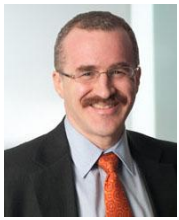
Manning the *Daubert* Gate: A Defense Primer in Response to *Milward v. Acuity Specialty Products*

By Eric Lasker

ON JANUARY 9, 2012, the United States Supreme Court denied *certiorari* in *Milward v. Acuity Specialty Prods. Group, Inc*.[1] and, in so doing, let stand a First Circuit holding that a plaintiff expert's medical causation opinion resting solely on a self-proclaimed "weight of the evidence" analysis satisfied the *Daubert* requirements of scientific reliability and relevance. Even prior to the Supreme Court's *certiorari* decision, the plaintiff bar and its allies heralded *Milward* as holding out the "promise of reshaping toxic tort causation law,"[2] and the newly-issued Restatement (Third) of Torts had labeled *Milward* "[o]ne of the most significant toxic tort causation cases in recent memory."[3] With *Milward* now final, defendants in toxic tort, pharmaceutical, and other science-based litigation can anticipate confronting *Milward* in response to any future *Daubert* challenge to plaintiff causation experts.

In the author's opinion, *Milward* was wrongly decided and flies in the face of the Supreme Court's holdings in *Daubert v. Merrell Dow Pharms., Inc*.[4] and *General Elec. Co. v. Joiner*.[5] However, any discussion of the *Milward* opinion also cannot be divorced from the factual pattern from which it arose. In *Milward*, the plaintiffs' expert was opining on causation with respect to a very rare form of cancer, and each side acknowledged there currently was—and perhaps could only ever be—limited scientific evidence on causation. While *Daubert* clearly cautions that "[l]aw lags science"[6] and that "the balance … struck by the Rules of Evidence" requires exclusion even of potentially "authentic insights and innovations,"[7] *Daubert* decisions involving such potentially unprovable scientific issues have repeatedly proved the adage that "bad facts make bad law." The *Milward* should be properly understood in this limiting context.



Eric Lasker is a partner in the Washington, D.C. law firm, Hollingsworth LLP, and is Chair of the Toxics & Hazardous Substances Committee of the International Association of Defense Counsel. Mr. Lasker was amicus counsel for a coalition of industry associations that supported Petitioners' efforts to secure certiorari review of Milward *in the U.S. Supreme Court.*

[1] 639 F.3d 11 (1st Cir. 2011).

[2] Steve C. Gold, *The "Reshapement" of the False Negative Asymmetry in Toxic Tort Causation*, 37 WM. MITCHELL L. REV. 1507, 1580 (2011).

[3] Michael D. Green, *Introduction: The Third Restatement of Torts in a Crystal Ball*, 37 WM. MITCHELL L. REV. 993, 1010 n.53 (2011).

[4] 509 U.S. 579 (1993).

[5] 522 U.S. 136 (1997).

[6] Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996).

[7] *Daubert*, 509 U.S. at 597.

Defendants must, of course, continue to hold courts to their proper gate-keeping responsibilities under *Daubert* even in cases involving novel causation issues. By definition, however, the type of claimed-unprovable causation question at issue in *Milward* is more the exception than the rule. In most cases, including those involving an FDA- or EPA-regulated product, plaintiff experts will be offering causation opinions regarding relatively more common diseases and potential exposures as to which there is an established body of scientific evidence. *Milward* has little to say about these cases. Indeed, based upon the author's experience in prior litigation handled by his firm, *Milward* may not be predictive even of how the First Circuit will address expert causation testimony in future cases.

This article will provide a defense primer on how to respond to plaintiffs' use of *Milward*, both in cases involving novel causation issues and in the more common situation in which the plaintiff's expert is faced with an existing body of scientific knowledge. Section I reviews the *Milward* opinion, both at the district court and the First Circuit. Section II focuses on the numerous legal flaws in *Milward*, which should limit its applicability in other federal circuits that properly apply the *Daubert* gatekeeping standards. Section III addresses the narrow factual setting in which *Milward* arose, which also should limit its applicability in future cases, even within the First Circuit. Finally, Section IV recounts how the author's law firm addressed and negated a similarly flawed *Daubert* ruling from the Eighth Circuit Court of Appeals in successfully defending a *Daubert* victory in a pharmaceutical products liability action in the same Court less than a year later.

