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## Uncertainty and Informed Choice: Unmasking Daubert

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# UNCERTAINTY AND INFORMED CHOICE: UNMASKING DAUBERT

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Here is a company [Merrell Dow—the manufacturer of Bendectin] who has been in thalidomide, involved with thalidomide, and they know that the only animal that had the identical deformity to man was one species of macaque monkey. . . . They never went to higher animals. Here's a company who knows all about thalidomide, yet they haven't got the money to go to higher animals. . . . I feel like there were certainly enough [adverse reactions of limb reduction in children born after their mothers had taken Bendectin to alleviate symptoms of nausea] reported, given our bad reporting system . . . to have warranted some kind of acknowledgment of this on

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the labeling and to physicians. I think I should have had the choice to make up my mind whether I wanted to take this drug based on the fact of what you had in your files and what the FDA had. Then if I wanted to go ahead and take it and take my chances, we wouldn't be sitting across from each other. But, it's not fair to you to have this knowledge, whether or not you have established in your minds this causal relationship, and not share it with the medical community and with the public who is going to be consuming this stuff.<sup>1</sup>

## I. INTRODUCTION

In toxic tort litigation, causation is the rub. Plaintiffs have, in large part, been stymied by their inability to establish that toxic agents, no matter how potentially dangerous, were actually responsible for the harms they have suffered. Their difficulties in this regard have increased exponentially since the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*<sup>2</sup> With great frequency, plaintiffs have been unable to convince courts to admit expert testimony that a given agent was causally responsible for the plaintiff's injury.<sup>3</sup> Courts and scholars are in sharp disagreement as to the wisdom of *Daubert* and whether it has been fairly applied.<sup>4</sup> The authors of this Article are not of one mind on either of the above issues.<sup>5</sup> This Article is

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1. Deposition of Plaintiff Elizabeth Mekdeci at 568-70, *Mekdeci v. Merrell Nat'l Labs.*, Div. of Richardson-Merrell, Inc. (M.D. Fla. filed Jan. 20, 1978) (on file with the authors) [hereinafter *Mekdeci Deposition*], *aff'd* 711 F.2d 1510 (11th Cir. 1983). Mrs. Mekdeci was the first plaintiff to bring an action against Merrell Dow claiming that the Bendectin she had taken in the first trimester of pregnancy had caused her child to be born with limb reduction.

2. 509 U.S. 579 (1993). Even without the strictures of *Daubert*, described *infra* in text accompanying notes 7 to 58, plaintiffs would confront difficulties in establishing a causal relationship between a toxic agent and resulting harm. *Daubert* has, however, raised the barrier to a plaintiff's ability to prove causation since it licenses courts to act as gatekeepers to exclude expert testimony that does not meet the criteria for admissibility set forth by the Supreme Court. *Daubert*, 509 U.S. at 589-92, interpreted Federal Rule of Evidence 702, which was amended as of December 1, 2000 "in response to *Daubert*" and "the many cases applying *Daubert*." See FED. R. EVID. 702 advisory committee's note, 28 U.S.C. App. at 893 (2000). The new language at the end of Rule 702 allows an expert to testify "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." FED. R. EVID. 702.

3. See, e.g., *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1197-1202 (11th Cir. 2002); *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989-92 (8th Cir. 2001); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 797-809 (N.D. Ohio 2004); *Nelson v. Am. Home Prods. Corp.*, 92 F. Supp. 2d 954, 966-73 (W.D. Mo. 2000); *Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1164-78 (E.D. La. 1997); *Kelley v. Am. Heyer-Schulte Corp.*, 957 F. Supp. 873, 877-83 (W.D. Tex. 1997); *Grimes v. Hoffman-La Roche, Inc.*, 907 F. Supp. 33, 37-39 (D.N.H. 1995); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1476-85 (D.V.I. 1994).

4. See Symposium, *Expert Admissibility: Keeping Gates, Goals and Promises*, 34 SETON HALL L. REV. 1 (2003).

5. Professor Berger has been a vocal critic of the tendency of courts applying *Daubert* to confuse the issue of admissibility of expert testimony with the sufficiency of the evidence to establish causation. See Brief of Amici Curiae Margaret A. Berger & Jerome P. Kassirer in Support of Plaintiff-Appellant at 21-29, *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194 (11th Cir. 2002) (No. 61-11965 BB and 01-CC); Margaret A. Berger, *Upsetting the Balance Between Adverse Interests: The Impact of the Supreme Court's Trilogy on Expert Testimony in Toxic Tort Litigation*, 64 LAW &

agnostic as to the controversy swirling around *Daubert* and its progeny. We proceed on the premise that significant changes in the doctrine are not in the offing. Plaintiffs will continue to lose toxic tort cases because they will be unable to establish causation. This phenomenon would not be troubling if there were not a recurring pattern of drug cases in which: (1) the causal relationship between the toxic agent and plaintiff's harm is unresolved at the time of litigation and will likely remain unresolved; (2) the drug is not therapeutic but rather its purpose is to avoid discomfort or to improve lifestyle; (3) it is almost certain that a patient made aware of the risk that is alleged to be associated with consumption of the drug would have refused to take it; and (4) the defendant drug company was aware of the potential risk or should have undertaken reasonable testing to discover the risk and failed to provide the requisite information to the physician or patient.

We shall argue that the time has come for courts to recognize the right of patients to informed choice about risks associated with the use of a drug, a right that does not require plaintiffs to prove that the toxic agent was the cause of the plaintiff's harm.<sup>6</sup> To do so we shall suggest a new paradigm for this informed choice cause of action that protects the right of patient autonomy, yet does not impose liability for the full extent of damages as would be the case when a plaintiff is able to prove causation. Absent recognition of a right predicated on informed choice, plaintiffs will be deprived of vital information necessary to make critical decisions regarding lifestyle drugs and pharmaceutical manufacturers will have little incentive to discover and warn about uncertain risks. With causation standing as a barrier to recovery, defendants will sit back confident that liability is highly unlikely to attach to conduct that is admittedly negligent.

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CONTEMP. PROBS. 289 (2001). Professor Twerski is in general sympathetic to *Daubert* and its progeny but has cautioned against overly rigid application of the doctrine. See AARON D. TWERSKI & JAMES A. HENDERSON, JR., *TORTS: CASES AND MATERIALS* 207 (2003); James A. Henderson, Jr. & Aaron D. Twerski, *Intuition and Technology in Product Design Litigation: An Essay on Proximate Cause*, 88 GEO. L.J. 659, 682 (2000).

6. Several commentators including one of the authors of this Article have suggested that the role of causation ought to be eliminated or drastically altered in toxic tort cases. These proposals would permit recovery for the actual injury the plaintiff allegedly suffered as a result of exposure to the toxic agent even though the plaintiff could not establish causation under traditional tort principles. See Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2142 (1997) (suggesting the elimination of the requirement of general causation and instead imposing liability on defendants for failing to adequately test or disclose information regarding potential hazards to defendants subject to several defenses); Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 45 (1995) (arguing that when strong uncertainty regarding causation can be established, the burden of proof should be shifted to defendant or defendant should be required to pay 50% of plaintiff's losses); Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 832 (1997) (proposing a presumption that an insufficiently tested product caused the plaintiff's harm); see also Ariel Porat & Alex Stein, *Liability for Uncertainty: Making Evidential Damage Actionable*, 18 CARDOZO L. REV. 1891, 1941 (1997) (arguing that the burden of proof on causation should be shifted to the defendant when the defendant is responsible for evidential uncertainty). The focus of this paper is on recognizing and compensating for the deprivation of informed choice rather than compensating for the physical injury caused by the toxic substance. See authorities cited *infra* note 118.

This Article will first examine why it is that plaintiffs have been unable to prove causation under the *Daubert* guidelines in toxic tort litigation. Second, it will look at the two existing models for informed choice litigation—medical malpractice and products liability—and demonstrate why neither of these models gives toxic tort plaintiffs a fair opportunity to recover for the deprivation of patient autonomy against drug manufacturers who have breached their duty to warn of known or knowable risks. Finally, this Article will explore the elements of a causation-free informed choice cause of action. It will suggest the appropriate standard for defining materiality of risk in informed choice where the goal is to protect patient autonomy, and having established the substantive right to recovery, the Article will then suggest a measure of damages for depriving the patient of her right to autonomous decisionmaking.

### I. *DAUBERT*: THE DIFFICULTY OF ESTABLISHING CAUSATION IN TOXIC TORT CASES

A plaintiff who brings an action for the failure of a pharmaceutical company to warn about a material risk that allegedly caused her injury faces significant obstacles to recovery. A trilogy of cases decided by the U.S. Supreme Court dealing with the admissibility of expert testimony in the federal courts has made it very difficult for a plaintiff to successfully prosecute a toxic tort case.<sup>7</sup> The three opinions—starting in 1993 with *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,<sup>8</sup> and continuing with *General Electric Co. v. Joiner*<sup>9</sup> in 1997 and *Kumho Tire Co. v. Carmichael*<sup>10</sup> in 1999—do not purport to deal with tort law. Ostensibly, they deal solely with the evidentiary test a trial judge must use in determining whether an expert will be allowed to state an opinion. But the *Daubert* trilogy speaks very directly to the issue of what it takes to establish the causal nexus between wrongful defendant conduct and the harm suffered by the plaintiff—the crucial issue in each of the Supreme Court cases and in virtually all toxic tort litigation.<sup>11</sup>

Before looking at what the courts have done post-*Daubert* and the consequences therefrom, we need to consider briefly how much evidence

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7. Although *Daubert* and the Supreme Court's subsequent opinions in *General Electric Co. v. Joiner*, 522 U.S. 136 (1997), and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), interpret Rule 702 of the Federal Rules of Evidence and as such apply only in federal court, a considerable number of states have also adopted *Daubert*. See David E. Bernstein & Jeffrey D. Jackson, *The Daubert Trilogy in the States*, 44 JURIMETRICS J. 351, 355–56 (2004) (finding that nine states have adopted *Daubert* but noting that others have put the number at thirty-three).

8. 509 U.S. 579 (1993).

9. 522 U.S. 136 (1997).

10. 526 U.S. 137 (1999).

