLean v. Ontario Ltd.*, 224 F.3d 797, 801 (6th Cir. 2000), which itself quotes from *United States v. L.E. Cooke Co.,* 991 F.2d 336, 342 (6th Cir. 1993)("[W]eaknesses in the factual basis of an expert witness' opinion ... bear on the weight of the evidence rather than on its admissibility.").

[78] *See* May 1, 1999 Report of the Advisory Committee on Evidence Rules, *supra* n. 15, at 7.

[79] Apr. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.31, at 24.

III. CLARIFICATION IS NECESSARY FOR RULE 702 TO FUNCTION AS INTENDED AND SAFEGUARD THE TRIAL PROCESS AGAINST MISLEADING OPINION TESTIMONY

The intended aims of Rule 702, including establishment of a uniform approach[80] and protection of jurors against deception by influential but unreliable opinions as *Daubert* directs,[81] remain essential for a properly functioning national rule to govern expert admissibility. Twenty years of inconsistency, however, have turned Rule 702 into a mosaic of standards in which the same testimony that one court excludes would be admissible in a sister court.[82] Misunderstanding Rule 702 is no matter of small consequence: litigation outcomes change depending on the court's

[80] In light of the increasing proportion of federal civil cases assigned to multidistrict litigation matters, in which the presiding court that tries a case may sit in a different circuit than the transferor court in which the matter was originally filed, a uniform standard for admitting expert testimony is now even more important than it was in 2000. *See* Daniel S. Wittenberg, MULTIDISTRICT LITIGATION: DOMINATING THE FEDERAL DOCKET AMERICAN BAR ASSOCIATION (2020), https://www.americanbar.org/groups/litigation/publications/litigation-news/business-litigation/multidistrict-litigation-dominating-federal-docket / (last visited Feb 28, 2020)(describing rise of MDL case proportion such that "MDLs accounted for 51.9 percent of all pending federal civil cases at the end of 2018.").

[81] *See In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 613 (8th Cir. 2011)("The main purpose of *Daubert* exclusion is to protect juries from being swayed by dubious scientific testimony."). *See also* Minutes of the Meeting of May 3, 2019, Advisory Comm. on Evidence Rules, *supra* n. 22, at 23.

[82] *See*, *e.g.*, *In re Roundup Products Liability Litigation*, No. 16-md-02741-VC, 2018 WL 3368534, at *5 (N.D. Cal. July 10, 2018)("[The Ninth Circuit's] emphasis has resulted in slightly more room for deference to experts in close cases than might be appropriate in some other Circuits. This is a difference that could matter in close cases."). *See also United States v. Raniere*, No. 18-CR-204-1 (NGG)(VMS), 2019 WL 2212639, at *6 (E.D.N.Y. May 22, 2019)("The Second Circuit's standard for admissibility of expert testimony is especially broad.")(citations omitted); *McCluskey*, 954 F. Supp. 2d at 1255 (recognizing that "the approach of the Eighth and Third Circuits is somewhat more restrictive than the approach of the First and other Circuits.").

conception of the admissibility standard.[83]

The Advisory Committee's acknowledgement that courts neglect or misapply critical aspects of Rule 702[84] leads to the conclusion that courts have become confused about what the rule requires, and so steps must be taken to halt ongoing misunderstanding of the law. Amending Rule 702 is necessary to restore a common understanding of the standard. Just as in 2000, the widespread inconsistency among the courts cries out for amendments to clarify the rule, with an accompanying Committee Note to eliminate any precedential value from off-the-mark prior rulings and to solidify a single approach to the expert admissibility question.[85] Although Rule 702 currently contains language describing the scope of the gatekeeping responsibility, that language has failed to guide courts in understanding that an expert's factual basis and methodology application only become credibility matters for the jury to decide after the court initially determines that the proponent has met

[83] *Compare*, *e.g.*, *Adams*, 867 F.3d at 915-16 (affirming admission of engineer's causation opinion in which hypothesis derived from exemplar testing was applied to the facts at issue by "rul[ing] out pedal misapplication," in unintended acceleration case that resulted in partial jury verdict for plaintiff) *with Nease*, 848 F.3d at 230-32 (reversing jury verdict in plaintiffs' favor and directing entry of judgment for defendant in unintended acceleration case where district court improperly dismissed challenges to engineer's application of methodology to case facts in forming causation opinion as "go[ing] to the weight, not admissibility, of [the expert's] testimony.").

[84] *See* Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 52 ("[T]he fact remains that some courts are ignoring the requirements of Rule 702(b) and (d). That is frustrating.").

[85] *See* Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 53 (indicating that "it may be possible to tweak the existing language [of Rule 702] in some way, and then write a Committee Note that strongly reaffirms the admissibility requirements in Rule 702 and criticizes the cases that treat these requirements as questions of weight rather than admissibility.").

the burden of establishing by a preponderance of the evidence that the expert meets the standard of admissibility. Similarly, courts need new direction that Rule 702 does not incorporate a presumption of admissibility or otherwise prefer admitting over excluding proffered opinion testimony, but instead requires the sponsor to fulfill the burden of production. Amending Rule 702's language on these issues and publishing a detailed Committee Note that identifies common misstatements of law and describes erroneous practices would create a new understanding of the rule's requirements and disrupt the pattern of recycled citations to outmoded conceptions of the court's role.