I. The Flawed *Milward* Ruling

Milward is a products liability case in which the plaintiff alleges that workplace exposures to benzene-containing products caused a rare type of acute myeloid leukemia (AML) called acute promyelocytic leukemia (APL). As the defendants' own experts acknowledged before the district court, there is no dispute that scientific and medical evidence supports a causal link between benzene and the development of AML.[8] However, as the defendants' experts also explained, "clear differences exist among AML subtypes that may make inappropriate a broad extrapolation from AML generally to APL specifically."[9] Plaintiffs' expert acknowledged that there are no epidemiological studies demonstrating a causal link between benzene and APL, but he argued that the rarity of APL made it very difficult to perform such an epidemiological study.[10] Instead, plaintiffs' expert argued that causation could be inferred from an analogy between APL and other types of AML known to be associated with benzene, experimental research on AML etiology, and toxicological studies of chromosomal impacts of benzene exposure through the inhibition of an enzyme called topoisom erase II (topo II). While none of these pieces of evidence

[8] Milward v. Acuity Specialty Prods. Group, Inc., 664 F. Supp.2d 137, 144 (D. Mass. 2009), *rev'd*, 639 F.3d 11 (1st Cir. 2011).
[9] *Id.*
[10] *See Milward*, 639 F.3d at 24.

provided reliable support of causation in and of itself, plaintiffs' expert opined that the "weight of the evidence" demonstrated that benzene could cause APL.[11]

After carefully reviewing each of the plaintiff experts' different lines of scientific evidence, the district court excluded the expert's causation opinion under *Daubert*. The district court explained that the plaintiffs' expert's opinion "that because benzene metabolites inhibit topo II and because some classes of topo II inhibitors appear to have a causal relationship to APL, therefore benzene has a causal relationship to APL is at best a theory and at worst an error." [12] The district court held that while the plaintiffs' expert causation hypotheses were "'plausible,' they remain hypotheses, the validity of which has not been reliably established. As such, they are not admissible as 'scientific knowledge' under Rule 702."[13]

The First Circuit reversed. The First Circuit did not directly dispute any of the district court's conclusions with respect to the individual lines of causation evidence. The Court held, however, that the district court "erred in reasoning that because no one line of evidence supported a reliable inference of causation, an inference of causation based on the totality of the evidence was unreliable."[14] The district court's error – according to the First Circuit –

> derived from a mistake in its understanding of the weight of the evidence methodology employed by [plaintiffs' expert]. The court treated the separate evidentiary components of [the expert's] analysis atomistically, as though his ultimate opinion was *independently* supported by each. … [But in the expert's] weight of the evidence approach, no body of evidence was itself treated as justifying an inference of causation. Rather, each body of evidence was treated as grounds for the subsidiary conclusion that it would, if combined with other evidence, support a causal inference.[15]

The First Circuit explained that the plaintiffs' expert's "weight of the evidence" approach employed the methodology of abductive inference or inference to the best explanation, whereby rather than drawing conclusions through logical inferences from known propositions or from a range of known particulars, conclusions "are drawn about a particular proposition or event by a process of eliminating all other possible conclusions to arrive at the most likely one, the one that best explains the available data."[16] The Court further explained that "[b]ecause no scientific methodology exists for this process … reasonable scientists may come to different judgments about whether such an inference is appropriate."[17]

In reversing the district court opinion, the First Circuit held that "[n]o serious argument can be made that the weight of the evidence approach is

[11] *See id.* at 19-20.
[12] *Milward*, 664 F. Supp.2d at 148.
[13] *Milward*, 664 F. Supp.2d at 149.
[14] *Milward*, 639 F.3d at 23.
[15] *Id.*
[16] *Id.* at 18 n.7.
[17] *Id.* at 18 (internally quotations omitted).