11. For commentary arguing that *Daubert* and its progeny transcend mere evidence and have had a profound effect on the normative rules of causation, see Neil B. Cohen, *The Gatekeeping Role in Civil Litigation and the Abdication of Legal Values in Favor of Scientific Values*, 33 SETON HALL L. REV. 943 (2003), and Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335 (1999).

relevant to foreseeable risks and their causal consequences there is likely to be when a drug first appears on the market. The safety and efficacy studies done by manufacturers to obtain Food and Drug Administration ("FDA") approval will often provide inadequate data to prove the causal relationship between a toxic agent and the harm suffered by a plaintiff. The time frame for pre-marketing studies means that latent effects will not have had a chance to appear, the size of the studies is not sufficiently large to detect rare toxicities, the studies are conducted on a different population than the persons to whom the product will be marketed, the consumers who use the product once it is marketed may well be taking other medications that interact with the new drug, and we as yet know little about the role genetic susceptibilities play.<sup>12</sup> Once the product is approved, the FDA lacks authority to require the drug manufacturer to undertake further research, and physicians may prescribe off-label uses that have never been tested.<sup>13</sup> Because of escalating budget cuts and a statutory shift to requiring swifter new drug approvals, the FDA's system of post-market surveillance has been drastically curtailed since 1993. Although the manufacturer is required to gather Adverse Reaction Reports from a variety of sources that recount unusual or unanticipated toxicities in patients who are using the drug,<sup>14</sup> busy health providers infrequently make these reports which are crucial to identifying a problem. A former Acting Commissioner of the Food and Drug Administration stated, "It is popularly believed that less than 10% of the true adverse events are reported."<sup>15</sup> At some point in time evidence may surface that a drug is causing one or more adverse reactions. But even if the evidence is sufficient for the FDA to remove the drug from the market or to warrant a warning about the drug's possible toxic effect, proving an actual causal connection has been an uphill battle for plaintiffs post-*Daubert*.

In *Daubert*, the chief controverted issue was whether Bendectin, an anti-morning sickness pill taken by millions of pregnant women, could cause birth defects in their offspring, and had caused limb reduction in the plaintiffs.<sup>16</sup> The difficulty in establishing causation arose from the fact that there is a significant background risk of birth defects. The mere fact that a child was born with a limb reduction to a mother who had ingested Bendectin did not necessarily point to Bendectin as the cause of the birth defect. The court below, like many others that had granted judgments n.o.v. or summary judgments in Bendectin cases, found plaintiffs' expert testimony insufficient

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12. Michael A. Friedman, *What Is the Value of an FDA Approval in a Judicial Matter?*, 12 J.L. & POL'Y 559, 570-71 (2004). For a discussion of the impact genetic information may have on proving causation in toxic tort cases, see Gary E. Marchant, *Genetics and Toxic Torts*, 31 SETON HALL L. REV. 949 (2001).

13. Steven R. Salbu, *Off-Label Use, Prescription, and Marketing of FDA-Approved Drugs: An Assessment of Legislative and Regulatory Policy*, 51 FLA. L. REV. 181 (1999).

14. Applications for FDA Approval to Market a New Drug, 21 C.F.R. § 314.80-.81 (2003).

15. Friedman, *supra* note 12, at 570.

16. See MICHAEL D. GREEN, *BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION* 221 (1996) (finding that approximately fifteen million live births occurred in which the mother was exposed to Bendectin during pregnancy).

to prove a causal connection, and granted summary judgment.<sup>17</sup> The Supreme Court first held that the *Frey* or “general acceptance” test—used by some federal courts in determining when expert proof was admissible—had not survived the enactment of the Federal Rules of Evidence. Instead, the Court told trial judges that they must screen all “purportedly scientific evidence” on which an expert plans to rely to ensure that it is “not only relevant, but reliable.”<sup>18</sup> By reliability, the Court meant that the trial court had to ascertain whether the proffered expert’s opinion was “ground[ed] in the methods and procedures of science.”<sup>19</sup> The Court then examined the characteristics of a scientific methodology and set out a number of nonexclusive factors for the trial court to consider that bear on “whether the reasoning or methodology underlying the testimony is scientifically valid.”<sup>20</sup> Mentioned by the Court as indicators of good science are hypothesis testing, subjecting studies to peer review and publication, determining known or potential error rates, adopting standards for controlling the technique, and general acceptance of the methodology in the scientific community.<sup>21</sup> The Supreme Court then reversed, leaving it to the court below to apply the new test on remand.<sup>22</sup>

Defendants immediately realized that *Daubert* furnished them with a new procedural opportunity, as they could make in limine motions asking

17. *Daubert v. Merrell Dow Pharms., Inc.*, 727 F. Supp. 570 (S.D. Cal. 1989), *aff’d* 951 F.2d 1128 (9th Cir. 1991). For an extensive discussion of the trial and appellate court decisions on Bendectin, see JOSEPH SANDERS, *BENDECTIN ON TRIAL: A STUDY OF MASS TORT LITIGATION* 144–55 (1998). For leading opinions denying recovery because expert testimony did not support a finding of causation based on the inability of plaintiff to establish causation, see, for example, *Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307 (5th Cir. 1989) (reversing judgment for plaintiff); *Lynch v. Merrell-Nat’l Labs.*, 830 F.2d 1190 (1st Cir. 1987) (affirming grant of summary judgment for defendant); and *Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799 (D.D.C. 1986), *aff’d* 857 F.2d 823 (D.C. Cir. 1988) (affirming judgment n.o.v. for defendant).

18. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993).

19. *Id.* at 590.

20. *Id.* at 592–94.

21. *Id.*

22. On remand, the court of appeals struggled with the new test set forth in the Supreme Court’s opinion. In *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311 (9th Cir. 1995), the court affirmed the district court’s grant of summary judgment. Judge Kozinski expressed skepticism about the ability of courts to fairly apply the *Daubert* criteria:

[T]hough we are largely untrained in science and certainly no match for any of the witnesses whose testimony we are reviewing, it is our responsibility to determine whether those experts’ proposed testimony amounts to “scientific knowledge,” constitutes “good science,” and was “derived by the scientific method.”

The task before us is more daunting still when the dispute concerns matters at the very cutting edge of scientific research, where fact meets theory and certainty dissolves into probability. As the record in this case illustrates, scientists often have vigorous and sincere disagreements as to what research methodology is proper, what should be accepted as sufficient proof for the existence of a “fact,” and whether information derived by a particular method can tell us anything useful about the subject under study.

*Id.* at 1316.

After expressing his frustration, Judge Kozinski concluded that the expert testimony proffered by the plaintiff was not sufficiently reliable to establish causation. *Id.* at 1319.

the trial judge to exclude plaintiffs' experts as witnesses. In a traditional toxic tort action, if the motion is successful in excluding plaintiff's expert testimony on causation, a defendant is entitled to summary judgment because of the plaintiff's inability to prove a crucial element of the cause of action.<sup>23</sup> That is what happened in *General Electric Co. v. Joiner*, a lawsuit brought against General Electric by a plaintiff who claimed that his exposure to polychlorinated biphenyls ("PCBs") and their derivatives had promoted his small-cell lung cancer.<sup>24</sup> The district court granted the defendant's motion for summary judgment on the ground that the plaintiff's experts' opinions that PCBs caused small-cell lung cancer did not meet the exacting standards demanded by *Daubert*.<sup>25</sup> The judgment for the defendant was, however, reversed by the Eleventh Circuit; it subjected the exclusion of the plaintiff's expert testimony to a stringent standard of review which the court found was required when the exclusion resulted in dismissal of the action.<sup>26</sup> The Supreme Court granted certiorari.<sup>27</sup>

Although it is *Daubert* itself that is the most cited case in the *Daubert* trilogy, it is probably *Joiner* that has had the greatest impact in toxic tort cases. In the first place, the Court rejected a strict scrutiny standard of review and instead adopted an abuse of discretion standard for reviewing *Daubert* rulings.<sup>28</sup> Trial judges were thereby given enormous control over the outcome of a case and considerable immunity from review; their decisions would stand unless "manifestly erroneous."<sup>29</sup> If the plaintiff's expert was barred from testifying about a material issue like causation, the case would never reach a jury, and would end instead with a grant of summary judgment for the defendant. Although grants of summary judgment are reviewed de novo,<sup>30</sup> the exclusion of the expert—the crucial decision that led to the grant—would evade this strict standard of review even though the Supreme Court acknowledged that the decision on expert testimony was "outcome determinative."<sup>31</sup>

Second, in the course of finding that the district court had not abused its discretion in excluding the plaintiff's experts on toxicology and epidemiology, the *Joiner* Court endorsed an approach that provided trial courts with a template for excluding expert testimony on causation. First, it approved the district court's finding that the animal studies on which the plaintiff's experts relied did not support the plaintiff's contention that PCBs contributed

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23. FED. R. CIV. P. 56(c).

24. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 139 (1997).

25. *Joiner v. Gen. Elec. Co.*, 864 F. Supp. 1310, 1327 (N.D. Ga. 1994).

26. *Joiner v. Gen. Elec. Co.*, 78 F.3d 524, 529 (11th Cir. 1996) ("[W]e apply a particularly stringent standard of review to the trial judge's exclusion of expert testimony.").

27. *Gen. Elec. Co. v. Joiner*, 520 U.S. 1114 (1997).

28. *Joiner*, 522 U.S. at 141–43.

29. *Id.* at 142 (quoting *Spring Co. v. Edgar*, 99 U.S. 645, 658 (1879)).

30. *Joiner*, 78 F.3d at 529.

31. *Joiner*, 522 U.S. at 142–43.



to his cancer.<sup>32</sup> The Court pointed to differences between the studies and the facts of the litigation: the study subjects—infant mice—had been exposed to much higher doses of PCBs by a different mechanism of exposure, and the mice and plaintiff did not develop the same type of cancer. Furthermore, the Court observed that no study showed that PCBs led to cancer in any species other than mice.<sup>33</sup> The Court brushed aside the plaintiff's contention that the issue for the Court was whether animal studies can ever be a proper foundation for an expert's opinion. "The issue," said the Court, "was whether *these* experts' opinions were sufficiently supported by the animal studies on which they purported to rely."<sup>34</sup>

The four epidemiological studies on which the plaintiff's experts relied fared no better.<sup>35</sup> The Court noted that the district court had rejected the first because the authors failed to find causation even though lung-cancer deaths of workers exposed to PCBs in an Italian plant "were higher than might have been expected."<sup>36</sup> A second study, which also found a higher than expected incidence of lung-cancer deaths, did not count because the increase was not statistically significant.<sup>37</sup> The third, which noted a statistically significant increased rate of lung-cancer deaths in workers exposed to fluids that often contain PCBs, did not mention PCBs.<sup>38</sup> And the fourth, which involved a PCB-exposed group of Japanese workers who experienced a statistically significant increase in lung cancer, was faulted because the workers had also been exposed to numerous potential carcinogens.<sup>39</sup> Consequently, the Supreme Court found that the court of appeals had erred in reversing the district court's determination that the toxicological and epidemiological studies "were not sufficient, whether individually or in combination, to support [the experts'] conclusions that Joiner's exposure to PCB's [sic] contributed to his cancer."<sup>40</sup>

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32. *Id.* at 144.

