

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

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APPENDIX A

Traditional Tort Actions Analyses:

Toxic Torts, Products Liability, Negligence/Wrongful Death, Medical Malpractice

(**Editor's Note:** The introductory text to follow is from Section VI of the main document of the WLF WORKING PAPER *Weight of the Evidence: A Lower Standard for Expert Evidence Metastasizes in Federal Courts*. This main document is available on WLF's website at <https://www.wlf.org/2020/02/19/publishing/wlf-working-paper-kogan-march-2020/>.)

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. Consequently, one cannot determine whether the reasoning or 'weighting' methodology underlying the expert's testimony properly can be applied to the facts in issue.

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 reveal, by reference to traditional 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)¹ (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.

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."² "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."³

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

¹ Civ. No. 09-cv-205-JD (D.N.H. 2012).

² Slip op. at 2.

³ *Id.*

that “*may be considered* in determining whether an expert witness’ opinion is based on reliable principles and methods.”⁴ “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.’”⁵

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.”⁶ 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.”⁷

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.”⁸ 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 warning itself ha[d] been peer reviewed, but whether Vigilante’s technique or theory ha[d] been subjected to peer review and publication.”⁹

[West v. Bell Helicopter Textron, Inc.](#) (D.N.H. 2013)¹⁰ (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

⁴ *Id.* quoting *Milward v. Acuity Special Products Group, Inc.* 639 F.3d 11, 14 (1st Cir. 2011) (emphasis added).

⁵ *Id.* at 2 quoting *Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 81 (1st Cir. 1998).

⁶ *Id.* at 3.

⁷ *Id.*

⁸ *Id.* at 4, quoting *Milward*, 639 F.3d at 22.

⁹ *Id.* at 4, citing *Milward*, 639 F.3d at 14.

¹⁰ Civ. No. 10-cv-214-JL (D.N.H. 2013).

“the force of the landing caused him injuries,” including “a worsening of his pre-existing gastrointestinal syndrome,” and “post-traumatic stress disorder.”¹¹

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).”¹² 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.”¹³

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*.’”¹⁴

¹¹ *Id.* at 1.

¹² *Id.* at 3.

¹³ *Id.* (emphasis added).

¹⁴ *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 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.*,

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.”¹⁵

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.”¹⁶ 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.”¹⁷

[Zagklara v. Sprague Energy Corp. \(Zagklara II\)](#) (D. Me. 2013)¹⁸
(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.¹⁹ The ship had arrived in Portland, Maine “to discharge rock salt for storage at [...] Merrill Marine Terminal.”²⁰

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.”²¹ 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.”²² The port captain “was injured while attempting to move one of the power reel boxes on the deck of the vessel.”²³ The

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.

¹⁵ *Id.* at 4.

¹⁶ *Id.* at 4-5.

¹⁷ *Id.* at 5, quoting *Milward*, 639 F.3d at 22. (emphasis added).

¹⁸ Civ. No. 2:10-cv-445-GZS (D. Me. 2013).

¹⁹ *Zagklara v. Sprague Energy Corp.*, Civ. No. 2:10-cv-445-GZS (D. Me. 2012) (“*Zagklara I*”).

²⁰ *Id.* at 9.

²¹ *Id.* at 9-10.

²² *Id.* at 11.

²³ *Id.* at 12.

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.²⁴ 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."²⁵ 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."²⁶

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."²⁷ The court thus concluded that "on the [then] current available record," plaintiff's expert's "proposed testimony falls within [FRE] 702's limits."²⁸

[Calisi v. Abbott Laboratories](#) (D. Mass. 2013)²⁹ (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]."³⁰

²⁴ *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.

²⁵ *Id.* at 1.

²⁶ *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 v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 596 (1993) and *Milward*, 639 F.3d at 15.

²⁷ *Id.* at 2-3.

²⁸ *Id.* at 3.

²⁹ Civ. No. 11-10671-DJC (D. Mass. 2013).

³⁰ *Id.* at 4.

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 warn³¹ plaintiff about the alleged risk of lymphoma.³² 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.³³

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.'"³⁴ As the district court found, "[t]his does not mean that trial courts are empowered 'to determine which of several competing scientific theories has the best provenance.'"³⁵ "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.'"³⁶ 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.'"³⁷ "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."³⁸

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 702.³⁹ According to the court, plaintiff failed to satisfy, the burden of showing "that Hamrell's opinion on

³¹ 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.

³² *Id.* at 5.

³³ *Id.* at 1, 4, 7-8.

³⁴ *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)).

³⁵ *Id.*, quoting *Milward*, 639 F.3d at 15.

³⁶ *Id.*, quoting *Milward*, 639 F.3d at 15, (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *Daubert*, 509 U.S. at 592 & n. 10).

³⁷ *Id.*, quoting *Milward*, 639 F.3d at 15 (quoting *Daubert*, 509 U.S. at 590).

³⁸ *Id.*

³⁹ *Id.* at 11, n. 6, 12-14.

adequacy [was] not ‘connected to existing data only by the *ipse dixit* of the expert.’”⁴⁰

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.”⁴¹ 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.”⁴² Consequently, the court concluded that Hamrell did not establish that his “adequacy” opinion had been based “on sufficient data so as to be reliable.”⁴³

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 prescribing medical doctor. He took no steps to determine if the label is misleading, confusing or downplayed any relevant risk.”⁴⁴ 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.”⁴⁵ 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.”⁴⁶ 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.”⁴⁷

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.⁴⁸ 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.⁴⁹

⁴⁰ *Id.* at 14-15, quoting *Milward*, 639 F.3d at 14.

⁴¹ *Id.* at 15.

⁴² *Id.* at 17.

⁴³ *Id.*

⁴⁴ *Id.* at 17-18.

⁴⁵ *Id.* at 18.

⁴⁶ *Id.*

⁴⁷ *Id.* at 19-20.

⁴⁸ *Id.* at 20-21.

⁴⁹ *Id.* at 21.

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.’”⁵⁰ It also reasoned that “Hamrel’s proffered basis for his expert opinion [was] conclusory and circular,”⁵¹ 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.’”⁵²

Torres v. Mennonite General Hospital, Inc. (D.P.R. 2013)⁵³ (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.”⁵⁴ The court denied a motion in limine the defendant had filed to exclude the opinion testimony of plaintiff’s medical expert, Dr. Carl Adams.⁵⁵

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.”⁵⁶ 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.”⁵⁷

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.’”⁵⁸ 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

⁵⁰ *Id.* at 22, quoting *Milward*, 639 F.3d at 15 (citing *Daubert*, 509 U.S. at 85).

⁵¹ *Id.* at 23.

⁵² *Id.*

⁵³ 988 F. Supp. 2d 180 (D.P.R. 2013).

⁵⁴ *Id.* at 189-90.

⁵⁵ *Id.* at 182.

⁵⁶ *Id.* at 183.