inherently unreliable."[18] The Court allowed, however, that the "admissibility [of weight of the evidence testimony] must turn on the particular facts of the case."[19] One of the key "particular facts" in *Milward* was the rarity of the disease at issue.[20] This fact was central in the First Circuit's discussion of the lack of epidemiological support for the plaintiffs' expert's causation opinion: "[T]his is a case in which there is a lack of statistically significant epidemiological evidence, and in which the rarity of APL and difficulties of data collection in the United States make it very difficult to perform an epidemiological study of the causes of APL that would yield statistically significant results."[21] In this context, the First Circuit's findings of a "near-consensus among government agencies, experts, and active researchers in the field that benzene can cause AML as a class" undoubtedly carried even more weight.[22]

II. Attacking *Milward* on the Law

The First Circuit's opinion in *Milward* is premised on legal holdings that are contrary to the Supreme Court's clear instructions in *Daubert* and *Joiner*. As such, *Milward* should have only limited value to plaintiffs and plaintiffs' experts confronting *Daubert* challenges in other jurisdictions.

Milward's central legal error lies in its failure to address the inherently *ipse dixit* nature of the plaintiffs' expert's "weight of the evidence" methodology. In endorsing plaintiffs' expert's "inference to the best explanation" approach, the First Circuit readily acknowledged that "no scientific methodology exists for this process."[23] But *Daubert* expressly holds that "in order to qualify as 'scientific knowledge,' an [expert's] inference or assertion *must* be derived by the scientific method."[24] And *Daubert* explains that "scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry."[25] While a trial court can—as the district court did in *Milward*—review individual lines of scientific evidence to determine whether they meet this admissibility threshold, there is no way for a court to so evaluate the "weight of the evidence" approach followed by the Milwards' expert. An "inference to the best explanation" cannot be tested, it cannot be falsified, and it cannot be validated against known or potential rates of error. Ultimately, then, the court is left with nothing but the expert's self-serving assurances that he has weighed the evidence in a scientifically appropriate manner.

In *Joiner*, the Supreme Court made clear that such expert assurances are not enough. In reversing an Eleventh Circuit

[18] *Id.* at 17.
[19] *Id.*
[20] As the First Circuit noted, APL "is an extremely rare disease. APL accounts for only five to ten percent of all cases of AML, which is itself rare, with an annual incidence of 3.5 cases per 100,000 people." *Id.* at 16.
[21] *Id.* at 24.
[22] *Id.* at 19.
[23] *Id.* at 18.
[24] *Daubert*, 509 U.S. at 590 (emphasis added).
[25] *Id.* at 593.

opinion very much like the First Circuit opinion in *Milward*, the Court first examined each line of evidence proffered by the plaintiffs' causation expert to determine whether that evidence supported the expert's opinion under the scientific method, and the Court concluded that each line of evidence was deficient.[26] The Court then rejected plaintiffs' argument that a court must nonetheless defer to an expert's conclusion based on an undefined weighing of this same evidence, explaining that "conclusions and methodology are not entirely distinct from one another."[27] As the Court explained, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit evidence that is connected to existing data only by the *ipse dixit* of an expert." Accordingly, the "weight of the evidence" approach advocated by Mr. Joiner's experts—the same methodology improperly endorsed by the First Circuit in *Milward*—was only able to garner a single vote on the Court.[28] Remarkably, the First Circuit does not even note the *Joiner* majority's holding in its opinion.

While the First Circuit now stands in direct contravention of *Joiner*, courts in other jurisdictions properly have followed the Supreme Court's guidance. The Fifth and Tenth Circuits, along with numerous courts in other jurisdictions, have expressly rejected causation opinions in which experts sought to aggregate individually unreliable lines of scientific evidence into a purportedly reliable "weight of the evidence."[29]

[26] *Joiner*, 522 U.S. at 144-145.
[27] *Id.* at 146.
[28] *See id.* at 153-154 (Stevens, J., dissenting).