33. *Id.*

34. *Id.*

35. *Id.* at 145.

Epidemiologic evidence identifies agents that are associated with an increased risk of disease in groups of individuals, quantifies the amount of excess disease that is associated with an agent, and provides a profile of the type of individual who is likely to contract a disease after being exposed to an agent.

Michael D. Green et al., *Reference Guide on Epidemiology*, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333, 335–36 (Fed. Judicial Ctr. ed., 2d ed. 2000); see also *id.* at 338–47 (describing different kinds of epidemiological studies such as randomized trials and various types of observational studies).

36. *Joiner*, 522 U.S. at 145.

37. *Id.*

38. *Id.* at 145–46.

39. *Id.* at 146.

40. *Id.* at 146–47.

District court judges have found ample ammunition in the *Joiner* opinion to support rulings excluding plaintiffs' experts on causation.<sup>41</sup> Some courts, like the *Joiner* district judge who was found not to have abused her discretion, ignore statistically significant studies unless the authors found causation,<sup>42</sup> despite the fact that researchers use a stringent scientific standard of proof that far exceeds the preponderance of the evidence standard that applies in civil litigation.<sup>43</sup> Or they reject experts who rely on studies that lack a .05 level of statistical significance,<sup>44</sup> without acknowledging that a lack of statistical significance does not mean that a study has no probative value.<sup>45</sup> Or they disregard studies because of the possible presence of confounders, even though some studies are able to adjust for such factors.<sup>46</sup> Few epidemiological studies cannot be attacked on one of the above grounds.<sup>47</sup> And courts have also rejected the relevance of animal studies to establish causation relying on the Supreme Court's emphasis in *Joiner* on the dissimilarities between animal studies and the litigation facts.<sup>48</sup> One question is whether any trial judge who rejects or ignores an animal study will ever be reversed for doing so. The problem of extrapolating from animal species to humans will by definition exist; the animals' dosage will always be much higher, and the method of exposure may vary considerably because one cannot ethically treat humans like laboratory animals.<sup>49</sup> Furthermore, we know little as of yet about how particular substances are metabolized in humans and animals, or whether substances that affect health invariably cause the same effects in humans and animals. Because of these uncertainties,

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41. See, e.g., *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1314–15 & n.16 (11th Cir. 1999); *In re Rezulin Prods. Liab. Litig.*, No. MDL 1348, 00 Civ. 2843(LAK), 2004 WL 2884327, at \*3 (S.D.N.Y. Dec. 10, 2004); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 797–807 (N.D. Ohio 2004); *Blanchard v. Eli Lilly & Co.*, 207 F. Supp. 2d 308, 314 (D. Vt. 2002) (discussing cases claiming that selective serotonin reuptake inhibitors caused suicide; in most, summary judgment was granted after defendant's successful *Daubert* motion); *Miller v. Pfizer, Inc.*, 196 F. Supp. 2d 1062 (D. Kan. 2002), *aff'd*, 356 F.3d 1326 (10th Cir. 2004); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1224–44 (D. Colo. 1998); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1396–414 (D. Or. 1996); see also cases cited *infra* note 69.

42. See, e.g., *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 277 n.8 (5th Cir. 1998) (en banc) (approving *Joiner* analysis as “particularly relevant to our case. . . . Dr. Brooks was unable to reach any conclusions.”).

43. Cohen, *supra* note 11, at 952–54.

44. *Raynor v. Merrell Pharms., Inc.*, 104 F.3d 1371, 1374 (D.C. Cir. 1997); *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1226–27.

45. Sander Greenland, *The Need for Critical Appraisal of Expert Witnesses in Epidemiology and Statistics*, 39 WAKE FOREST L. REV. 291, 297–301 (2004).

46. Green et al., *supra* note 35, at 373.

47. *Id.* at 337; *In re Orthopedic Bone Screw Prods. Liab. Litig.*, No. 1014, 1997 WL 230818, at \*8–9 (E.D. Pa. May 5, 1997) (“[T]here is no such thing as a perfect epidemiological study.”).

48. E.g., *Hollander v. Sandoz Pharms. Corp.*, 95 F. Supp. 2d 1230, 1238 (W.D. Okla. 2000), *aff'd* 289 F.3d 1193 (10th Cir. 2002).

49. Green et al., *supra* note 35, at 345 (“animals can be sacrificed and their tissues examined”).

courts have been loath to permit experts to rely on animal studies, particularly when epidemiological data are available.<sup>50</sup>

Some trial courts have gone beyond *Joiner*. Although few courts say outright that epidemiological evidence is essential to prove causation,<sup>51</sup> many denigrate all other types of evidence, such as expert opinions that seek to establish causation on the basis of differential diagnosis,<sup>52</sup> and dismiss Adverse Reaction Reports as mere anecdotal evidence not worthy of serious consideration on the issue of causation.<sup>53</sup> Furthermore, even when epidemiology shows an increased risk, some courts exclude expert testimony based on such studies unless the reported relative risk exceeds two,<sup>54</sup> and courts generally do so without acknowledging that the treatment of relative risk "is a legal question, not a scientific question."<sup>55</sup>

50. And when epidemiological data are not available, the court may conclude that the lack of concordance of animal data and human data means that there are insufficient grounds to extrapolate from the animal studies to humans. *E.g.*, *Fabrizi v. Rexall Sundown, Inc.*, No. 01-289, 2004 WL 1202984, at \*7 (W.D. Pa. June 2, 2004).

51. Indeed, courts often go out of their way to discuss in great detail that epidemiological evidence is not essential (in a case in which no epidemiological studies were done) before rejecting all the other evidence offered by the plaintiff. *See, e.g.*, *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 800-801 (N.D. Ohio 2004); *Parlodel* cases cited *infra* note 69. But see *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1164 (S.D. Fla. 1996), *aff'd*, 158 F.3d 588 (11th Cir. 1998), stating:

[T]he generally accepted view in the scientific community is that [the expert's] methodology [case reports, spontaneous reports of adverse medical events collected by the FDA, and animal studies] can be used to generate hypotheses about causation, but not causation conclusions. . . . [S]cientifically valid cause and effect determinations depend on controlled clinical trials and epidemiological studies.

52. *See In re Rezulin Prods. Liab. Litig.*, No. MDL 1348, 00 Civ. 2843(LAK), 2004 WL 2884327, at \*3 (S.D.N.Y. Dec. 10, 2004) (holding that differential diagnosis cannot be used to prove general causation); Edward J. Imwinkelried, *The Admissibility and Legal Sufficiency of Testimony About Differential Diagnosis (Etiology): Of Under- and Over-Estimations*, 56 BAYLOR L. REV. 391, 415 (2004).

53. *See, e.g.*, *Cloud v. Pfizer, Inc.*, 198 F. Supp. 2d 1118, 1133 (D. Ariz. 2001) ("[Case reports] are merely compilations of occurrences, and have been rejected as reliable scientific evidence supporting an expert opinion that *Daubert* requires.") (citing *Jones v. United States*, 933 F. Supp. 894, 899-900 (N.D. Cal. 1996)). The extraordinarily high burden that courts place on plaintiffs in satisfying *Daubert* challenges is illustrated in one of the *Parlodel* cases, in which the court explained under what circumstances it would have allowed an expert to testify:

This would be a different case if there was at least some support for the causal hypothesis in the peer-reviewed epidemiological literature, a predictable chemical mechanism, general acceptance in learned treatises and other scientific literature of a causal relationship, a plausible animal model, and dozens of well-documented case reports involving postpartum women with no other risk factors for stroke. In such a case, the totality of the evidence would be enough to satisfy the demands of *Daubert*.

*Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1370 (N.D. Ga. 2001), *aff'd sub nom.*, *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194 (11th Cir. 2002).

54. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1321 (9th Cir. 1995) *remanded from* 509 U.S. 579 (1993).

55. Russellyn S. Carruth & Bernard D. Goldstein, *Relative Risk Greater than Two in Proof of Causation in Toxic Tort Litigation*, 41 JURIMETRICS J. 195, 202 (2001) (surveying cases); *see also* Vern R. Walker, *Restoring the Individual Plaintiff to Tort Law by Rejecting "Junk Logic" About Specific Causation*, 56 ALA. L. REV. 381 (2004).

Finally, there is the issue of transaction costs. Preparing for and litigating *Daubert* issues has undoubtedly made litigation even more expensive than before. For example, courts have noted that when a disease is relatively rare, a researcher may need a very large sample size to ensure that results of an epidemiological study are not simply due to chance.<sup>56</sup> This may mean that sample sizes running into the hundreds of thousands or millions of patients may be needed to validate a retrospective study.<sup>57</sup> Prospective studies may be impossible to perform once a drug has been withdrawn from the market.<sup>58</sup> Thus no matter what the ultimate bona fides of a case, cost may serve as an efficient deterrent to bringing a credible cause of action. As noted earlier, in this Article we take no position as to whether *Daubert* and its progeny have got it right. We simply report that proving causation in many toxic tort cases is well nigh impossible. In the ensuing Section, we consider whether the failure to establish traditional causation should negate a plaintiff's right to recover for the failure of a pharmaceutical manufacturer to warn of material risks.

## II. THE FORGOTTEN RIGHT OF INDIVIDUAL CHOICE AND PATIENT AUTONOMY

It is clear that in many toxic tort cases plaintiffs will not be able to overcome the substantial burden of establishing that a suspected toxic risk actually caused their injuries. The failure to establish causation does not, however, mean that pharmaceutical manufacturers met their obligation to warn of potential risks that may result from the ingestion of their drugs. To establish fault in a negligence case, it is not necessary to prove that the foreseeable harm to the plaintiff is more likely than not to occur.<sup>59</sup> The duty to warn is breached when a risk is of sufficient consequence that a reasonable

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56. See *Brasher v. Sandoz Pharms. Corp.*, 160 F. Supp. 2d 1291, 1297 (N.D. Ala. 2001); *Globetti v. Sandoz Pharms. Corp.*, 111 F. Supp. 2d 1174, 1179 (N.D. Ala. 2000); *Kelley v. Am. Heyer-Schulte Corp.*, 957 F. Supp. 873, 880 n.8 (W.D. Tex. 1997).

57. See cases cited *supra* note 56.

58. Once a drug has been withdrawn from the market because it is considered too dangerous for human consumption, it would be unethical to subject humans to the risks of ingestion in prospective controlled studies. *E.g.*, *Brasher*, 160 F. Supp. 2d at 1297; *Globetti*, 111 F. Supp. 2d at 1179 n.13.