⁵⁷ *Id.*

⁵⁸ *Id.* at 184, quoting *Milward*, 639 F.3d at 14-15.

testimony as reliable.”⁵⁹ 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.’”⁶⁰

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.’”⁶¹ 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.’”⁶² 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 the practice of an expert in the relevant field.’”⁶³

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.”⁶⁴ 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.”⁶⁵ 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.”⁶⁶

Campos v. Safety-Kleen Systems, Inc. (D.P.R. 2015)⁶⁷ (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”).⁶⁸ 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

⁵⁹ *Id.*, quoting *Milward*, 639 F.3d at 15.

⁶⁰ *Id.*, citing *Ruiz-Troche*, 161 F.3d at 85.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *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.

⁶⁵ *Id.* at 184.

⁶⁶ *Id.* at 184-85.

⁶⁷ Civ. No. 12-1529 (PAD) (D.P.R. 2015).

⁶⁸ *Id.* at 1.

the conclusions that expert testimony generates.”⁶⁹ 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.”⁷⁰ 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.”⁷¹

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.”⁷² The district court, thus, held that Goldsmith’s “opinions [were] based on reliable scientific evidence.”⁷³

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.”⁷⁴ 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.”⁷⁵

[Quilez-Velar v. Ox Bodies, Inc.](#) (1st Cir. 2016)⁷⁶ (Wrongful death/Negligence)

The plaintiff filed this wrongful death/negligence and products liability action in

⁶⁹ *Id.* at 2, quoting *Daubert*, 509 U.S. at 580.

⁷⁰ *Id.* at 2, quoting *Milward*, 639 F.3d at 14, citing *Kumho Tire Co., Ltd.*, 526 U.S. at 150.

⁷¹ *Id.* at 3, quoting *Milward*, 639 F.3d at 15, citing *Daubert*, 509 U.S. at 590, 596.

⁷² *Id.* at 3.

⁷³ *Id.*

⁷⁴ *Id.* at 4.

⁷⁵ *Id.* (emphasis added).

⁷⁶ 823 F.3d 712 (1st Cir. 2016).

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.⁷⁷ 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.⁷⁸

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 underride guard design ‘would have been a safer design in the instant accident,’ and that his opinions should be excluded under *Daubert* [...]”⁷⁹ The presiding magistrate judge denied the motion to exclude Ponder’s testimony.⁸⁰ 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.⁸¹

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.⁸² 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.”⁸³

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.”⁸⁴ 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.”⁸⁵ It also held that the reliability “factors *Daubert* mentions do *not* constitute a ‘definitive checklist or test’”⁸⁶ (*i.e., inter alia*, the factor relating to) “whether a theory or

⁷⁷ *Id.* at 715.

⁷⁸ *Id.*

⁷⁹ *Id.* at 715-16, n. 3.

⁸⁰ *Id.*, citing *Quilez-Velaz v. Ox Bodies, Inc.*, No. CIV. 12-1780, 2015 WL 418151, at *7 (D.P.R. Feb. 1, 2015).

⁸¹ *Id.*

⁸² *Id.* at 712, 716 citing *Quilez-Velaz v. Ox Bodies, Inc.*, No. CIV. 12-1780, 2015 WL 898255, at *1-3 (D.P.R. Mar. 3, 2015).

⁸³ *Id.* at 712.

⁸⁴ *Id.* at 718.

⁸⁵ *Id.* at 719.

⁸⁶ *Id.* (emphasis in original).

technique can be and has been tested.”⁸⁷ According to the court, *Daubert required only that the district court had “conduct[ed] a fact-specific ‘reliability’ inquiry.”*⁸⁸

Second Circuit

[*Drake v. Allergan, Inc.*](#) (D. Vt. 2015)⁸⁹ (Products Liability/Negligence)

In *Drake*, the parents of a 5 ½-year old minor child (“J.D.”) afflicted with cerebral palsy 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.”⁹⁰

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.’”⁹¹ 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.’”⁹² 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.”⁹³

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.’*”⁹⁴ 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.”⁹⁵

[*Sullivan et al. v. Saint-Gobain Performance Plastics Corp.*](#) (D. Vt. 2019)⁹⁶ (Toxic Tort)

Plaintiffs, individual residents from Bennington and North Bennington, Vermont,

⁸⁷ *Id.* at 12, 13 and n. 7.

⁸⁸ *Id.* at 12 citing and quoting *Milward*, 639 F.3d at 16-20. (emphasis added).

⁸⁹ 111 F. Supp. 3d 562 (D. Vt. 2015).

⁹⁰ *Id.* at 566.

⁹¹ *Id.* at 567-68.

⁹² *Id.* at 568, quoting *Joiner*, 522 U.S. at 146.

⁹³ *Id.*

⁹⁴ *Id.*, quoting *Milward*, 639 F.3d at 26 (emphasis added).

⁹⁵ *Id.*, citing *Milward*, 639 F.3d at 23.

⁹⁶ Case No. 5:16-cv-125 (D. Vt., July 16, 2019).

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 perfluorooctanoic acid (“PFOA”) as a dispersant. The court found, as a matter of fact, that PFOA is “highly resistant to degradation in the natural environment,” is “readily transported by wind in the form of airborne particles as well as by ground and surface water,” is known to “enter[] the food chain and [to] accumulate[] in the bodies of people and animals,” and “is now detectable at low levels throughout the world.”⁹⁷

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.”⁹⁸ 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.⁹⁹

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.”¹⁰⁰ 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.”¹⁰¹ 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

⁹⁷ *Sullivan*, slip op. at 3.

⁹⁸ *Id.* at 5.

⁹⁹ *Id.* at 6.

¹⁰⁰ *Id.* at 9, citing *Daubert*, 509 U.S. at 592-93.

¹⁰¹ *Id.*

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.”¹⁰²

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...”¹⁰³—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.”¹⁰⁴ 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.”¹⁰⁵

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.”¹⁰⁶ 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.”¹⁰⁷ Ducatman concluded that there was an *association* between PFOA and these illnesses, based, in part, on a 2017 Vermont Health Department report.¹⁰⁸ 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

¹⁰² *Id.*, citing *Daubert*, 509 U.S. at 596, and *Joiner*, 522 U.S. at 146.

¹⁰³ *Id.* at 10, quoting *Joiner*, 522 U.S. at 146-47.

¹⁰⁴ *Id.* at 11, citing *Kumho Tire Co.*, 526 U.S. 137 (emphasis added).

¹⁰⁵ *Id.* at 10, quoting *Joiner*, 522 U.S. at 154.

¹⁰⁶ *Id.* (emphasis added).

¹⁰⁷ *Id.*

¹⁰⁸ *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).

improved outcomes for these conditions.”¹⁰⁹

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.”¹¹⁰ 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.”¹¹¹ 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.”¹¹²

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.”¹¹³ 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.¹¹⁴ 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 ATSDR factors would support medical monitoring.¹¹⁵ 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.”¹¹⁶ The court held that “[t]hese traditional *Daubert* factors support the admissibility of Ducatman’s testimony.”¹¹⁷

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.¹¹⁸ Grandjean

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 26, 32.

¹¹¹ *Id.* at 32.

¹¹² *Id.*

¹¹³ *Id.* at 32-33.

¹¹⁴ *Id.* at 33.