[29] *See* Allen v. Pa. Eng'g Corp., 102 F.3d 194, 198 (5th Cir. 1996) ("We are also unpersuaded that the 'weight of the evidence' methodology these experts use is scientifically acceptable for demonstrating a medical link between Allen's EtO exposure and brain cancer."); Hollander v. Sandoz Pharms. Corp., 289 F.3d 1193, 1216 n.21 (10th Cir. 2002) (plaintiffs "maintain that even though each individual category of evidence may be insufficient, all of the evidence considered as a whole raises factual questions as to whether Parlodel caused her stroke. [Plaintiffs] cite no legal authority in support of this approach, and in our view, this argument is inconsistent with *Daubert*."); Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp.2d 584, 608 (D. N.J. 2002) ("Where, as here, elements of judgment pervade the methodology, it is essential that the expert set forth the method for weighing the evidence upon which his opinion is based. Absent that, this Court's role as gatekeeper to assess the reliability of the methodology applied in this case is nullified."); Caraker v. Sandoz Pharms. Corp., 188 F. Supp.2d 1026, 1040 (S.D. Ill. 2001) (plaintiffs' experts' reliance on the totality of individually deficient lines of scientific evidence "amounts to a hollow whole of hollow parts"); Siharath v. Sandoz Pharms. Corp., 131 F. Supp.2d 1347, 1371 (N.D. Ga. 2001) ("one cannot lump together lots of hollow evidence in an attempt to determine what caused a medical harm"), *aff'd* Rider v. Sandoz Pharms. Corp., 295 F.3d 1194 (11th Cir. 2002). For similar rulings in states that have adopted *Daubert*, *see also* Merck & Co. v. Garza, 347 S.W.3d 256, 268 (Tex. 2011) ("The totality of the evidence cannot prove general causation if it does not meet the standards for scientific reliability .... A plaintiff cannot prove causation by presenting different types of unreliable evidence."); Estate of George v. Vermont League of Cities & Towns, 993 A.2d 367, 379-380 (Vt. 2010)

Moreover, the First Circuit's *Milward* "weight of the evidence" analysis is in no way bolstered by the use of the weight of the evidence approach by regulatory agencies. Regulatory agencies are governed by a preventative perspective, in which regulators will often err on the side of caution in the absence of clear scientific evidence. In this context, the weight of the evidence approach can be a useful tool because it aids regulators in developing precautionary standards whereby hypothetical risks then can be tested in a more effective manner. But the scientific methodology set forth in *Daubert* requires that testing and validation occur before evidence is admissible in court. Thus, a number of courts have rejected the argument that a regulatory decision-making constitutes admissible scientific evidence of causation in a tort case.[30] Notably, regulatory decision makers agree.[31]

The First Circuit also erred as a matter of law to the extent that it lowered the admissibility bar based upon a perceived difficulty in the case of an extremely rare disease to obtain the scientific evidence that would normally be required to establish causation.[32] Under the scientific method, an expert witness cannot reliably opine based upon the assumption that missing evidence, if it existed, would support a causal hypothesis. Rather, "[p]roposed testimony must be supported by appropriate validation – *i.e.*, 'good grounds,' based on what is known."[33] In apparently following the contrary rule of allowing law to lead science, the First Circuit once again broke from the holdings of other federal circuits that have more faithfully hewed to the Supreme Court's teachings.[34]

(affirming exclusion of "weight of the evidence" causation testimony where plaintiffs' expert "did not specify the precise weight he gave each study or how he reached his conclusion when the studies, taken together, demonstrated a statistically significant result, when seventy-five percent of the studies, individually, failed to reach that conclusion.").

