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WEIGHT OF THE EVIDENCE:
A LOWER EXPERT EVIDENCE STANDARD METASTASIZES IN FEDERAL COURTS

By

Lawrence A. Kogan
The Kogan Law Group, P.C.

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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.

WEIGHT OF THE EVIDENCE:
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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."

Eight 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

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[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,

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[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]

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[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]

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[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]

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[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.

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[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

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[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

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[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.

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[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]

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[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]

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[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

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[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]

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[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

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[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

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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

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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

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[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

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[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

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[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

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[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

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[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

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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-

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[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

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[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

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[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]

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[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-

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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

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[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

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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

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'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—

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[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*

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[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.

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[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

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[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]

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[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]

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[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

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[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

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[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

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[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]

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[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

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[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

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[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 solution containing Teflon, which, in turn, contained perflouroctanoic acid ("PFOA") as a

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[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).

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]

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[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]

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[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

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[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

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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

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[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]
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> 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

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[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]

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

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[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.

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 their general use. Inasmuch as Dr. Madigan's recently completed report aids in this testimony, he should be permitted to rely on it,

[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).

> 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, including epidemiology."[402] The court continued, "Egilman's experience as a family doctor

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[397] *Id*.
[398] *Id*. at 8.
[399] *Id*.
[400] *Id*.
[401] *Id*. at 9.
[402] *Id*. at 10.

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 many other workers who were also exposed to benzene."[408] The court granted in part, and

[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).
[408] *Id*. at 11, quoting and citing *Milward*, 639 F.3d at 20.

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 insufficient, on its own, to support the expert's conclusion.'"[417] According to plaintiffs, one

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[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.

[417] *Id*.

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]

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[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]

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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

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[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]

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[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

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[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

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[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

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[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

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[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'

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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]

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[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 regarding 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]

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[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

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[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

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[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]

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[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]

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[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]

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[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

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[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

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[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

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[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]

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[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

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[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]

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[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

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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

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[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.

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[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.

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[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]

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[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]

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[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]

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[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]

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[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]

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[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).

"'Given that 'there are many different kinds of experts, and many different kinds 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

[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.

not a reason to exclude Mr. Butler's opinion."[76]

"[…] 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]

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[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.'")).

[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)

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[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]

Fifth Circuit

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]

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[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** =======