¹¹⁵ *Id.*

¹¹⁶ *Id.* at 34.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 35.

opined in his rebuttal report and testimony that, despite the limited data available about the 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."¹¹⁹ 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."¹²⁰

The district court found that Grandjean's research and report and his overall methodological approach "satisf[ie]d 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."¹²¹ 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."¹²² 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."¹²³

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."¹²⁴ 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."¹²⁵ 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 "not unduly exaggerated the strength of his conclusions."¹²⁶ Fourth, the court accepted

¹¹⁹ *Id.* at 35-36 (emphasis added).

¹²⁰ *Id.* at 36 (emphasis added).

¹²¹ *Id.* at 36-37.

¹²² *Id.* at 39, quoting *Joiner*, 522 U.S. at 153.

¹²³ *Id.* at 37 (emphasis added).

¹²⁴ *Id.* at 36.

¹²⁵ *Id.* at 38; *see also id.* at 40.

¹²⁶ *Id.* at 38 (emphasis added).

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.”¹²⁷ 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.”¹²⁸

Thus, Grandjean’s “weight of the evidence review [was] not a subjective, ‘black box’ opinion that c[ould] not be examined.”¹²⁹ 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.”¹³⁰

Third Circuit

[In re Fosamax](#) (D.N.J. 2013)¹³¹ (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.¹³² 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.”¹³³ It also noted “[i]n applying the nine Bradford Hill factors, [Cornell] reviewed [p]laintiff’s medical records, his office notes and depositions of

¹²⁷ *Id.* at 38-39.

¹²⁸ *Id.* at 39.

¹²⁹ *Id.*

¹³⁰ *Id.* at 40.

¹³¹ *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).

¹³² *Id.*, slip op. at 1.

¹³³ *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 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.

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.”¹³⁴ Cornell had also “‘review[ed] the original trials, the randomized trials, which led to the approval of Fosamax for the treatment of osteoporosis.’”¹³⁵ 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.’”¹³⁶ 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.’”¹³⁷

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.”¹³⁸ 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.”¹³⁹ 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.”¹⁴⁰

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.”¹⁴¹ The court also emphasized how Klein’s report “noted a strong association between delayed fracture 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.”¹⁴² 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

¹³⁴ *Id.* at 3-4.

¹³⁵ *Id.* at 4.

¹³⁶ *Id.*

¹³⁷ *Id.* at 4, quoting *Gannon*, 292 Fed. Appx. at 173. n. 1; *In re Avandia Mktg., Sales Practices & Products Liab. Litig.*, 2011 WL 13576, at *3.

¹³⁸ *Id.* at 4 (emphasis added).

¹³⁹ *Id.*

¹⁴⁰ *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.’”).

¹⁴¹ *Id.* at 6.

¹⁴² *Id.*

prudent for women on therapy who sustain nonvertebral fracture.”¹⁴³ 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.’¹⁴⁴ 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.”¹⁴⁵

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.”¹⁴⁶ 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.”¹⁴⁷ 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.”¹⁴⁸

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.”¹⁴⁹ The court also noted how Blume opined that defendant “should have changed the Fosamax label ‘to include escalating warning and *precautionary 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 2009.¹⁵⁰

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

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.* at 7, quoting *Third Edition*, *supra* note 14, at 563.

¹⁴⁸ *Id.*, citing and quoting *Milward*, 639 F.3d at 15 (the same passage it quoted above).

¹⁴⁹ *Id.* at 10-11.

¹⁵⁰ *Id.* at 11 (emphasis added).

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."¹⁵¹

[In re Zoloft \(Sertraline Hydrochloride\)](#) (3d Cir. 2017)¹⁵² (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.¹⁵³

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[.]'"¹⁵⁴ 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."¹⁵⁵ 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."¹⁵⁶

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 draw conclusions about one factor based on a particular combination of evidence."¹⁵⁷ 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.¹⁵⁸

¹⁵¹ *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").

¹⁵² 858 F.3d 787 (3d Cir. 2017).

¹⁵³ 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).

¹⁵⁴ *In re Zoloft*, 858 F.3d at 795, quoting *Milward*, 639 F. 3d at 17.

¹⁵⁵ *Id.*, citing *In re Paoli*, 35 F.3d at 758.

¹⁵⁶ *Id.* at 796, citing *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 602 (D.N.J. 2002).

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 795.

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).¹⁵⁹

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.”¹⁶⁰

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.”¹⁶¹ According to the court, “[c]laiming a consistent result without meaningfully addressing [...] alternate explanations as noted in *In re Paoli*, undermines reliability.”¹⁶² 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 confusing.”¹⁶³ “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.”¹⁶⁴

¹⁵⁹ *Id.* at 796 quoting *Magistrini*, 180 F. Supp. 2d at 602, 607.

¹⁶⁰ *Id.* at 798 (emphasis added).

¹⁶¹ *Id.* at 799.

¹⁶² *Id.*, citing *In Re Paoli*, 35 at 760 (“(noting the importance of explaining why a conclusion remains reliable in the face of alternate explanations.”).

¹⁶³ *Id.* at 800.

¹⁶⁴ *Id.* At least one court sitting in the Second Circuit has expressed its agreement with the Third Circuit’s assessment in *In re Zolof* 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 Zolof*, 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

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)¹⁶⁵
(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.¹⁶⁶

Thousands of individual suits and numerous class actions were thereafter filed against Merck in state and federal courts alleging various products liability, tort, fraud, and warranty claims. Levitt brought this action against Merck in the Western District of Missouri. Her complaint alleged that she suffered two heart attacks in 2001 as a result of taking Vioxx and sought compensatory and punitive damages. On November 8, 2006, the matter became part of the Vioxx MDL before the Eastern District of Louisiana.¹⁶⁷

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

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.”).

¹⁶⁵ *Levitt v. Merck Sharp & Dohme Corp. (In re Vioxx Prods.)*, MDL No. 1657 Section L (E.D. La. 2016).

¹⁶⁶ *Id.* at 1.

¹⁶⁷ *Id.*

weighing the risks and benefits of medical treatment, including pharmaceuticals, was not an epidemiologist, and had no experience designing or conducting clinical drug trials.¹⁶⁸ Dr. Madigan also was “not an expert in pharmacology, cardiology, rheumatology, gastroenterology, neurology, vascular biology, or any other medicine related to Vioxx.”¹⁶⁹ 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.”¹⁷⁰

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.”¹⁷¹

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.’”¹⁷² 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, 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.¹⁷³

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

¹⁶⁸ *Id.* at 4.

¹⁶⁹ *Id.* at 4-5.

¹⁷⁰ *Id.* at 2 (emphasis added).

¹⁷¹ *Id.* at 4.

¹⁷² *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).

¹⁷³ *Id.*

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."¹⁷⁴ 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."¹⁷⁵

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 bellwether trial in Texas, and his testimony "in numerous courts throughout the country on issues similar to the opinions presented in this case."¹⁷⁶ 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."¹⁷⁷

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."¹⁷⁸ The court continued, "Egilman's experience as a family doctor provide[d] him an adequate basis for rudimentary observations regarding Levitt's psychiatric and emotional well-being," and he was "qualified to offer basic opinions in the fields of neurology to the extent such opinions are limited to what may be observed by a general family doctor."¹⁷⁹ 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."¹⁸⁰ 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,

¹⁷⁴ *Id.* at 8.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.* at 9.