[30] *See*, *e.g.*, *Rider*, 295 F.3d at 1201 ("A regulatory agency such as the FDA may choose to err on the side of caution. Courts, however, are required by the *Daubert* trilogy to engage in objective review of the evidence to determine whether it has sufficient scientific basis to be considered reliable."); Glastetter v. Novartis Pharms. Corp., 252 F.3d 986, 991 (8th Cir. 2001) ("The methodology employed by a government agency results from the preventive perspective that the agencies adopt in order to reduce exposure to harmful substances. ... The FDA's 1994 decision that Parlodel can cause strokes is unreliable proof of medical causation in the present case because the FDA employs a reduced standard (vis-a-vis tort liability) for gauging causation when it decides to rescind drug approval.") (internal quotations omitted).

[31] *See Labeling of Diphenhydramine-Containing Drug Products for Over-the-Counter Human Use*, 67 Fed. Reg. 72,555, at 72,556 (Dec. 6, 2002) ("FDA's decision to act in an instance such as this one need not meet the standard of proof required to prevail in a private tort action. ... To mandate a warning or take similar regulatory action, FDA need not show, nor do we allege, actual causation.") (citing *Glastetter*).

[32] *Milward*, 639 F.3d at 24.

[33] *Daubert*, 509 U.S. at 590.

[34] *See*, *e.g.*, Wells v. SmithKline Beecham Corp., 601 F.3d 375, 381 (5th Cir. 2010)

III. Limiting *Milward* On Its Facts

While the First Circuit erred as a matter of law in factoring the lack of existing science into its *Daubert* analysis, defendants should take pains in future *Daubert* challenges to explain the limiting factual context from which *Milward* arose. There certainly will continue to be cases like *Milward* in which defendants are confronted with speculative expert causation opinions on novel or uncharted scientific issues. However, toxic tort and pharmaceutical litigation today is driven by mass, serial claims against deep pocket manufacturers of FDA- and EPA-regulated products. By their nature, these claims often involve relatively more common medical conditions and purported causative agents that have been extensively tested for human safety. Accordingly, in most cases, plaintiffs' experts will not be able to hide behind a lack of existing scientific knowledge as a defense for their speculative causation theories. *Milward* does not speak to these cases.

In *Milward*, plaintiffs had at least a facially plausible argument to explain away the lack of statistically significant epidemiological studies associating benzene with APL. While the First Circuit's conclusion that APL is so rare as to preclude any meaningful epidemiological study is likely mistaken,[35] it is certainly the case that one would expect less scientific evidence to exist for a disease with an annual incidence of 1 in a million than for more common medical ailments like heart disease, stroke, diabetes, or more common cancers. But it is often these more common diseases that predominate in toxics and pharmaceutical liability litigation, both because of the inherently larger potential plaintiff pool and the governing litigation model in which

("Perhaps Requip is a cause of problem gambling, but the scientific knowledge is not yet there. [Plaintiff] urges the law to lead science – a sequence not countenanced by *Daubert*. And while the possibilities of their relationship properly spark concerns sufficient to warrant caution, the courts must await its result."); *Rider*, 295 F.3d at 1202 ("Given time, information, and resources, courts may only admit the state of science as it is. Courts are cautioned not to admit speculation, conjecture, or inferences that cannot be supported by sound scientific principles."); *Rosen*, 78 F.3d at 319 ("The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.") *See also, e.g.*, Perry v. Novartis Pharms. Corp., 564 F. Supp.2d 452, 468 (E.D. Pa. 2008) ("In cases where no adequate study shows the link between a substance and a disease, expert testimony will generally be inadmissible, even if there are hints in the data that some link might exist. This may mean that early victims of toxic torts are left without redress because they are unable to prove their cases with the scientific data that exists. While this is a regrettable result in those individual cases, it is an unavoidable reality of the structure of our legal system and is necessary to protect the interests of defendants who might otherwise be subject to crippling verdicts on the basis of slender scientific evidence.").