59. As one court explained:

When the inquiry is upon an issue whether a certain alleged fact existed or happened in the past, it is not sufficient to prove only or no more than a possibility, however substantial the possibility may be. . . . There the proof must establish the fact as a probability. . . . But when the inquiry is one of foreseeability, is as regards a thing that may happen in the future, and to which the law of negligence holds a party to anticipation as a measure of duty, that inquiry is not whether the thing is to be foreseen . . . as one which will probably happen . . . but whether it is likely to happen, even though the likelihood may not be sufficient to amount to a comparative probability.

*Gulf Refining Co. v. Williams*, 185 So. 234, 236 (Miss. 1938); see also W. PAGE KEETON ET AL., *PROSSER AND KEETON ON THE LAW OF TORTS* § 3 (5th ed. 1984).

person would warn against it.<sup>60</sup> The Learned Hand risk-utility test requires that an actor take precautions to warn against even remote risks when the gravity of the foreseeable harm is great.<sup>61</sup> That there be a causal nexus between the defendant's wrongful conduct and the harm suffered is a principle deeply ingrained in tort jurisprudence and we do not question that hoary maxim.<sup>62</sup> However, in the context of toxic tort cases, to require that the plaintiff actually demonstrate that the toxic agent caused the plaintiff's harm flies in the face of the well-recognized right of a patient to make an autonomous decision as to whether she wishes to expose herself to even an uncertain risk.<sup>63</sup> The assault on autonomy is especially egregious in the case of lifestyle drugs where the drug has little therapeutic value. In such cases one can predict with a high level of confidence that a patient informed of the potential risk would almost certainly have opted against taking the drug and subjecting herself to the risk.

Consider the following two examples. In 1956, the FDA approved the application of Richardson-Merrell, Inc., to market Bendectin as a treatment for morning sickness during pregnancy.<sup>64</sup> The drug was used by millions of women between 1957 and 1983 and was withdrawn by the manufacturer from the market due to widespread fears that it caused severe birth defects in the children whose mothers ingested the drug while pregnant.<sup>65</sup> Parents brought actions on behalf of children born with limb reductions that the parents attributed to Bendectin. Plaintiffs introduced evidence of (1) *in vitro* (test tube) studies, (2) *in vivo* (animal) studies, (3) similarities between ingredients in Bendectin with chemical structures similar to known teratogens, and (4) retrospective epidemiological studies to support their contention that the drug caused the birth defects.<sup>66</sup> After some early victories, the overwhelming weight of authority both pre- and post-*Daubert* was that the evidence was too uncertain to allow for a finding of causation.<sup>67</sup> That the evidence was found wanting on causation does not mean that a reasonable

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60. See RESTATEMENT (THIRD) OF TORTS § 2(c) (1998); DAN B. DOBBS, *THE LAW OF TORTS* § 363 (2000).

61. See *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947).

62. See generally ARNO C. BECHT & FRANK W. MILLER, *THE TEST OF FACTUAL CAUSATION IN NEGLIGENCE AND STRICT LIABILITY CASES* (1961); DOBBS, *supra* note 60, §§ 166-69; Wex S. Malone, *Ruminations on Cause-in-Fact*, 9 STAN. L. REV. 60 (1956); Richard W. Wright, *Causation in Tort Law*, 73 CAL. L. REV. 1735 (1985).

63. See discussion *infra* accompanying notes 78-94.

64. Bendectin was the drug in question in *Daubert*. The history of the litigation and the scientific controversy about Bendectin is fully developed in two outstanding studies. See SANDERS, *supra* note 17; GREEN, *supra* note 16.

65. GREEN, *supra* note 16, at 91, 180 (finding that approximately thirty-six million women took Bendectin during the twenty-seven years it was marketed).

66. *Daubert*, 509 U.S. 579, 580 (1993). For an exhaustive discussion of the nature of the scientific evidence offered by the plaintiffs in the Bendectin litigation, see SANDERS, *supra* note 17, at 45-89. Sanders notes that many of the epidemiological studies that ultimately proved decisive were begun in response to the litigation. *Id.* at 79 (finding that the quality and quantity of studies improved dramatically from the mid-1970s to the mid-1980s).

67. See, e.g., *DeLuca v. Merrell Dow Pharms., Inc.*, 911 F.2d 941, 943 (3d Cir. 1990).

person in a pregnant woman's position would not have wanted to have the information that Bendectin may be a teratogen before ingesting the drug. There is little doubt that the vast majority of expectant mothers suffering from the discomfort of morning sickness would have refused to take Bendectin to alleviate their discomfort if told that the drug carried with it an uncertain risk of birth defects to their fetuses.

A second example of toxic tort litigation that has generally failed because of the inability to establish causation between the drug and the resulting harm concerns Parlodel, an anti-lactation drug taken after childbirth. Parlodel was approved by the FDA in 1980 to prevent post-partum lactation in women who could not or elected not to breast-feed their offspring.<sup>68</sup>

Following its approval, there was evidence that Parlodel was implicated as a possible cause of strokes. Women who suffered strokes after ingesting Parlodel sought to recover for the failure of Sandoz/Novartis to warn about the dangers associated with ingestion of the drug. A majority of courts found that the evidence on causation did not meet *Daubert* guidelines.<sup>69</sup> Adverse Reaction Reports were deemed too idiosyncratic and unreliable.<sup>70</sup> Animal studies were given short shrift because one cannot accurately liken animal reactions to those of humans.<sup>71</sup> Evidence that Parlodel, when administered to a patient, caused vascular constriction that receded when the drug was withdrawn and then reappeared when the drug was introduced to the patient (dechallenge/rechallenge), was not sufficient because the patient did not actually suffer a stroke from the use of the drug.<sup>72</sup> And finally, the epidemiological studies were deemed inconclusive.<sup>73</sup> As Adverse Reaction Reports began coming in from the use of Parlodel, the FDA sought to get Sandoz to issue warnings about the possible relationship of the drug and strokes.<sup>74</sup> Parlodel was, however, a very lucrative drug and the company resisted for fear that it would cause a sharp decrease in its profits.<sup>75</sup> In 1989, the FDA requested that Sandoz withdraw Parlodel from the market for

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68. See *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 442 (W.D. Pa. 2003).

69. See, e.g., *id.* at 525–72; *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 676–84 (M.D.N.C. 2003); *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1046, 1048–53 (S.D. Ill. 2001); *Shiharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1351–74 (N.D. Ga. 2001), *aff'd sub nom.*, *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194 (11th Cir. 2002); *Glastetter v. Novartis Pharms. Corp.*, 107 F. Supp. 2d 1015, 1017–46 (E.D. Mo. 2000), *aff'd*, 252 F.3d 986 (8th Cir. 2001); *Hollander v. Sandoz Pharms. Corp.*, 95 F. Supp. 2d 1230, 1233–39 (W.D. Okla. 2000), *aff'd*, 289 F.3d 1193 (11th Cir. 2002). *But see* *Brasher v. Sandoz Pharms. Corp.*, 160 F. Supp. 2d 1291, 1299 (N.D. Ala. 2001) (denying motion for summary judgment on grounds that expert testimony was reliable); *Eve v. Sandoz Pharms. Corp.*, No. IP 98–1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531, at \*55–88 (S.D. Ind. March 7, 2001) (same); *Globetti v. Sandoz Pharms. Corp.*, 111 F. Supp. 2d 1174, 1180 (N.D. Ala. 2000) (same).

70. *Soldo*, 244 F. Supp. 2d at 461–65.

71. *Id.* at 466–70.

72. *Rider*, 295 F.3d at 1199–1200; *Hollander*, 289 F.3d at 1211.

73. *Shiharath*, 131 F. Supp. 2d at 1347; *Rider*, 295 F.3d at 1197.

74. See *Eve*, 2001 U.S. Dist. LEXIS 4531, at \*14–20.

75. See *id.* at \*17, 20, 28.

post-partum lactation. Its reason for doing so was that no drug, including Parlodel, was shown to be more effective than aspirin and breast support in alleviating the discomfort of the cessation of lactation.<sup>76</sup> In short, Parlodel created gratuitous risk with very little benefit. It is hard to believe that a woman warned of the risk of strokes and told of the comparative safety of treatment by over-the-counter analgesics would opt to take Parlodel.

One might expect that the right to informed choice would be worthy of protection whether or not a plaintiff could establish causation under the traditional norms of tort law. In both medical malpractice and products liability litigation, courts have sought to promote the right of patient autonomy by holding either the physician or drug manufacturer liable for failing to provide adequate information about risks associated with a medical procedure or a drug.<sup>77</sup> Though these two developed bodies of law purport to recognize the right of a patient to informed choice, neither can serve as an appropriate model for recognition of a cause of action where the causal relationship between the uncertain risk and the plaintiff's harm cannot be established.

#### A. *Medical Malpractice: The Informed Consent Paradigm*

The right of a patient to informed consent has been a staple of U.S. medical malpractice law for over three decades.<sup>78</sup> In order for a plaintiff to establish a prima facie case that she has been deprived of informed consent, she must show: (1) that a physician failed to disclose a material risk of the therapy undertaken or reasonable alternatives to it (materiality); (2) that the patient would have chosen against the recommended therapy (decision-causation); and (3) that as a result of the therapeutic intervention the plaintiff suffered injury (injury-causation).<sup>79</sup> The action for informed consent stands separate and apart from a claim that the physician was negligent in

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76. *Id.* at \*26–29.

77. See *infra* discussion accompanying notes 78–94.

78. See Allan H. McCoid, *A Reappraisal of Liability for Unauthorized Medical Treatment*, 41 MINN. L. REV. 381, 426–30 (1957). Prior to the McCoid article, there was no mention of informed consent in any of the major tort treatises. A California appellate court first coined the term “informed consent” in *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957). As late as 1964, Prosser made only passing reference to this cause of action, citing one case in support. See WILLIAM L. PROSSER, HANDBOOK ON THE LAW OF TORTS 107 (3d ed. 1964). Sporadic case law and commentary appeared during the 1960s. See, e.g., *Shetter v. Rochelle*, 409 P.2d 74, 86 (Ariz. Ct. App. 1965), *modified*, 411 P.2d 45 (Ariz. Ct. App. 1966); *Natonson v. Kline*, 350 P.2d 1093 (Kan. 1960); see generally Michael Justin Meyers, Comment, *Informed Consent in Medical Malpractice*, 55 CAL. L. REV. 1396 (1967). It was not until *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972), however, that informed consent was pushed into the national limelight and became a popular theory for recovery.