Although concerns have been voiced that wayward judges who already disregard the requirements of Rule 702 may not respond to renewed exhortations to apply Rule 702 as written,[86] this speculation should not deter the Advisory Committee from clarifying the rule for the great majority of judges and practitioners who read the rule and do their best to follow it. Doing nothing in the face of demonstrated judicial misunderstanding amounts to tacit acceptance of a different rule of expert admissibility—a rule the Advisory Committee never wrote. Without new direction, courts will continue to carry forward errors that effectively dilute the standard of admissibility, such as a court determining it "will err on the side of admissibility" [87] or

[86] *See* Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 52 ("[I]t is hard to conclude that the problem of courts straying from the text will be solved by more text.").

[87] *See*, *e.g.*, *Lombardo v. Saint Louis*, No. 4:16-CV-01637-NCC, 2019 WL 414773, at *12 (E.D. Mo. Feb. 1, 2019)("[T]he Court will err on the side of admissibility."). *See also* cases cited at n.40, n.44, and n.47, *supra*.

demanding that a party seeking exclusion show that an "expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury,"[88] into future generations of misguided decisions.[89]

Until the Advisory Committee amends Rule 702 to clarify its meaning, litigants should appeal rulings that fail to follow Rule 702's mandates, including when courts rely on nonexistent presumptions or defer admissibility questions to the jury. Such practices involve errors of law[90] in determining the admissibility of evidence, which "is

[88] *See*, *e.g.*, *Pacific Indem. Co. v. Dalla Pola*, 65 F. Supp. 3d 296, 302 (D. Mass. 2014):

> The defendant has not shown that [the expert's] testimony falls within this exception [for opinion testimony so fundamentally unsupported that it can offer no assistance to the jury], and that his expert opinion is inadmissible. Therefore, the weight of that testimony must be evaluated by the finder of fact at trial.

[89] *See*, *e.g.*, *Paul Beverage*, 2019 WL 1044057, at *2 (admitting challenged opinion testimony without addressing the expert's basis or application, following Eighth Circuit's incorrect statement in *Nebraska Plastics, Inc. v. Holland Colors Americas, Inc.*, 408 F.3d 410, 416 (8th Cir. 2005) that "[a]s a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination[,]" which traces to *Loudermill*, 863 F.2d at 570); *Powell*, 2015 WL 7720460, at *2 (2015 decision quoting *MacDermid Printing Sols., Inc. v. Cortron Corp.*, No. 3:08-cv-1649 MPS, 2014 WL 2615361, at *2 (D. Conn. June 12, 2014), which in turn cites to *Borawick*, 68 F.3d at 610, for the proposition that the Second Circuit embraces the idea that there should be a presumption of admissibility of evidence.).

[90] *See* Advisory Committee Note to 2000 Amendments to Rule 702 (the proponent of the expert's testimony "has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence."); May 1, 1999 Report of the Advisory Committee on Evidence Rules, *supra* n. 15, at 5 ("The proposed amendment to Evidence Rule 702 . . . requires a showing of reliable methodology and sufficient basis, and provides that the expert's methodology must be applied properly to the facts of the case."); Oct. 1, 2019 Memorandum from Daniel J. Capra, Reporter, *supra* n.23, at 30 ("[Some courts] routinely state the misguided notion that arguments about sufficiency of basis and reliability of application almost always go to weight and not admissibility"); Apr. 1, 2018 Memorandum from Daniel J. Capra, Reporter, *supra* n.1, at 52 ("[T]he fact remains that some courts are ignoring the requirements of Rule 702(b) and (d).").

by definition an abuse of discretion."[91] The recognized fact that courts are not applying Rule 702 as written, and are instead assessing admissibility using different considerations and divergent standards across the circuits[92] presents a situation that warrants appellate redress.[93]

In light of the developed patterns of Rule 702 misunderstanding, maintaining the *status quo* amounts to resignation that the rule no longer demands what the 2000 amendments intended it to require. The lower courts need the Advisory Committee's direction to understand that approaches commonly taken in the gatekeeping process rely on misunderstandings of Rule 702. Unless these patterns are displaced with a new amendment, courts will continue addressing the admissibility of opinion testimony in ways that depart from the intent of Rule 702.[94] Rulemaking action is

[91] *Nease*, 848 F.3d at 228 (quoting *Anderson v. Westinghouse Savannah River Co*., 406 F.3d 248, 260 (4th Cir. 2005)).

[92] *See supra* n. 1, n.72 & n.82.

[93] Notably, the Supreme Court granted *certiorari* in *Kumho Tire* to rectify inconsistency among the lower courts in applying the *Daubert* standard to technical experts. 526 U.S. at 146-47; ("We granted certiorari in light of uncertainty among the lower courts about whether, or how, *Daubert* applies to expert testimony that might be characterized as based not upon 'scientific' knowledge, but rather upon 'technical' or 'other specialized' knowledge."). Similarly, the Court granted *certiorari* in *Weisgram* to resolve a split among the circuits regarding whether "Federal Rule of Civil Procedure 50 permits an appellate court to direct the entry of judgment as a matter of law when it determines that [expert] evidence [critical for establishing a prima face case] was erroneously admitted at trial[.]" 528 U.S. at 446.

[94] *See*, *e.g.*, *Citizens State Bank*, 2020 WL 1065723, at *4 (dismissing argument that opinion was "not based on sufficient facts" without assessing the expert's factual basis, following Fifth Circuit's pre-*Daubert* statement in *Viterbo*, 826 F.2d at 422, that "[q]uestions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility"); *Orion Drilling*, 2019 WL 4273861, at *34 (shifting burden to party challenging admissibility to show the proffered opinion testimony is unreliable, following Third Circuit's

necessary to re-orient courts to the expert admissibility standard envisioned for Rule 702.

misleading characterization of Rule 702 in *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) as embodying "a liberal policy of admissibility[.]").