[35] *See, e.g.*, Mandegary A., et al., *Gluthatione-S-Transferase T1-null Genotype Predisposes Adults to Acute Promyelocytic Leukemia; a Case-Control Study*, 12(5) ASIAN PAC. J. CANCER PREV. 1279-1282 (2011) (finding statistically significant increased risk of APL associated with certain polymorphisms of GST proteins).

plaintiffs' counsel aggregate claims through mass marketing and other forms of solicitation. For similar reasons, toxics and pharmaceutical litigation is comprised primarily of claims against products as to which there are (at least arguably) widespread exposures.

In a case involving a relatively more common medical condition and a relatively more common exposure, a plaintiff expert's argument that he should not be required to proffer existing, reliable scientific evidence in support of his causation theory is unavailing. Certainly, in cases in which there is an existing body of epidemiological evidence, *Milward* is inapposite on its face.[36] But *Milward* apparently turned not only on the lack of existing epidemiological studies, but on the perceived inequity in requiring scientific studies that the Court believed because of the rarity of APL would be extremely difficult to conduct.[37] No such arguable inequity exists in cases involving more common diseases and exposures. In this more frequent, the lack of existing epidemiological or other reliable scientific studies instead suggests that there is no causal association or, at the very least, provides a court with greater comfort in requiring an expert to proffer such studies before bringing a causation claim before a jury.

Moreover, where—as is often the case—the product that has allegedly caused a plaintiff's injury is regulated by the FDA or EPA for human health safety, there will be a significant body of scientific evidence that may speak to the causation issue before the court. For example, to obtain FDA approval of a prescription drug, a pharmaceutical company must submit voluminous scientific evidence to the agency in accordance with statutory requirements set forth in the Food, Drug and Cosmetic Act.[38] Likewise, the EPA requires manufacturers to submit extensive scientific studies demonstrating that chemicals, pesticides, and other FDA regulated products do not pose unreasonable human health risks.[39] Even under the reasoning of *Milward*, it cannot be enough in the face of such extensive scientific testing for a causation expert to rely solely on speculative inferences in support of a weight of the evidence causal hypothesis. Rather, the expert must show that the existing scientific evidence

[36] *See Milward*, 639 F.3d at 24 ("To be clear, this is not a situation in which the available epidemiological studies found that there was no causal link.").

[37] *See id.* at 24-25 (citing case law for the proposition that epidemiological evidence should not be required where such studies "would be almost impossible to perform").

[38] 21 U.S.C. § 355. *See* U.S. FDA, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, available at http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last visited February 18, 2012).

[39] *See* Toxic Substances Control Act, 15 U.S.C. § 2601, *et seq*., *see also* U.S. EPA, *Chemical Testing and Date Collection*, available at http://www.epa.gov/oppt/chemtest/index.html. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136, *et seq*. *See also* U.S. EPA, *Assessing Health Risks from Pesticides*, available at http://www.epa.gov/pesticides/factsheets/riskassess.htm (last visited February 18, 2012).

provides a reliable basis for his causation opinion.

IV. *Turner* Redux: A Case Study for Defendants in Responding to *Milward*

While the *Milward* opinion marks a step back in the proper application of the *Daubert* standards for expert admissibility, the plaintiff bar's proclamation that *Milward* will reshape toxic tort causation law is overblown. The legal battles over the *Daubert* admissibility standards have been hard fought for nearly 20 years, and until and unless resolved by future rulings from the Supreme Court, there will most certainly be continued battles over the foreseeable future. *Milward* is but one (wrongly decided) case, and if properly addressed by defendants in future *Daubert* litigation, its impact can and should be minimized.