79. These three elements have been reiterated by numerous courts. See, e.g., *Canterbury*, 464 F.2d at 787–91; *Williams v. Boyle*, 72 P.3d 392, 397 (Colo. Ct. App. 2003); *Barton v. Estate of Buckley*, 867 So. 2d 271, 272 (Miss. Ct. App. 2004); *Grasser v. Kitzis*, 553 A.2d 346 (N.J. Super. Ct. App. Div. 1988); *Scott v. Bradford*, 606 P.2d 554, 559 (Okla. 1979); see also DOBBS, *supra* note 60, § 250 (setting forth five elements).

either recommending or performing a given therapy.<sup>80</sup> It assumes no operational negligence but instead focuses on the failure to deliver to the patient information about risks attached to the therapy.<sup>81</sup>

Courts differ as to the standard that governs the determination of whether a risk is material such that it warrants disclosure to the patient. Some jurisdictions measure materiality based on what information a "reasonable doctor" would provide.<sup>82</sup> Others refuse to cede to the medical profession the decision of what risks ought to be disclosed. Emphasizing that the heart of an informed consent right is patient autonomy, they opt for a "reasonable patient" standard to determine materiality.<sup>83</sup> With regard to causation, courts are also not in agreement. Some require that for the causal nexus to be met, a plaintiff must establish that a "reasonable patient"<sup>84</sup> would have chosen against the therapeutic intervention. Other courts take the position that if the patient herself would have chosen otherwise, causation is established.<sup>85</sup>

Commentators have argued that requiring the plaintiff to prove what decision would have been made had the material information been communicated to the plaintiff undercuts the goal of patient autonomy.<sup>86</sup> The

80. See Aaron D. Twerski & Neil B. Cohen, *Informed Decision Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. ILL. L. REV. 607, 616-17 (1988).

81. *Id.*

82. See, e.g., *Rush v. Miller*, 648 F.2d 1075, 1076 (6th Cir. 1981); *Shetter v. Rochelle*, 409 P.2d 74, 86 (Ariz. Ct. App. 1965), *modified*, 411 P.2d 45 (Ariz. Ct. App. 1966); *Fuller v. Starnes*, 597 S.W.2d 88, 89 (Ark. 1980); *Williams v. Boyle*, 72 P.3d 392, 398 (Colo. Ct. App. 2003); *Ditlow v. Kaplan*, 181 So. 2d 226, 228 (Fla. Dist. Ct. App. 1965); *Doe v. Chand*, 781 N.E.2d 340, 347 (Ill. App. Ct. 2002); *Natanson v. Kline*, 350 P.2d 1093 (Kan. 1960), *reh'g denied*, 354 P.2d 670 (Kan. 1960); *Osburn v. Danek Med., Inc.*, 520 S.E.2d 88, 91 (N.C. Ct. App. 1999); *Mitchell v. Kayem*, 54 S.W.3d 775, 779 (Tenn. Ct. App. 2001). The reasonable doctor standard for materiality is mandated by statute in some states. See, e.g., N.Y. PUB. HEALTH LAW § 2805-d (McKinney 2002); N.Y. C.P.L.R. § 4401-a (McKinney 1992); N.C. GEN. STAT. § 90-21.13 (2003); see also Laurent B. Frantz, Annotation, *Modern Status of Views as to General Measure of Physician's Duty to Inform Patient of Risks of Proposed Treatment*, 88 A.L.R.3d 1008 (1978).

83. See, e.g., *Canterbury*, 464 F.2d at 787 (D.C. Cir. 1972); *Cobbs v. Grant*, 502 P.2d 1, 10 (Cal. 1972); *Ketchup v. Howard*, 543 S.E.2d 371, 378 (Ga. Ct. App. 2000); *Mannina v. Borland*, 869 So. 2d 946, 953 (La. Ct. App. 2004); *Jamison v. Kolgore*, No. 2003-CA-00599-COA, 2004 WL 614780, at \*2 (Miss. Ct. App. Mar 30, 2004); *Howard v. Univ. of Med. & Dentistry of N.J.*, 800 A.2d 73, 78 (N.J. 2002); *Koapke v. Herfendal*, 660 N.W.2d 206, 212 (N.D. 2003); *State v. Breen*, 767 A.2d 50, 58 (R.I. 2001).

84. *Canterbury*, 464 F.2d at 790; *Fluck v. Coffman*, 862 So. 2d 1105 (La. Ct. App. 2003); *Barton v. Estate of Buckley*, 867 So. 2d 271, 272 (Miss. Ct. App. 2004); *Spano v. Bertocci*, 749 N.Y.S.2d 275, 278 (N.Y. App. Div. 2002).

85. See, e.g., *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979); *Arena v. Gingrich*, 733 P.2d 75 (Or. Ct. App. 1987); *Kenny v. Wepman*, 753 A.2d 924, 926 (R.I. 2000); *Wilkenson v. Vesey*, 295 A.2d 676, 690 (R.I. 1972).

86. See, e.g., PAUL S. APPELBAUM ET AL., *INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE* 122 (1987) ("By conditioning the availability of compensation on the congruence between the patient's own decision and what a so-called reasonable person would have decided, the objective test undercuts a patient's right of self-determination."). Other commentators have voiced similar criticism. See, e.g., JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* 79-80 (1984); Richard A. Epstein, *Medical Malpractice: The Case for Contract*, 1976 AM. B. FOUND. RES. J. 87, 121 n.72 (1976); Joseph Goldstein, *For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L.J. 683, 691 (1975); Marjorie



undeniable fact is that the patient was not provided with the information necessary to decide whether to undergo the therapy. The physician proceeded unilaterally. Though this argument is theoretically sound, as a practical matter the issue of decision-causation is rarely decided against plaintiffs as a matter of law.<sup>87</sup> It is almost always given over to the sound discretion of juries. The requirement that the plaintiff establish the causal connection between the therapeutic intervention and the injury actually suffered is almost never a matter of contention.<sup>88</sup> Indeed, it is only when the plaintiff suffers from the undisclosed risk that the plaintiff is moved to bring suit. The damages for failure to provide informed consent are measured by the unwarned-against adverse outcome that the plaintiff suffered.<sup>89</sup>

In the case of uncertain risk that is the hallmark of the cases in which *Daubert* forecloses recovery, the issue of decision-causation is rarely in doubt. As noted earlier, patients taking lifestyle drugs if informed of uncertain risks that could have disastrous consequences, would most often choose against exposing themselves to them. However, as long as the law demands that injury-causation be proven, *Daubert* will block recovery whenever a plaintiff cannot establish that the toxic agent caused her injury. It matters not that the defendant was undeniably negligent in failing to warn about the risk so that the plaintiff could make an informed choice as to whether she wishes to subject herself to it. Unlike decision-causation, which is almost always a jury issue in medical malpractice cases and thus opens the path for recovery based on the denial of the right to make an autonomous choice, the injury-causation issue in cases of uncertain risk will be decided for the defendant under *Daubert* as a matter of law, making *Daubert* an insurmountable bar-

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Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 249-51 (1985).

87. The authors have yet to find a case where a court has directed a verdict for a defendant-physician on the grounds that had the plaintiff been informed of a material risk, she nevertheless would have chosen the therapeutic intervention that caused her injury.

88. *But see* Lugenbuhl v. Dowling, 701 So. 2d 447, 452-53 (La. 1997) (holding that where patient insisted that surgeon use a surgical mesh in repairing his hernia and surgeon did not do so, the failure to do so was not the cause of patient's subsequent massive herniation).

89. Courts regularly award plaintiffs damages for the adverse consequences suffered as a result of the failure of the physician to provide the requisite information necessary to make an informed choice. Professor Richard Epstein notes that courts do not address the question of what might have happened to the patient if appropriate disclosures had led the patient to refuse the proposed treatment. He argues:

While it might be tempting to hold the physician responsible for the harm caused by the treatment, that position is quite unsound if it does not take into account the harm that would have occurred in any event. In tort actions for harm caused to strangers, the plaintiff's preexisting condition is usually not an issue, since such plaintiff is normally of sound mind and body. In those cases where he is not, the accepted view, whenever apportionment is possible, is to allow recovery only for the additional harm that was caused by the tortfeasor's conduct and not for the total amount of harm experienced thereafter. For those patients (doubtless a significant proportion) who were not healthy at the outset of treatment, their precarious condition carries with it the substantial risk of further harm if prompt corrective steps are not taken. We are not talking of remote or speculative possibilities. In the medical context the possible reduction in damages required by the application of the rule is likely to be substantial in many cases and total in others.

Epstein, *supra* note 86, at 121-22; *see also*, TWERSKI & HENDERSON *supra* note 5, at 80-81.

rier to recovery for the deprivation of informed choice. The maxim that there is no injury if there is no harm should not apply because the denial of the right to choose not to expose oneself to an uncertain risk violates a very basic human right of autonomous decisionmaking, yet it will receive no recognition under the existing medical malpractice informed consent paradigm.

### B. *Products Liability: The Informed Choice Paradigm*

In a parallel development, courts began recognizing an informed choice cause of action in drug cases as early as 1968. In *Davis v. Wyeth Laboratories, Inc.*,<sup>90</sup> the defendant manufacturer sold polio vaccine without warning of the risk that one person in a million would contract polio from taking the vaccine. The court held that the manufacturer had a duty to warn the consumer of the risks involved and that the failure to meet this duty rendered the drug unfit and unreasonably dangerous within the meaning of § 402A of the Restatement (Second) of Torts. The court stated:

In such cases, then, the drug is fit and its danger is reasonable only if the balance is struck in favor of its use. Where the risk is otherwise known to the consumer, no problem is presented, since choice is available. Where not known, however, the drug can properly be marketed only in such fashion as to permit the striking of the balance; that is, by full disclosure of the existence and extent of the risk involved.

...

There will, of course, be cases where the personal risk, although existent and known, is so trifling in comparison with the advantage to be gained as to be de minimis. Appellee so characterizes this case. It would approach the problem from a purely statistical point of view: less than one out [of] a million is just not unreasonable. This approach we reject. When, in a particular case, the risk qualitatively (e.g., of death or major disability) as well as quantitatively, on balance with the end sought to be achieved, is such as to call for a true choice judgment, medical or personal, the warning must be given.<sup>91</sup>

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90. 399 F.2d 121 (9th Cir. 1968).

91. *Id.* at 129-30.

The Restatement (Third) of Torts: Products Liability<sup>92</sup> has endorsed these grounds for liability and this position is supported by a substantial body of case law.<sup>93</sup> However, the informed choice theory only triggers recovery if injury-causation has been established under traditional causation rules. Thus, it is only because plaintiff could prove that the vaccine actually brought about his polio that plaintiff was able to recover.<sup>94</sup> Had plaintiff failed to establish injury-causation, the right to informed choice based on a drug manufacturer's negligent failure to warn would have been irretrievably lost.