¹⁷⁸ *Id.* at 10.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

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.”¹⁸¹ 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.”¹⁸²

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.”¹⁸³ 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.”¹⁸⁴ The court granted in part, and denied in part, Merck’s motion to exclude.¹⁸⁵

[Sparling ex rel. Sparling v. Doyle](#) (W.D. Tex. 2016)¹⁸⁶ (Products Liability)

Plaintiffs alleged that the decedent died after using defendants’¹⁸⁷ dietary supplement product containing DMAA—the compound 1,3-Dimethylamylamine.¹⁸⁸ 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.¹⁸⁹ Plaintiffs appealed to the district court.

¹⁸¹ *Id.* at 10, citing *Allen v. Pennsylvania Eng’g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996).

¹⁸² *Id.* at 11.

¹⁸³ *Id.* at 11, citing *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 20 (1st Cir. 2011).

¹⁸⁴ *Id.* at 11, quoting and citing *Milward*, 639 F.3d at 20.

¹⁸⁵ 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.

¹⁸⁶ *Sparling ex rel. Sparling v. Doyle*, Civ. No. EP-13-CV-00323 DCG (W.D. Tex. 2016).

¹⁸⁷ *Sparling ex rel. Sparling v. Doyle*, Civ. No. EP-13-CV-323-DCG (W.D. Tex. 2015).

¹⁸⁸ *Id.*

¹⁸⁹ *Sparling ex rel. Sparling v. Doyle*, Civ. No. EP-13-CV-00323 DCG (W.D. TX 2016), Slip op. at 2.

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.'"¹⁹⁰ 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."¹⁹¹

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.'"¹⁹² 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.'"¹⁹³ According to plaintiffs, one expert's [Cantilena's] "'calculations bridge[d] the gap the Magistrate said existed in the class effect discussion by accounting for differences in route of administration, pharmacokinetics, potency, and by providing an established mechanism of action.'"¹⁹⁴

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."¹⁹⁵ 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."¹⁹⁶ 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

¹⁹⁰ *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.").

¹⁹¹ *Id.*

¹⁹² *Id.* at 11.

¹⁹³ *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *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 the 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.'").

has the best provenance.”¹⁹⁷

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.’”¹⁹⁸ 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.”¹⁹⁹ 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 sympathomimetics and he pointed to no literature making these comparisons to validate his approach.’”²⁰⁰ 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.”²⁰¹ “Consequently, [the court] determined that Dr. Cantilena was unreliable.”²⁰²

Sixth Circuit

[In re Heparin Products Liability Litigation](#) (N.D. Ohio 2011)²⁰³ (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.²⁰⁴

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].”²⁰⁵ 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

¹⁹⁷ *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.”).

¹⁹⁸ *Id.*, quoting *Milward*, 639 F.3d at 15, citing *Daubert*, 509 U.S. at 85.

¹⁹⁹ *Id.*

²⁰⁰ *Id.* at 12.

²⁰¹ *Id.* at 12-13.

²⁰² *Id.* at 13.

²⁰³ *In re Heparin Products Liability Litigation*, 803 F. Supp. 2d 712 (N.D. Ohio 2011).

²⁰⁴ *Id.* at 719.

²⁰⁵ *Id.* at 727, citing *Turpin v. Merrell Dow Pharmaceutical Inc.*, 736 F. Supp. 737, 743 (E.D. Ky. 1990).

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.²⁰⁶

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."²⁰⁷ 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."²⁰⁸).

DeGidio v. Centocor Ortho Biotech, Inc. (N.D. Ohio 2014)²⁰⁹ (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."²¹⁰ 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.'²¹¹ 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.²¹²

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.'²¹³ 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.'²¹⁴

²⁰⁶ *Id.* at 728.

²⁰⁷ *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).

²⁰⁸ *Id.* at 728, 756 n. 6, quoting *Milward*, 639 F.3d at 24.

²⁰⁹ *DeGidio v. Centocor Ortho Biotech, Inc.*, 3 F. Supp. 3d 674 (N.D. Ohio 2014).

²¹⁰ *Id.* at 675.

²¹¹ *Id.*, citing *De Gideo v. Centocor Ortho Biotech*, 2010 WL 4628903, at *1 (N.D. Ohio 2010).

²¹² *Id.* at 675.

²¹³ *Id.* at 677.

²¹⁴ *Id.*

One report Thorton had referenced concerned findings by Tel Aviv Medical Center doctors that, of thirteen patients treated with Remicade for Chrones disease, four had been observed to suffer “from anaphylactic shock, disseminated eruption and eosinophilic pneumonitis.”²¹⁵ 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.”²¹⁶ 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.’”²¹⁷

Thorton furthermore looked to the Bradford Hill criteria to support his professional opinion. Although Bradford Hill posited nine criteria, the *DiGidio* court emphasized that 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.”²¹⁸

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.’”²¹⁹ 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.”²²⁰ 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[.]’”²²¹ 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.”²²²

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 Pentasa to have caused plaintiff’s injuries.”²²³

²¹⁵ *Id.*

²¹⁶ *Id.* at 678.

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.* at 679.

²²⁰ *Id.*

²²¹ *Id.*

²²² *Id.*

²²³ *Id.* at 679-80.

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.”²²⁴ 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.’”²²⁵

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 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.”²²⁶ 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.”²²⁷

Eighth Circuit

[Kuhn v. Wyeth, Inc.](#) (8th Cir. 2012)²²⁸ (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.”²²⁹ 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.”²³⁰

²²⁴ *Id.* at 684.

²²⁵ *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.

²²⁶ *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.

²²⁷ *Id.* at 685.

²²⁸ *Kuhn v. Wyeth, Inc.*, 686 F.3d 618 (8th Cir. 2012).

²²⁹ 686 F.3d at 620-21.

²³⁰ *Id.* at 621.

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.²³¹

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.²³² Plaintiffs appealed, and an 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.²³³ 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."²³⁴ 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."²³⁵ 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."²³⁶

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."²³⁷ He also opined that the NIH-WHI "study's

²³¹ *Id.* at 620.

²³² *Id.*

²³³ *Id.* at 621.

²³⁴ *Id.* at 622.

²³⁵ *Id.*

²³⁶ *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.

²³⁷ *Id.* at 623

estimate of short-term risk was ‘quite poor’ due to shortcomings ‘that diminish[ed] the estimate of the effect of short-term exposure.’”²³⁸ 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 progestin] E + P.”²³⁹ 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 eleven percent of the placebo group began taking E + P.”²⁴⁰

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.²⁴¹ 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.²⁴² 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.’”²⁴³ 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.’”²⁴⁴ 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.”²⁴⁵

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.”²⁴⁶ 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

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ *Id.*

²⁴¹ *Id.* at 624.

²⁴² *Id.*

²⁴³ *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.

²⁴⁴ *Id.* at 625, quoting *Milward*, 639 F.3d at 15.

²⁴⁵ *Id.* at 625, quoting *Daubert*, 509 U.S. at 595 and *Milward*, 639 F.3d at 15.