To place *Milward* in its proper context, it is useful to look back at another appellate court opinion that likewise departed from the Supreme Court's *Daubert* teachings and that likewise—for a short time at least—was heralded by plaintiffs' counsel as a harbinger of things to come. In *Turner v. Iowa Fire Equipment*,[40] a plaintiff sought review of a district court opinion excluding his expert's opinion that exposure to discharge from a fire extinguisher caused a hyperreactive airway disorder. The Eighth Circuit ultimately affirmed, holding that the plaintiffs' expert did not even purport to support his causation opinion with scientific evidence or a differential diagnosis.[41] In discussing the *Daubert* standard, however, the Eighth Circuit seemingly went out of its way to endorse a liberal rule favoring admissibility of expert causation opinions in other cases. The Court began its analysis by announcing that it did "not believe that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness."[42] The Court then explained its view that "[t]he first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victims' condition and the toxic substance, has not yet been completed."[43] Finally, the Court reasoned, "[i]f a properly qualified medical expert performs a reliable differential diagnosis through which, to a reasonable degree of medical certainty, all other possible causes of the victim's condition can be eliminated, leaving only the toxic substance as the cause, a causation opinion based on that differential diagnosis should be admitted."[44] Plaintiffs' counsel promptly heralded the *Turner* opinion, announcing

[40] 229 F.3d 1202 (8th Cir. 2000).

[41] *See id.* at 1208, 1209.

[42] *Id.* at 1208 (citation omitted).

[43] *Id.* at 1209.

[44] *Id. See also id.* at 1208 ("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. … We agree that a medical opinion about causation, based upon a proper differential diagnosis, is sufficiently reliable to satisfy *Daubert*.").

that the Eighth Circuit "is a differential diagnosis friendly circuit."[45]

It was in the immediate wake of *Turner* that the author's law firm sought to defend the exclusion of another plaintiff expert causation opinion in a pharmaceutical products liability case arising out of the Parlodel litigation. In *Glastetter v. Novartis Pharms. Corp.*,[46] issued roughly one month prior to the Eighth Circuit ruling in *Turner*, the district court excluded plaintiffs' experts' opinion that Parlodel had caused the 36-year old plaintiff's postpartum intracerebral hemorrhage (ICH). Plaintiffs' experts based their causation opinion on a number of different lines of evidence, including case reports, animal studies, chemical analogies, and FDA regulatory actions. In excluding the experts' testimony, the district court concluded that none of these individual lines of evidence provided a reliable basis for a causation opinion, that the experts could not cite to any supportive epidemiological studies, and that the experts' purported differential diagnosis did not provide a reliable scientific basis to rule in Parlodel as a cause of the plaintiff's stroke.[47]

Plaintiffs appealed, and the 3-judge panel assigned to hear the case for the Eighth Circuit included two of the judges that had served on the *Turner* panel. Not surprisingly, plaintiffs relied heavily on *Turner* in their appeal, arguing that the district court erred in requiring plaintiffs' experts to cite published studies on general causation and that, because their experts had professed to use a "differential diagnosis" methodology, their opinions must pass *Daubert* scrutiny.[48] The plaintiffs also challenged the district court's *Daubert* ruling on the same grounds accepted by the First Circuit in *Milward*, arguing that the district court erred in looking "at each piece of evidence in isolation … without considering the cumulative effect…."[49]

In our opposition brief for the defendant, we squarely confronted plaintiffs' assertion that the district court had erred in separately analyzing each of the plaintiffs' experts' different lines of evidence, noting that this was the exact approach that had been taken by the Supreme Court in *Joiner*.[50] We then defended in detail each of the district court's findings on these separate lines of evidence, explaining not only that the same type of evidence repeatedly had been rejected under *Daubert* by other courts but also why the particular studies and analogies relied upon by plaintiffs' experts in our case did not support their causal hypotheses.[51] We then explained why, without reliable scientific evidence

---

[45] M. Dunleavy, *The Darwin Guide to Survival at a* Daubert *Challenge*, ATLA Annual Convention Reference Materials, 2 Ann.2001 ATLA-CLE 2775 (July 2001).

[46] 107 F. Supp.2d 1015 (E.D. Mo. 2000).

[47] *See id.* at 1044-1045 & n.29.

[48] Brief for Plaintiff-Appellant at 38, 51-52, Glastetter v. Novartis Pharms. Corp., Nos. 00-3087/00-3467 (8th Cir. Nov. 30. 2000) (on file with author).

[49] *Id.* at 43.