If indeed there is a right to informed choice, conditioning the right on proof that the harm was actually brought about by the defendant's conduct makes no sense whatsoever. If an uncertain risk of harm should have been communicated to the plaintiff so that the plaintiff could assess whether she wished to play this game of russian roulette, to then say that the plaintiff is not entitled to recovery because she cannot prove that the harm was actually caused by the suspect drug, renders the right to informed choice illusory.

If the courts are truly committed to the principle of autonomous decisionmaking, why is it that they have failed to see that insisting on injury-causation sabotages the autonomy right? And why have plaintiffs' counsel

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92. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. i (1997) provides:

In addition to alerting users and consumers to the existence and nature of product risks so that they can, by appropriate conduct during use or consumption, reduce the risk of harm, warnings also may be needed to inform users and consumers of nonobvious and not generally known risks that unavoidably inhere in using or consuming the product. Such warnings allow the user or consumer to avoid the risk warned against by making an informed decision not to purchase or use the product at all and hence not to encounter the risk. In this context, warnings must be provided for inherent risks that reasonably foreseeable product users and consumers would reasonably deem material or significant in deciding whether to use or consume the product. Whether or not many persons would, when warned, nonetheless decide to use or consume the product, warnings are required to protect the interests of those reasonably foreseeable users or consumers who would, based on their own reasonable assessments of the risks and benefits, decline product use or consumption. When such warnings are necessary, their omission renders the product not reasonably safe at time of sale. Notwithstanding the defective condition of the product in the absence of adequate warnings, if a particular user or consumer would have decided to use or consume even if warned, the lack of warnings is not a legal cause of that plaintiff's harm. Judicial decisions supporting the duty to provide warnings for informed decisionmaking have arisen almost exclusively with regard to those toxic agents and pharmaceutical products with respect to which courts have recognized a distinctive need to provide risk information so that recipients of the information can decide whether they wish to purchase or utilize the product.

93. See, e.g., *Watkins v. Ford Motor Co.*, 190 F.3d 1213, 1219 (11th Cir. 1999) (holding that purchaser of SUV should have been warned of rollover characteristics of vehicle allowing him to make an informed choice whether to take the risks warned against); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1274 (5th Cir. 1974) (holding that polio vaccine is unavoidably dangerous but defendant is liable for failure to warn parents that vaccine may cause polio); *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1089 (5th Cir. 1973) (holding that asbestos benefits may outweigh risk but defendant is liable for failing to give workers an informed choice as to whether they wish to expose themselves to the risk); *Williams v. Lederle Labs.*, 591 F. Supp. 381, 383 (S.D. Ohio 1984) (holding that beneficial but dangerous drugs must be accompanied by adequate warnings of risk); *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377, 1379 (Okla. 1975) (same).

94. See *Reyes*, 498 F.2d at 1280 (requiring plaintiff to prove that vaccine caused polio); *Cunningham*, 532 P.2d at 1381 (finding that medical testimony established that plaintiff's polio was caused by vaccine).

not been vigorous advocates for the recognition of the autonomy right as a freestanding cause of action when faced with the reality that their cases are in jeopardy of dismissal on *Daubert* grounds? We believe that there are two reasons that courts and litigants have shied away from recognizing a causation-free autonomy right. First, they have not developed criteria for deciding materiality of risk in the autonomy-only paradigm. Second, without injury-causation that defines the harm in concrete terms, they find themselves at sea in valuing the denial of the right to autonomy. Without some guidance on how to resolve these two questions, it is likely the courts will not recognize or pursue the autonomy right.

### III. REDEFINING MATERIALITY FOR A CAUSATION-FREE INFORMED CHOICE ACTION

In a causation-free informed choice cause of action, a *prima facie* case for liability is established when a drug manufacturer fails to warn about a material risk and plaintiff subsequently suffers from that undisclosed risk. The plaintiff makes out her case even if she cannot establish that the toxic agent caused her specific injury. Plaintiff bases her claim of informed choice solely on the grounds that defendant failed to disclose a material risk that warranted a warning by the defendant. What constitutes a material risk in the causation-free informed choice setting warrants careful attention.

In the classic malpractice or product liability action in which causation must be established, the law can tolerate a vague definition of materiality. Regardless of whether the applicable materiality standard is what a reasonable patient would expect to be told or what a reasonable doctor would reveal, the utilization of a fact-sensitive reasonableness test is counterbalanced by the requirement that the injury was actually caused by the therapeutic intervention or drug. In the causation-free informed choice cause of action that we propose, the claim of failure to warn about a material risk is not buttressed by a finding of injury-causation. If causation-free informed choice litigation is to become a reality, we shall need to provide some direction to courts as to what factors they should take into account in deciding whether a risk is material. We do not suggest a litmus test for materiality. However, we do suggest that a scientific framework exists for determining risk, and that many of the factors spurned by courts under *Daubert* as insufficient to establish causation are highly relevant to the determination that a risk was of sufficient moment to deserve an informed choice warning.

We begin by noting that whether a risk is of sufficient moment that a patient is entitled to know of it before ingesting a lifestyle drug requires an evaluation of information stemming from a host of sources.<sup>95</sup> Even if these

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95. For prescription drugs the patient will learn of the risks associated with taking the drug from her physician. The overwhelming majority of courts requires only that the pharmaceutical manufacturer provide information regarding risks to the learned intermediary and not directly to the consumer herself. See *RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY* § 6(d)(1) (1997); see also *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806–12 (E.D. Tex. 2002) (comprehensively reviewing state law endorsing the learned intermediary rule). *But see* *Perez v.*

risk-related data do not suffice to establish legal causation, that does not mean that these data do not raise serious questions about the existence of substantial risks. At the moment a drug is prescribed, because of the lack of data, no one, including the manufacturer of the drug or device, may know whether the product is capable of causing harm.<sup>96</sup> However, over time sufficient signals may emerge to alert scientists that injuries may eventuate. Animal studies that are almost always challenged under *Daubert* because of the dissimilarity between both the dosages administered to animals and the biological differences between animals and humans may be highly probative as to the potential toxicity of a drug.<sup>97</sup> Adverse Reaction Reports, regularly dismissed by courts as too sporadic and anecdotal to support causation,<sup>98</sup> are viewed by scientists as enormously important in evaluating whether a risk is sufficiently credible to warrant an informed choice warning.<sup>99</sup> Other evidence that fails to impress judges at *Daubert* motions, such as evidence relating to the suspect chemical's structural similarity to a known toxic agent,<sup>100</sup> *in vitro* studies,<sup>101</sup> or inconclusive epidemiological studies,<sup>102</sup> are all relevant to the issue of whether a risk worthy of warning is present.

In dealing with each genre of scientific evidence on which plaintiffs' experts rely to prove causation, many courts have evaluated the strength of each category standing alone.<sup>103</sup> If an individual study within a species of

Wyeth Labs., Inc., 734 A.2d 1245, 1250–60 (N.J. 1999) (rejecting the learned intermediary rule where the drug was directly advertised to patients); William A. Dreier, *Direct-To-Consumer Advertising Liability: An Empty Gift to Plaintiffs*, 30 SETON HALL L. REV. 806 (2000) (arguing that the New Jersey rejection of the learned intermediary rule in cases of direct advertising will not broaden plaintiffs' rights to recover). What standard should be used to determine whether a risk is sufficiently material so as to warrant disclosure to the physician is the subject of this section.

96. See *supra* discussion accompanying notes 12–15, as to why pre-marketing tests for efficacy and safety cannot establish that a product will cause no harm.

97. See sources cited *supra* note 49.

98. See, e.g., *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002).

99. The limitations of such reports are well-recognized, but they serve a critical warning function, and may point to an unreasonable risk, especially if other types of data support the same conclusion. Fewer reports will be needed the rarer the event. *Id.* It is sobering to note that the causal relationship between asbestos and lung cancer had been established in Germany by 1943, but that no scientific consensus existed on this issue in the United States until 1964. An article that examined 104 papers or writings that were published through 1965 concluded that at least part of the problem was that case reports were “given little weight.” See Philip E. Enterline, *Changing Attitudes and Opinions Regarding Asbestos and Cancer 1934–1965*, 20 AM. J. INDUS. MED. 685, 694 (1991).

100. See, e.g., *Rider*, 295 F.3d at 1200–01.

101. See, e.g., *Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co.*, 189 F. Supp. 2d 482 (S.D. W. Va. 2002) (“courts have overwhelmingly found unreliable the methodology of extrapolating human teratogenicity from *in vivo* and *in vitro* tests”), *aff'd*, 85 Fed. Appx. 964 (4th Cir. 2004).

102. See *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 318 F. Supp. 2d 879, 897 (C.D. Cal. 2004) (finding that there was inconclusive epidemiology as to whether breast implants coated with polyurethane caused breast cancer).

103. The problem of examining each study standing alone to determine whether it supports a finding of causation was raised by Justice Stevens in his concurring opinion to *General Electric Co. v. Joiner*, 522 U.S. 136, 152–53 (1997). He notes:

[Plaintiff's experts] did not suggest that any one study provided adequate support for their conclusions, but instead relied on all the studies taken together (along with their interviews of

evidence is found to be weak, such as a particular epidemiological or toxicological study, it is faulted as not providing a reliable basis for the expert's opinion. After excluding the studies one by one, the court rejects the expert's opinion for failing to meet the *Daubert* criteria. Courts rarely ask whether the information in toto is probative on the issue of causation. It is debatable whether this fragmented approach to admitting expert proof on causation is justified, but we doubt that anyone would countenance a fragmented approach to risk evaluation. Indeed, it is only when you put together all the evidence from all the sources that one can divine whether a risk is sufficiently significant that it should be the subject of an informed choice warning.

That all forms of data must be considered in order to assess risk is not only mandated by fundamental principles of tort law but is also grounded in good science. Several years ago the FDA requested that the Institute of Medicine and the National Research Council of the National Academies undertake a study to set forth guidelines for evaluating the safety of dietary

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Joiner and their review of his medical records). The District Court, however, examined the studies one by one and concluded that none was sufficient to show a link between PCB's [sic] and lung cancer. The focus of the opinion was on the separate studies and the conclusions of the experts, not on the experts' methodology. . . .

Unlike the District Court, the Court of Appeals expressly decided that a "weight of the evidence" methodology was scientifically acceptable. To this extent, the Court of Appeals' opinion is persuasive. It is not intrinsically "unscientific" for experienced professionals to arrive at a conclusion by weighing all available scientific evidence—this is not the sort of "junk science" with which *Daubert* was concerned.