²⁴⁶ *Id.* at 626.

and inconsistent with his reliance on the study in other hormone therapy cases.”²⁴⁷

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 test whether Prempro causes breast cancer.”²⁴⁸ 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.”²⁴⁹ In other words, “his previous reliance on and testimony regarding the [NIH-]WHI study d[id] not render his opinion inadmissible.”²⁵⁰ 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.”²⁵¹

O’Neal v. Remington Arms Co. (D.S.D. 2016)²⁵² (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.²⁵³ The district court granted defendants’ summary judgment motion, but it denied their motion to exclude Powell’s testimony “as moot.”²⁵⁴ The Eighth Circuit reversed and remanded, concluding that “the record contained sufficiently disputed material facts to preclude entry of summary judgment in Defendants’ favor.”²⁵⁵

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.²⁵⁶ 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

²⁴⁷ *Id.* at 627.

²⁴⁸ *Id.*

²⁴⁹ *Id.* (emphasis added).

²⁵⁰ *Id.* at 627-28.

²⁵¹ *Id.* at 629, 631, 632.

²⁵² *O’Neal v. Remington Arms Co.*, Civ. No. 4:11-CV-04182 (KES) (D.S.D. 2016).

²⁵³ *Id.* at 1.

²⁵⁴ *Id.*

²⁵⁵ *O’Neal v. Remington Arms Co., LLC*, 803 F.3d 974, 982 (8th Cir. 2015).

²⁵⁶ *O’Neal v. Remington Arms Co.*, *supra* note 252, slip op. at 2-3.

is scientifically valid,” employing various factors.²⁵⁷ 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 expert’s conclusions.’”²⁵⁸

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.”²⁵⁹ 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.”²⁶⁰ 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.²⁶¹

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 users from “easily inspect[ing] the connector’s engagement with the sear.”²⁶² 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.”²⁶³

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.”²⁶⁴ According to Powell, the manufacturing defect consisted of “an insufficient

²⁵⁷ *Id.* at 3, quoting *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010).

²⁵⁸ *Id.*, quoting *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012), quoting *Milward*, 639 F.3d at 15.

²⁵⁹ *Id.* at 4.

²⁶⁰ “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.

²⁶¹ *Id.*

²⁶² *Id.*

²⁶³ *Id.* at 6.

²⁶⁴ *Id.*

clearance between the sear and the connector such that if the safety is on and you pull the trigger, the connector will get trapped in front of the sear and [be] allowed to drop.”²⁶⁵ 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.”²⁶⁶

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.”²⁶⁷ 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.”²⁶⁸ 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.”²⁶⁹ 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.²⁷⁰ 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.”²⁷¹

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.”²⁷² 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.’”²⁷³ “Rather, ‘it is [O’Neal’s] burden to show that [Powell] arrived at his...opinion in a scientifically sound and methodological

²⁶⁵ *Id.*

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ *Id.* at 7.

²⁶⁹ *Id.*

²⁷⁰ *Id.*

²⁷¹ *Id.*

²⁷² *Id.* at 8, quoting *Crandell v. Larkin & Jones Appliance Co.*, 334 N.W.2d 31, 34 (S.D. 1983).

²⁷³ *Id.*, quoting *Kuhn*, 686 F.3d at 625 (quoting *Milward*, 639 F.3d at 15).

fashion.”²⁷⁴

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.”²⁷⁵ 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.”²⁷⁶ 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.”²⁷⁷ 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.²⁷⁸

[Sioux Steel Co. v. KC Engineering, P.C.](#) (D.S.D. 2018)²⁷⁹ (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 engineer Chad Kramer, a failure that plaintiff argues led to the bin’s collapse and the employees’ deaths.

²⁷⁴ *Id.*

²⁷⁵ *Id.* at 8.

²⁷⁶ *Id.* at 9 (emphasis added).

²⁷⁷ *Id.*

²⁷⁸ *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.”).

²⁷⁹ *Sioux Steel Co. v. KC Engineering, P.C.*, Civ. No. 4:15-CV-04136-KES (D.S.D. 2018).

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.²⁸⁰ 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.”²⁸¹ 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).²⁸²

Carson’s second report focused on the firing of air cannons based on his review of Agropecuaria’s surveillance video of the failure.²⁸³ 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.²⁸⁴ 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.”²⁸⁵ 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.”²⁸⁶ Plaintiff moved to exclude Carson’s testimony based on his lack of expert qualifications and because his testimony was not reliable.²⁸⁷

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 is scientifically valid.’”²⁸⁸ 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.’”²⁸⁹ The district court quoted *Milward* for the following proposition: “At

²⁸⁰ *Id.*

²⁸¹ *Id.*

²⁸² *Id.* at 2-3.

²⁸³ *Id.* at 3.

²⁸⁴ 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.

²⁸⁵ See SCE, *FAQ Overview: What is Bridging in a Silo?*, <http://sce.be/en/faq/what-is-bridging-in-a-silo>.

²⁸⁶ *Sioux Steel Co. v. KC Engineering, P.C.*, slip op. at 3.

²⁸⁷ *Id.*

²⁸⁸ *Id.* at 5, quoting *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 980 (8th Cir. 2010).

²⁸⁹ *Id.* at 6, quoting *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 625 (8th Cir. 2012) (citing *Daubert*, 509 U.S. at 595).

times, conclusions and methodology are not entirely distinct from one another, and the court ‘need not completely pretermitt judicial consideration of an expert’s conclusions.’”²⁹⁰

The district court found Carson’s expert testimony related to the agricultural industry grain-bin standard reliable²⁹¹ 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;²⁹² 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;²⁹³ 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.”²⁹⁴

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;²⁹⁵ 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;²⁹⁶ 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;²⁹⁷ 4) Carson’s examination of emails between 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’”;²⁹⁸ 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”;²⁹⁹ and 6) although Carson’s “opinions have

²⁹⁰ *Id.* at 6, quoting *Kuhn v. Wyeth, Inc.*, 686 F.3d at 625 (quoting *Milward*, 639 F.3d at 15).

²⁹¹ *Id.* at 11.

²⁹² *Id.* at 8-9.

²⁹³ *Id.* at 10.

²⁹⁴ *Id.* at 10-11.

²⁹⁵ *Id.* at 13-14.

²⁹⁶ *Id.* at 14.

²⁹⁷ *Id.*

²⁹⁸ *Id.*

²⁹⁹ *Id.* at 16.

not been tested nor subject to peer review,” they were “based on his review of other peer reviewed material and his own publications.”³⁰⁰

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.”³⁰¹

[In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation](#) (D. Minn. 2019)³⁰² (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.”³⁰³ 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.”³⁰⁴ 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.”³⁰⁵ Pursuant to the “‘dirty machine’ theory,” “the device, which lacks an adequate filtration system, emits contaminants into the OR, and thus, increases the bacterial load reaching the surgical site.”³⁰⁶

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.³⁰⁷ Defendants countered

³⁰⁰ *Id.*

³⁰¹ *Id.* at 16-17.

³⁰² *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).

³⁰³ *Id.*, slip op. at 1.

³⁰⁴ *Id.* at 2.