[50] Brief for Defendant-Appellee at 22-23, 28, Glastetter v. Novartis Pharms. Corp. Nos. 00-3087/00-3467 (8th Cir. Jan. 19. 2001) (on file with author).

[51] *Id.* at 29-49. In discussing the plaintiffs' putative causation evidence, defendant's brief drew heavily as well on the concession that secured from plaintiffs' experts during a four day evidentiary *Daubert* hearing.

to "rule in" Parlodel as a cause of the plaintiff's stroke, the experts' purported differential diagnoses could not support a reliable general causation opinion.[52] And, importantly, we presented the Court with the overarching factual context of the causation issue in our case that distinguished it from the purportedly novel causation issue in *Turner*. We explained that that there are "approximately 700,000 [strokes] a year in the United States," that "stroke in young adults is not a rare event," and that the postpartum period is a known risk factor for stroke.[53] We also noted that there had been "millions of Parlodel prescriptions written for all indications."[54]

The Eighth Circuit unanimously affirmed the district court's ruling.[55] The Court began its opinion by reasserting its holding in *Turner* that "a medical opinion about causation, based upon a proper differential diagnosis, is sufficiently reliable to satisfy *Daubert*," and it explained that "[b]ecause a differential diagnosis is presumptively admissible, a district court may exercise its gatekeeping function to exclude only those diagnoses that are scientifically invalid.[56] But the Court "agreed with the district court's conclusion" in our case that the differential diagnoses performed by Ms. Glastetter's expert physicians were not scientifically valid "because they lacked a proper basis for 'ruling in' Parlodel as a potential cause of ICH in the first place."[57] The Eighth Circuit then reviewed with particularity and affirmed the district court's findings on each of the separate lines of causation evidence proffered by the plaintiffs' experts. This analysis turned not only on the generally unreliable nature of the types of evidence at issue but on the Court's proper understanding of why the particular studies relied upon by the plaintiffs' experts did not support their causation opinions.[58] Finally, the Court rejected plaintiffs' argument that the district court had failed to properly consider the "cumulative effect" of plaintiffs' causation evidence: "Viewed in isolation, Glastetter's different pieces of scientific evidence do not substantiate her experts' conclusion that Parlodel can cause ICHs. Likewise, we do not believe the aggregate of this evidence presents a stronger scientific basis for Glastetter's supposition that Parlodel can cause ICHs."[59]

In the over ten years since *Turner* and *Glastetter* were decided, the analytical debate framed by the two opinions has continued in courts around the country. Although an inexact measure to be sure, the significance of the two opinions can be partially gauged by the extent to which the cases have been cited by other courts. By this measure, *Turner* certainly has been significant, with 102 judicial citations as of the date

[52] *Id.* at 57-61.
[53] *Id.* at 7-8.
[54] *Id.* at 11.
[55] *See* Glastetter v. Novartis Pharms., 252 F.3d 986 (8th Cir. 2001).
[56] *Id.* at 989 (internal citations omitted).
[57] *Id.*
[58] *See id.* at 991 n.5 ("We do not discount the value of animal studies *per se*. Rather, we find that the particular animal studies submitted in this case do not present scientifically compelling evidence of causation.").
[59] *Id.* at 992.

this article is being prepared. But *Glastetter* has been even more significant, with 122 judicial citations to date. The history of *Milward* over the next ten years is yet to be written, but there is every reason to believe that with continued and focused defense efforts in support of *Daubert*, *Milward*'s influence over other courts in future *Daubert* litigation will be similarly countered.

V. Conclusion

With its unquestioning endorsement of "weight of the evidence" reasoning and law-leads-science analysis, the First Circuit's *Milward* opinion represents a significant departure from the expert admissibility standards set forth by the Supreme Court in the *Daubert* trilogy. But while plaintiffs' counsel may hear in *Milward* a call to victory, for the defense bar, *Milward* is but a call back to the trenches. *Daubert* remains—much as it has been for the past 19 years—a powerful weapon in the fight against frivolous litigation and junk science in the courtroom. *Milward* does not and cannot change this fact.