*Id.* (citations and footnotes omitted); *see also* the Parlodel cases cited *supra* note 69. In these cases, in which the courts found that plaintiff's experts did not meet the *Daubert* criteria, they appeared to consider each category of scientific evidence separately and showed no inclination to evaluate all the evidence to determine whether the experts' opinions taken together established causation. *See, e.g.,* *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1216 n.21 (10th Cir. 2002). For example, the Tenth Circuit stated:

The Hollanders also suggest that a totality of the circumstances approach establishes that there are controverted issues of material fact. In essence they 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. The Hollanders cite no legal authority in support of this approach, and in our view, this argument is inconsistent with *Daubert*. To suggest that those individual categories of evidence deemed unreliable by the district court may be added to form a reliable theory would be to abandon "the level of intellectual rigor" of the expert in the field.

*Id.* (citation omitted). The systemic nature of this trend toward fractionalization of causation testimony to decide whether the *Daubert* criteria have been met is noted by Finley, *supra* note 11, at 353, in her discussion of *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996) (holding that expert testimony that silicone breast implant caused various auto-immune diseases did not meet *Daubert* test). *But see In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1248 (W.D. Wash. 2003) (finding that "cumulative effect . . . satisfies the mandate of *Daubert*"); Jerome P. Kassirer & Joe S. Cecil, *Inconsistency in Evidentiary Standards for Medical Testimony*, 288 J. AM. MED. ASS'N 1382, 1383-84 (2002) (discussing the epidemiologist's perspective and concluding: "In the final analysis, assessment of evidence and causal inferences depend on accumulating all potentially relevant evidence and making a subjective judgment about the strength of the evidence.").

supplements.<sup>104</sup> The FDA has no authority to regulate dietary supplements before they are marketed. It can only take action against a manufacturer of a dietary supplement if it can show that the supplement (or its dietary ingredients) “presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling.”<sup>105</sup> In a 2004 report entitled *Dietary Supplements: A Framework for Evaluating Safety*, the committee charged by the FDA with the task of defining when the threshold triggering a need for regulation has been met concluded that no single criterion could adequately be used to determine whether a risk was “significant or unreasonable.”<sup>106</sup> The entire gamut of data from all sources must be garnered and evaluated. Thus, in vitro studies, animal testing results, Adverse Reaction Reports, chemical structural similarity, as well as epidemiological studies that suggest a weak association between the toxic agent and an adverse reaction may in combination lead one to conclude that the supposed benefits of the dietary supplement do not warrant the risks attendant to its use.<sup>107</sup> The report makes it clear that proof of causality or harm is not necessary for the determination that risk is significant or unreasonable.<sup>108</sup>

Furthermore, in evaluating and integrating the signals that point to a material risk, courts should bear in mind that they are not deciding whether the risk was significant enough to warrant forceful or drastic action by the FDA such as requiring black box warnings or removing the drug from the market. All a court need decide is whether the signs of risk and their potential gravity were sufficiently strong to require a drug manufacturer to alert physicians so they in turn can provide information to patients that will enable them to make a meaningful choice.

In addition, in determining whether a risk was material, courts should also consider evidence that a defendant willfully failed to disclose information that pertains to risks posed by its product. Traditional evidentiary principles permit negative inferences to be drawn from party admissions and evasive or destructive behavior. For example, a court should consider whether the defendant (1) failed to inform the medical community about the results of negative clinical drug trials,<sup>109</sup> (2) brushed off physicians’ inquiries

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104. INST. OF MED. & NAT’L RESEARCH COUNCIL, *DIETARY SUPPLEMENTS: A FRAMEWORK FOR EVALUATING SAFETY* 1–2 (2004), available at <http://www.nap.edu/books/0309091101/html> (last visited July 19, 2005).

105. 21 U.S.C. § 342(f)(1)(A)(i) (2001).

106. INST. OF MED. & NAT’L RESEARCH COUNCIL, *supra* note 104.

107. *Id.* at 255–56 (“[A]vailable evidence from each category of data, by itself, may be insufficient to indicate concern, but when a pattern of mechanistically related adverse effects is observed across two or more categories in a consistent manner, this can establish biological plausibility and warrant heightened concern for potential harmful effects in humans.”); see also *Joiner*, 522 U.S. at 522 n.4, and discussion in accompanying text (in which Justice Stevens notes that the Environmental Protection Agency gathers material from a host of sources to assess risks).

108. INST. OF MED. & NAT’L RESEARCH COUNCIL, *supra* note 106, at 12 (“Proof of causality or proof of harm is not necessary to determine unreasonable or significant risk.”).

109. The prevalence of such conduct has led to demands by the leading medical journals for registries of clinical trials, and the introduction of legislation to this effect. See Kay Dickersin & Drummond Rennie, *Registering Clinical Trials*, 290 J. AM. MED. ASS’N 516, 519 (2003) (“There is

about the safety of the product even though it knew that the FDA was considering whether to remove the drug from the market,<sup>110</sup> (3) distributed internal memoranda expressing fears about problems with the drug,<sup>111</sup> or (4) made advertising claims about the product's lack of side effects at a time when it was receiving reports to the contrary.<sup>112</sup> Admittedly, there is little social utility in providing information that is so tentative and unreliable that it will serve no purpose other than to frighten patients who need the drug away from its use. On the other hand, where the drug has little therapeutic value and provides only aesthetic or palliative relief but the risk is substantial, the balance in favor of disclosure shifts dramatically.

One could simply analogize to the law of informed consent that bases the standard of materiality on whether a reasonable doctor would disclose the risk, or whether a reasonable patient would consider the risk relevant in deciding whether to take the drug.<sup>113</sup> Critics of the physician-based standard for informed consent decry the delegation of an important autonomy decision to the custom of the medical profession.<sup>114</sup> However, since the issue in the drug cases is not whether the doctor was negligent, but rather whether the pharmaceutical manufacturers failed to provide physicians with adequate risk information, deferring to the medical profession has substantial advantages. Doctors are likely to ally themselves with the interests of patients and demand that relevant risk data be shared with them.<sup>115</sup> However, being

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evidence that many industry trials are never published. . . . Because there is commercial advantage to be gained by early publication of positive results and the suppression of negative results, industry reluctance to publish negative findings would not come as a surprise.”)

110. See *Nelson v. Sandoz Pharms. Corp.*, 288 F.3d 954, 959 (7th Cir. 2002) (finding that plaintiff asked her doctor to check whether Parlodel could have caused her post-partum stroke; Parlodel sales representative told doctor that strokes did not occur more frequently with patients taking Parlodel than those in the general post-partum population, but did not tell him that more than six months before plaintiff was prescribed Parlodel the FDA had requested the defendant to remove the drug from the market as a lactation suppressant and that Sandoz had refused; a second doctor whom plaintiff consulted was also unable to find any information that Parlodel posed a risk). For an extensive discussion of the lengthy negotiations between the FDA and the defendant that ultimately led to Parlodel's removal from the market, see *Eve v. Sandoz Pharms. Corp.*, No. IP 98-1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531, at \*10-40 (S.D. Ind. March 7, 2001).

111. Internal company documents and e-mails leaked to the *Wall Street Journal* suggest that Merck knew of problems with Vioxx by 2000. See Anna Wilde Matthews & Barbara Martinez, *E-Mails Suggest Merck Knew Vioxx's Dangers at Early Stage*, WALL ST. J., Nov. 1, 2004, at A1.

112. See *Desiano v. Warner-Lambert Co.*, 326 F.3d 339, 342 (2d Cir. 2003) (finding that although Warner-Lambert was claiming in advertisements that Rezulin, a drug for diabetes, had “[s]ide [e]ffects [c]omparable to [p]lacebo,” in fact “its own clinical trial data showed Rezulin users were three to six times more likely to suffer liver injury than patients taking the placebo”).

113. See *supra* discussion accompanying notes 82-83.

114. See sources cited *supra* note 83.

115. Pressure on physicians to prescribe particular drugs to their patients has increased enormously. Direct advertising by pharmaceutical companies to consumers now totals \$3.8 billion, leading patients to demand prescriptions for products they have heard about through ad campaigns and from surfing the Internet. Stuart Elliott, *With or Without Vioxx, Drug Ads Proliferate*, N.Y. TIMES, Dec. 6, 2004, at C17. In order to withstand such appeals, a doctor needs detailed information about drugs that pose the threat of a substantial risk. A physician cannot function as the learned intermediary who shields the patient from harm unless he or she is kept abreast of current data.



professionally trained to assess risk, they will not be prone to deem highly speculative risk as worthy of disclosure.

Finally, courts will have to remain alert to the danger of allowing junk science to enter the courtroom door. But, unlike in the *Daubert* causation cases, they will be looking at the totality of evidence of risk and asking themselves whether it is sufficiently probative to warrant a warning. There is no magic bullet that will insure that a case based on tentative and unreliable data will not find its way to a jury. Judicial vigilance will be necessary, but courts mindful that they are passing on materiality to support a cause of action that does not require proof of traditional causation should be up to the task of ferreting out unworthy and frivolous claims.

#### IV. FORMULATING A REMEDY FOR THE DEPRIVATION OF CHOICE

Formulating a remedy for the deprivation of choice is no easy matter. Case law is sparse on this issue. Plaintiffs have not pursued pure informed choice claims decoupled from injury-causation. They have almost always coupled their claims for violation of informed choice in both medical malpractice and products liability with proof that the unwarned-of risk was actually caused by the therapeutic intervention or the drug that the plaintiff ingested. Courts have had no difficulty awarding the full range of compensatory damages based on the adverse result.<sup>116</sup> On reflection, there are two forms of damages that foster either the corrective justice or efficiency goals of the law of torts. First, the failure to inform patients about material risks invades the right of autonomous decisionmaking, and could give rise to damages for dignitary harm. Second, a plaintiff who is subjected to a material risk and suffers from the very harm that should have been warned against, may experience serious mental anguish from the fact that the patient must live with the reality that the harm may have been avoidable. Even though courts ultimately decline to find causation because epidemiological studies demonstrate that the likelihood of causation is extremely low in the population of persons exposed, that does not prove an absence of causation with regard to each individual in the group.<sup>117</sup> Epidemiology does not deal with individuals, and does not claim that studies showing a lack of adverse effects to the population being studied prove that the particular substance can never cause harm to anyone. In the Bendectin cases, for example, it is impossible to rule out that the morning sickness remedy is a mild teratogen that contributed to birth defects in some indeterminate number of cases in which the causal effect was too low to be detected. A mother who used the drug and whose child is deformed may therefore experience lifelong regret. This form of human anguish is no small matter and does not depend on

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116. See *supra* note 89.

117. Green et al., *supra* note 35, at 337 (“[E]mploying the results of group-based studies of risk to make a causal determination for an individual plaintiff is beyond the limits of epidemiology.”).

proof that the drug actually caused the harm. It is quite sufficient that the material risk may have been responsible for the harm.