³⁰⁵ *Id.*

³⁰⁶ *Id.*

³⁰⁷ *Id.*

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.³⁰⁸ 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.”³⁰⁹

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 “Elghobashi’s testimony as well as on the epidemiological study for reliable mechanistic and statistical evidence that the Bair Hugger causes PJI.”³¹⁰

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.³¹¹ 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.’”³¹²

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 alternative design existed.”³¹³ 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.”³¹⁴

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]

³⁰⁸ *Id.* at 2, 3.

³⁰⁹ *Id.* at 2.

³¹⁰ *Id.* at 3.

³¹¹ *Id.*

³¹² *Id.* at 4.

³¹³ *Id.*

³¹⁴ *Id.*

developed for litigation, which raise[d] concerns about its reliability and objectivity.”³¹⁵ 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.”³¹⁶

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.³¹⁷ 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.”³¹⁸ 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.’”³¹⁹ 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.”³²⁰

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.”³²¹ 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.”³²² The court next compared how plaintiffs’

³¹⁵ *Id.* at 10.

³¹⁶ *Id.* at 22-23.

³¹⁷ *Id.* at 34.

³¹⁸ *Id.*, quoting *Third Edition*, *supra* note 14, at 55-3.

³¹⁹ *Id.* at 34-35.

³²⁰ *Id.* at 35, quoting the observational study (the McGovern (2011) Observational Study), at 8.

³²¹ *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.”).

³²² *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 IHH,’ 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*.

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.”³²³ 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.”³²⁴

The court also primarily emphasized how Samet had “depart[ed] from his own description of reliable methodology when opining about causation.”³²⁵ 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’”).³²⁶ 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.”³²⁷

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.”³²⁸ In support of this conclusion, the court compared Samet’s failure to follow his own methodology with his failure “to employ ‘the ‘same level of intellectual rigor’ that he employs in his academic work.”³²⁹ 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.”³³⁰

³²³ *Id.* at 37.

³²⁴ *Id.*

³²⁵ *Id.* at 37, quoting *Junk v. Terminix Int’l Co.*, 628 F.3d 439, 448 (8th Cir. 2010).

³²⁶ *Id.* at 37.

³²⁷ *Id.* at 37-38.

³²⁸ *Id.* at 38.

³²⁹ *Id.*, quoting *Milward*, 639 F.3d at 26 (quoting *Kumho Tire Co.*, 526 U.S. at 152).

³³⁰ *Id.*, quoting *In re Mirena (No. II)*, 341 F. Supp. 3d at 247.

Ninth Circuit

In re Roundup Products Liability Litigation (N.D. Cal. 2018)³³¹ (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.³³² 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."³³³ 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.³³⁴ 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."³³⁵ As "long as an opinion is premised on reliable scientific principles, it should not be excluded by the trial judge."³³⁶

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 carcinogenic to humans.'"³³⁷ 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."³³⁸ "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."³³⁹ IARC admits that, "although it uses the word 'probably,' it does not intend for that word to have any quantitative significance."³⁴⁰ 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

³³¹ *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).

³³² *Id.*, slip op. at 4, 5.

³³³ *Id.* at 1, 2, 5 (emphasis added).

³³⁴ *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).

³³⁵ *Id.* at 3.

³³⁶ *Id.*

³³⁷ *Id.* at 1.

³³⁸ *Id.* at 2 (emphasis added).

³³⁹ *Id.* (emphasis in original).

³⁴⁰ *Id.*

causation phase, “could conclude by a preponderance of the evidence that glyphosate can cause NHL at exposure levels people realistically could have experienced.”³⁴¹

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.”³⁴² 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.”³⁴³

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.”³⁴⁴ 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.”³⁴⁵

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,”³⁴⁶ based *inter alia* on the following four factors: “(1) whether the expert’s 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.”³⁴⁷ The district court further held that courts must “consider whether the expert’s testimony springs from research independent of the litigation.”³⁴⁸ 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.’”³⁴⁹ 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.”³⁵⁰ It also held that courts “must also

³⁴¹ *Id.*

³⁴² *Id.*

³⁴³ *Id.*

³⁴⁴ *Id.* at 3.

³⁴⁵ *Id.*

³⁴⁶ *Id.* at 7-8, quoting *Daubert v. Merrell Dow Pharmaceuticals, Inc. (Daubert II)*, 43 F.3d 1311, 1317 (9th Cir. 1995).

³⁴⁷ *Id.* at 8, citing *Daubert*, 509 U.S. at 593-94.

³⁴⁸ *Id.* at 8, citing *Daubert II*, 43 F.3d at 1317.

³⁴⁹ *Id.* at 8, citing *Daubert II*, 43 F.3d at 1317-19.

³⁵⁰ *Id.* at 8, citing *Kumho Tire Co., Ltd.*, 526 U.S. at 141-42.

consider whether, for a given conclusion, ‘there is simply too great an analytical gap between the data and the opinion proffered.’”³⁵¹ In sum, “both unsound methods and unjustified extrapolations from existing data can require the Court to exclude an expert.”³⁵²

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.”³⁵³

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”³⁵⁴ employing the Bradford Hill criteria.³⁵⁵ Accepting that reasonable 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*³⁵⁶ and *Milward*,³⁵⁷ 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

³⁵¹ *Id.* at 8, quoting *Joiner*, 522 U.S. at 146.

³⁵² *Id.* at 8.

³⁵³ *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).

³⁵⁴ *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.

³⁵⁵ *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 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).

³⁵⁶ 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.’”).

³⁵⁷ 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.

admissibility.³⁵⁸

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.”³⁵⁹ Consistent with *Milward*, the district court determined that a “broad survey of the available evidence is neither unusual in expert testimony nor necessarily inappropriate.”³⁶⁰ 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.”³⁶¹ 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.’”³⁶²

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.³⁶³ 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’ National Center for Environmental Health.³⁶⁴

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.”³⁶⁵

Third, the court found reasonable and “reliable” Portier’s heavier weighting of “the case-control studies than the AHS [Agricultural Health Study], a cohort study³⁶⁶ [...] 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

³⁵⁸ *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).

³⁵⁹ *Id.* at 35.

³⁶⁰ *Id.* at 35 citing *Milward*, 639 F.3d at 19-20.

³⁶¹ *Id.*

³⁶² *Id.*, citing and quoting *Milward*, 639 F.3d at 22.

³⁶³ *Id.* at 36.

³⁶⁴ *Id.*

³⁶⁵ *Id.* at 39.

³⁶⁶ *Id.*

glyphosate.”³⁶⁷ 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.”³⁶⁸

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.”³⁶⁹ 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.”³⁷⁰ The court then adjudged Portier’s assessment of animal carcinogenicity data, and thus his biological plausibility conclusion as admissible, except for his pooled analysis.³⁷¹

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.”³⁷²

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.”³⁷³

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.

³⁶⁷ *Id.* at 24-25.

³⁶⁸ *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.”).

³⁶⁹ *Id.* at 30-31.

³⁷⁰ *Id.* at 30.

³⁷¹ *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.”).

³⁷² *Id.* at 48.

³⁷³ *Id.* at 47, citing *Daubert II*, 43 F.3d at 1318.

Tenth Circuit

[Cattaneo v. Aquakleen Products, Inc.](#) (D. Colo. 2012)³⁷⁴ (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."³⁷⁵ 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.³⁷⁶

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."³⁷⁷ It then denied defendant's motion for summary judgment because it concluded there was insufficient evidence on whether AquaKleen had "knowingly or recklessly sent an unqualified person to inspect and investigate Plaintiffs' complaints, said person misrepresented the company had tested the water for the presence of contaminants, and the company had thereafter failed or otherwise refused to retest the water subjecting Plaintiffs to further sewage contaminated water."³⁷⁸

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.³⁷⁹ 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*."³⁸⁰

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]

³⁷⁴ *Cattaneo v. Aquakleen Products, Inc.*, Civ. No. 10-cv-02852-RBJ-MJW (D. Colo. 2012).

³⁷⁵ *Id.*, slip op. at 1.

³⁷⁶ *Id.* at 1, 5.

³⁷⁷ *Id.* at 2, 4.

³⁷⁸ *Id.* at 4-5.

³⁷⁹ *Id.* at 5.

³⁸⁰ *Id.*, citing *Milward*, 639 F.3d at 17-19.

from the facts [...]”, and that, “in his opinion, there [was] no plausible alternative explanation for the development of the illnesses.”³⁸¹ 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.”³⁸²

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.”³⁸³ 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 jury.”³⁸⁴

[Walker v. Spina](#) (D.N.M. 2019)³⁸⁵ (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.³⁸⁶

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,””³⁸⁷ 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]

³⁸¹ *Id.* at 5 (emphasis added).

³⁸² *Id.*

³⁸³ *Id.* at 6.

³⁸⁴ *Id.*

³⁸⁵ *Walker v. Spina*, Civ. No. 17-0991 JB\SCY (D.N.M. 2019).

³⁸⁶ *Id.*, slip op at 2.

³⁸⁷ *Id.*

not supported by economic principles or literature.”³⁸⁸ 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.’”³⁸⁹ 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.”³⁹⁰ 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.’”³⁹¹

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.”³⁹² 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 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.”³⁹³

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.”³⁹⁴ 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”³⁹⁵ because “New Mexico federal district courts routinely exclude such testimony.”³⁹⁶

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.”³⁹⁷ Recognizing that FRE 702 governs the admissibility of expert testimony and that ‘*Daubert* require[d] the Court to ‘scrutinize the proffered expert’s

³⁸⁸ *Id.* at 3.

³⁸⁹ *Id.* at 4.

³⁹⁰ *Id.*

³⁹¹ *Id.*

³⁹² *Id.* at 5.

³⁹³ *Id.*

³⁹⁴ *Id.*

³⁹⁵ *Id.* at 6.

³⁹⁶ *Id.*

³⁹⁷ *Id.* at 6-7.

reasoning to determine if that reasoning is sound,”³⁹⁸ 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.”³⁹⁹ 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.”⁴⁰⁰ To this end, the court also recited the five non-exclusive factors “that weigh into a district court’s first-step reliability determination,⁴⁰¹ 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.’”⁴⁰²

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.”⁴⁰³ The court quoted, on the one hand, the Second Circuit’s *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 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.⁴⁰⁴ *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.”⁴⁰⁵ *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.”⁴⁰⁶

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.”⁴⁰⁷ The court further held in dicta that the basis of this conflict derives from the discomfort lower federal district courts have experienced

³⁹⁸ *Id.* at 7, quoting *United States v. Gutierrez-Castro*, 805 F. Supp. 2d 1218, 1224 (D.N.M. 2011).

³⁹⁹ *Id.* at 8.

⁴⁰⁰ *Id.*, citing *Daubert*, 509 U.S. at 594-95.

⁴⁰¹ 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.*

⁴⁰² *Id.* at 9, quoting *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878 (10th Cir. 2005) (quoting *Daubert*, 509 U.S. at 589, 592).

⁴⁰³ *Id.* at 20, n. 4.

⁴⁰⁴ *Id.*

⁴⁰⁵ *Id.*, quoting *Ruggiero*, 424 F.3d at 255.

⁴⁰⁶ *Id.*, quoting *Milward*, 639 F.3d at 22.

⁴⁰⁷ *Id.* at 20, n. 4.

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.”⁴⁰⁸ 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.”⁴⁰⁹

Eleventh Circuit

[In re Chantix \(Varenicline\) Products Liability Litigation](#) (N.D. Ala. 2012)⁴¹⁰ (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.”⁴¹¹ 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.”⁴¹² Defendant moved to exclude certain general causation and liability opinions offered by plaintiffs’ experts.⁴¹³

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.’”⁴¹⁴ 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

⁴⁰⁸ *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”).

⁴⁰⁹ *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.”).

⁴¹⁰ *In re Chantix (Varenicline) Products Liability Litigation*, 889 F. Supp. 2d 1272 (N.D. Ala. 2012).

⁴¹¹ *Id.* at 1277.

⁴¹² *Id.*

⁴¹³ *Id.*

⁴¹⁴ *Id.* at 1279, quoting *Daubert*, 509 U.S. at 592.

that reasoning or methodology properly can be applied to the facts in issue.”⁴¹⁵ 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* factors⁴¹⁶ 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.’”⁴¹⁷

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.”⁴¹⁸

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.’”⁴¹⁹ 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.”⁴²⁰

In reaching this conclusion, the court referenced the U.S. Supreme Court’s decision in *Matrixx 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

⁴¹⁵ *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.

⁴¹⁶ *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.”

⁴¹⁷ *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.

⁴¹⁸ *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.”).

⁴¹⁹ *Id.* at 1285.

⁴²⁰ *Id.*

an inference of causation.”⁴²¹ 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.’”⁴²² The court declined to find Furberg’s testimony inadmissible because he could not “‘establish a valid statistical association between Chantix and serious neuropsychiatric events.’”⁴²³

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 statistical association, and her failure “consider the presence or absence of a dose-response relationship.”⁴²⁴ 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,”⁴²⁵ 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...”⁴²⁶

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.”⁴²⁷ 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*.”⁴²⁸ 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.”⁴²⁹

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

⁴²¹ *Id.* at 1286, quoting *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1319 (2011).

⁴²² *Id.*, quoting *Matrixx Initiatives, Inc.* (quoting *Wells*, 788 F.2d 741, 744-45 (11th Cir. 1986)).

⁴²³ *Id.* at 1286.

⁴²⁴ *Id.* at 1287.

⁴²⁵ *Id.* at 1288.

⁴²⁶ *Id.*

⁴²⁷ *Id.*

⁴²⁸ *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.”).

⁴²⁹ *Id.* at 1292-93.

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.”⁴³⁰ 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.”⁴³¹ The court recognized the difference in opinion between Bechara and defendant’s expert, Dr. Charles Dackis, over whether dopamine depletion can occur with 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.”⁴³² 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.”⁴³³ “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.”⁴³⁴

[Jones v. Novartis Pharmaceuticals Corporation](#), (N.D. Ala. 2017)⁴³⁵ (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.”⁴³⁶ 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.⁴³⁷

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 report⁴³⁸ which plaintiff had offered to establish general causation.⁴³⁹

⁴³⁰ *Id.* at 1298-99.

⁴³¹ *Id.* at 1299.

⁴³² *Id.* at 1300.

⁴³³ *Id.*, quoting *Milward*, 639 F.3d at 22.

⁴³⁴ *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.

⁴³⁵ *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).

⁴³⁶ *Jones*, 235 F. Supp. 3d at 1249.

⁴³⁷ *Id.*

⁴³⁸ *Id.* at 1265.

⁴³⁹ *Id.* at 1266-67.

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]”⁴⁴⁰ 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,”⁴⁴¹ the court then noted how the Bradford Hill factors are “widely used in the scientific community to assess general causation.”⁴⁴² The court cited *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.’”⁴⁴³

The district court, in addition, found that, while the Eleventh Circuit had “not yet directly commented on the Bradford 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.⁴⁴⁴ 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.’”⁴⁴⁵

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 Eesomeprazole*⁴⁴⁶),⁴⁴⁷ 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.⁴⁴⁸ “These resources explain that the Bradford Hill factors cannot

⁴⁴⁰ *Id.* at 1267.

⁴⁴¹ *Id.* citing *Milward*, 639 F.3d at 17.

⁴⁴² *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)).

⁴⁴³ *Id.* at 1267-68, quoting *Milward*, 639 F.3d at 17.

⁴⁴⁴ *Id.* at 1268.

⁴⁴⁵ *Id.*, quoting *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 28 cmt. c(3) (2010).

⁴⁴⁶ See *In re Nexium Eesomeprazole*, 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.”).

⁴⁴⁷ *Id.* at 1268-69.

⁴⁴⁸ *Id.*

be applied without first establishing a causal association,”⁴⁴⁹ consistent with *Milward*.⁴⁵⁰

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.⁴⁵¹ 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.”⁴⁵² 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*.⁴⁵³

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.”⁴⁵⁴ 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.”⁴⁵⁵

[In re Abilify \(Aripiprazole\) Products Liability Litigation](#) (N.D. Fla. 2018)⁴⁵⁶ (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 [...]

⁴⁴⁹ *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.”).

⁴⁵⁰ *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).

⁴⁵¹ *Id.* at 1269-70.

⁴⁵² *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.”).

⁴⁵³ *Id.* at 1272.

⁴⁵⁴ *Id.* at 1272-73.

⁴⁵⁵ *Id.* at 1273.

⁴⁵⁶ *In re Abilify (Aripiprazole) Products Liability Litigation*, 299 F. Supp. 3d 1291 (N.D. Fla. 2018).

impulsive gambling, eating, shopping, and sex.”⁴⁵⁷ Defendant manufacturers and marketers (Otsuka 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 uncontrollable impulsive behaviors in individuals taking the drug.”⁴⁵⁸ 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.⁴⁵⁹ 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.”⁴⁶⁰ In addition, the Eleventh Circuit has held “three ‘primary’ methodologies ‘indispensable’ for proving that a drug can cause a specific adverse effect: epidemiological studies,⁴⁶¹ dose-response relationship,⁴⁶² and background risk of disease.”⁴⁶³ Consequently, “[a] general causation opinion that is not supported by at least one of these primary methodologies is unreliable as a matter of law.”⁴⁶⁴ 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,⁴⁶⁵ case studies and adverse event reports, extrapolations from [*in*

⁴⁵⁷ *Id.* at 1300-01.

⁴⁵⁸ *Id.* at 1301.

⁴⁵⁹ *Id.* at 1304.

⁴⁶⁰ *Id.* at 1306.

⁴⁶¹ Epidemiology is “the branch of science that studies the incidence, distribution, and cause of disease in human populations.” *Id.*

⁴⁶² 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.

⁴⁶³ “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.

⁴⁶⁴ *Id.* at 1306, citing *Chapman v. Procter & Gamble Distributing, LLC*, 766 F.3d 1296, 1308 (11th Cir. 2014).

⁴⁶⁵ “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.*

vivo] animal⁴⁶⁶ and *in vitro* studies,⁴⁶⁷ and extrapolations from analogous drugs.”⁴⁶⁸

The district court considered epidemiological studies as providing the “best evidence of causation in toxic tort actions.”⁴⁶⁹ 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.”⁴⁷⁰ The district court emphasized that the “nine well-established” Bradford Hill factors, none of which is dispositive, serve to guide the causation inquiry.”⁴⁷¹ 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.”⁴⁷² 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.”⁴⁷³

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.”⁴⁷⁴ 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.”⁴⁷⁵ Again citing *Milward*, the

⁴⁶⁶ 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.” *Id.* at 1310.

⁴⁶⁷ “[I]n *in 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 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.

⁴⁶⁸ *Id.* at 1306.

⁴⁶⁹ *Id.* at 1306, quoting *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002),

⁴⁷⁰ *Id.* at 1306-07.

⁴⁷¹ *Id.* at 1307.

⁴⁷² *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.”).

⁴⁷³ *Id.* at 1307, citing *Rider*, 295 F.3d at 1198. See also *id.* at 1352, citing *Milward*, 639 F.3d at 18.

⁴⁷⁴ *Id.* at 1311.

⁴⁷⁵ *Id.* citing *Milward*, 639 F.3d at 17; *In re Zolofit (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

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 rigor’ used by experts in the field.”⁴⁷⁶

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.”⁴⁷⁷ The court also considered the defendants’ objections to the study’s deficient design, failure to consider the risk of confounders,⁴⁷⁸ 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*.⁴⁷⁹ 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.⁴⁸⁰ 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.”⁴⁸¹

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.”⁴⁸² 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

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; *Jones*, 235 F. Supp. at 1273.

⁴⁷⁶ *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.

⁴⁷⁷ *Id.* at 1313-14.

⁴⁷⁸ *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.* (“Confounding 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.”).

⁴⁷⁹ *Id.* at 1315-21 (design); at 1321-25 (confounding); at 1325-27 (bias).

⁴⁸⁰ *Id.* at 1327-29.

⁴⁸¹ *Id.* at 1330.

⁴⁸² *Id.*

their conclusions as to dose-response.”⁴⁸³ 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 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).”⁴⁸⁴

Furthermore, the court examined plaintiffs’ experts’ evidence “provid[ing] 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*.⁴⁸⁵

The district court, moreover, examined plaintiffs’ experts’ evidence of biological plausibility,⁴⁸⁶ which it distinguished from “biological certainty.”⁴⁸⁷ 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.”⁴⁸⁸ 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.”⁴⁸⁹ 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.⁴⁹⁰

⁴⁸³ *Id.* at 1331.

⁴⁸⁴ *Id.* (italicized emphasis in original; underlined emphasis added.).

⁴⁸⁵ *Id.* at 1332.

⁴⁸⁶ *Id.* at 1332-44.

⁴⁸⁷ *Id.* at 1344.

⁴⁸⁸ *Id.*

⁴⁸⁹ *Id.*

⁴⁹⁰ *Id.*, citing *Milward*, 639 F.3d at 25-26.