One might consider the possibility of awarding damages based on the increased risk that plaintiff was subjected to by taking the drug.<sup>118</sup> Whether recovery for proportional causation should be recognized outside of the medical malpractice arena is a subject of some debate.<sup>119</sup> However, even if theoretically one could consider some reduced proportional recovery for informed choice cases based on increased risk, it is not a practical option. We have been proceeding on the premise that epidemiological studies that accurately reflect increased risk are not likely to be readily available. As noted earlier, to commission studies for litigation purposes of low probability risks may be prohibitively expensive and, in some instances, ethically unallowable.<sup>120</sup> The non-epidemiological evidence which may support a duty

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118. Several authors have advocated recognizing an independent right for the deprivation of choice. See Mark Geistfeld, *Scientific Uncertainty and Causation in Tort Law*, 54 VAND. L. REV. 1011, 1017–21 (2001); Porat & Stein, *supra* note 6, at 1891. Professor Geistfeld correctly identifies the need to recognize a right for the deprivation of autonomous choice but does not analyze the issue in light of the rather substantial body of case law dealing with informed choice. Furthermore, Geistfeld concludes that once “the plaintiff has established a tortious invasion of her autonomy interest . . . [w]hether the product tortiously caused the plaintiff’s [injury] therefore involves a question of damages rather than of liability.” Geistfeld, *supra*, at 1018, 1021–22. He then suggests that the evidentiary standard for assessing damages for the physical injury that followed the deprivation of choice be relaxed so that plaintiff can recover some damages. *Id.* at 1021. Ultimately, Geistfeld retracts his autonomy argument by seeking to value its deprivation by some measure of physical injury damages. Professors Porat and Stein deal with the issue of uncertainty in tort litigation in a very different manner. They argue that evidential uncertainty resulting from defendant’s wrongdoing deprives the plaintiff of her ability to prosecute her case and deprives her of her autonomous choices in enforcing her legal rights. Porat & Stein, *supra* note 6, at 1894. They would value the uncertainty created by the defendant’s fault by assessing the market value of the missing information. *Id.* at 1926–27. The threat posed by a potential lawsuit and its settlement value can be monetized by treating the missing information as an asset that the plaintiff is willing to sell and the defendant is prepared to buy off for the right price. *Id.* It is clear that although Porat and Stein propose to value autonomy, they do not seek to value the right to choice in and of itself. They treat uncertainty in the context of awarding damages for a discounted value of the outcome of the trial for physical damages. *Id.* This Article does not predicate the awarding of damages on the wrongful conduct of the defendant in failing to develop adequate information nor does it tie recovery to the physical damages that plaintiff suffered. It values autonomy for its own sake and seeks to compensate the plaintiff for damages brought about because the plaintiff was not informed of the uncertain risks. For a critique of the Porat and Stein thesis, see Vern R. Walker, *Uncertainties in Tort Liability for Uncertainty*, 1 LAW, PROBABILITY & RISK 175 (2002). See also Stephen R. Perry, *Protected Interests and Undertakings in the Law of Negligence*, 42 U. TORONTO L.J., 247, 290–91 (1992) (arguing that lost chance should be taken into account in valuing the deprivation of the opportunity to follow a preferable course of action).

Also see Twerski & Cohen, *supra* note 80, at 648–62. The authors argue for the recognition of a cause of action for the deprivation of the right to make an autonomous choice separate and apart from physical injury and explore several options for valuing the right.

119. For a comprehensive review and analysis of the judicial and scholarly community dealing with the proper utilization of the lost chance theory of recovery, see David A. Fischer, *Tort Recovery For Loss of a Chance*, 36 WAKE FOREST L. REV. 605 (2001). See also RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM (BASIC PRINCIPLES) § 26 cmt.h (Tentative Draft No. 2, 2002). One of the authors has taken the position that when excellent statistical data supports a showing of increased risk, proportional causation may be appropriate. See Aaron D. Twerski & Neil B. Cohen, *The Second Revolution in Informed Consent: Comparing Physicians to Each Other*, 94 Nw. U.L. REV. 1, 24–31 (1999).

120. See cases cited *supra* note 56.

to give a plaintiff an informed-choice will not provide the hard data necessary to support a recovery based on proportional causation.

### A. Dignitary Tort Damages

It would seem only fair that a plaintiff who ingested a drug that was not accompanied with adequate information about risks that she should have been informed of should at least be entitled to dignitary tort damages. The law of torts provides such compensation for assault, battery and false imprisonment without regard to whether the plaintiff suffered physical harm.<sup>121</sup> However, dignitary rights are primarily protected when the defendant has acted intentionally to invade the well-recognized right of personal security. On occasion, dignitary rights receive some recognition through the tort of intentional infliction of emotional distress. The strictures of that tort are such that even if a drug manufacturer were to be found to have intentionally failed to disclose information about uncertain risks, a cause of action could not be maintained. Courts demand that to make out a prima facie case the plaintiff must establish that the defendant's conduct was "extreme and outrageous."<sup>122</sup> In the case of failing to provide information with regard to uncertain risk, it is highly unlikely that such conduct would rise to the level that it could be labeled "extreme and outrageous." When the defendant acts negligently, the law of torts does not protect dignitary rights. Thus, for example, a plaintiff may recover damages for the intentional tort of assault. There is, however, no cause of action for negligent assault.<sup>123</sup> To recover, plaintiff would have to seek to invoke the tort of negligent infliction of mental distress. That cause of action brings along with it considerable baggage. Some courts do not recognize it at all and others limit the cause of action in a variety of ways.<sup>124</sup> We shall explore the action for mental distress in the ensuing section.

### B. Damages for the Anguish of Choice Deprivation

A cause of action for emotional distress arising from the failure to divulge material risk information that deprives a patient of informed choice presents a theory of recovery that could result in significant damages to plaintiffs.<sup>125</sup> As noted earlier, there is little direct authority on this issue. However, fairly recently the New Jersey Supreme Court struggled with the

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121. DOBBS, *supra* note 60, § 42.

122. *Id.* §§ 303-06.

123. KEETON ET AL., *supra* note 59, § 10.

124. DOBBS, *supra* note 60, § 308.

125. For an early article suggesting recovery for emotional distress where uncertainty prevents a plaintiff from establishing traditional causation, see Nancy Levit, *Ethereal Torts*, 61 GEO. WASH. L. REV. 136 (1992). See also Lisa Heinzerling & Cameron Powers Hoffman, *Tortious Toxics*, 26 WM. & MARY ENVTL. L. & POL'Y REV. 67 (2001) (positing that recovery be allowed for negligent infliction of emotional distress based on the dread associated with exposure to toxic substances).

problem. In *Canesi v. Wilson*,<sup>126</sup> plaintiff consulted Dr. Wilson, an obstetrician, concerned that she might be pregnant because she was amenorrheic for eleven days. Dr. Wilson took a urine sample and concluded that she was not pregnant. He then prescribed Provera, a progestational agent designed to induce menstruation. At the time she took the Provera there was a warning in the Physicians' Desk Reference ("PDR") that if a woman was taking Provera while she was pregnant, she should be advised that there was a risk that the fetus would suffer from congenital anomalies, including limb reduction. Two weeks later, Dr. Wilson gave plaintiff a blood serum test to determine if she was pregnant. This time the test was positive. Plaintiff asked Dr. Wilson if the Provera she had been taking could have a deleterious effect on a fetus and he told her not to worry. Plaintiff saw another physician, Dr. Lowe, and told him that she had taken Provera during the first month of pregnancy. He, too, told her not to worry about injury to the fetus. Plaintiff gave birth to a child born with bilateral limb reduction. Ultimately, it turned out that there was no evidence that Provera caused limb reduction, and a later version of the PDR dropped the limb reduction warning. It remains true, however, that Provera can cause congenital anomalies.

Plaintiff sued both doctors for failing to provide her with information about the risks associated with taking Provera during pregnancy. She claimed that had she known of the risk of congenital defects generally, or limb reduction specifically, she would have terminated the pregnancy. Defendants moved for summary judgment contending that since plaintiff could not prove that Provera caused the child's limb reduction, she had not proved "medical causation" and hence the plaintiff could not make out an action for lack of informed consent.<sup>127</sup> The trial court granted the defense motion and was affirmed by the intermediate appellate court.<sup>128</sup> The New Jersey Supreme Court reversed, finding that the plaintiff's claim for lack of informed consent could not stand, but that her claim for wrongful birth should not have been dismissed.<sup>129</sup>

The court engaged in a lengthy discussion comparing the elements of an informed consent case and those of one predicated on wrongful birth, brought by parents claiming that, had they been properly warned, the mother would have aborted the fetus. Both causes of action are predicated on a plaintiff's right to self-determination. The difference between the two is that "because damages in informed consent cases include the harm or physical injury to the patient, there must be medical causation, that is, a causal connection between the undisclosed risk and the injury ultimately sustained."<sup>130</sup> Thus, the plaintiff must show that: "(1) [a] prudent patient would have refused consent if full and adequate disclosure had been made, and (2) [the]

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126. 730 A.2d 805 (N.J. 1999).

127. *Id.* at 810.

128. *Canesi v. Wilson*, 685 A.2d 49 (N.J. Super. Ct. App. Div. 1996), *modified*, 730 A.2d 805 (N.J. 1999).

129. *Canesi*, 730 A.2d at 812-13.

130. *Id.* at 812 (citing *Grasser v. Kitizis*, 553 A.2d 346 (N.J. Super Ct. App. Div. 1988)).

injury suffered was related to [the medical intervention] and did not occur spontaneously or by independent means."<sup>131</sup> The court said that these two elements must be made out in cases that involve the prescription of drugs as well.<sup>132</sup> In sharp distinction, the court argued that in the wrongful birth case the plaintiff's claim is not for the birth defect of the child. Instead, it is "whether the doctors' inadequate disclosure deprived the parents of their deeply personal right to decide for themselves whether to give birth to a child who could possibly be afflicted with a physical abnormality."<sup>133</sup> It is for "their own mental and emotional anguish at having lost the opportunity to decide for themselves whether or not to terminate the pregnancy."<sup>134</sup>

The New Jersey Supreme Court thus concluded that the plaintiff's claim for informed consent seeking to recover damages for the limb reduction failed because there was insufficient evidence to establish medical causation and upheld the trial court's grant of summary judgment for the defendant on this issue.<sup>135</sup> As to the wrongful birth claim, the court held that the plaintiff was entitled to recover: (1) "special medical expenses attributable to raising a child with a congenital impairment" and (2) "the emotional injury attributable to the deprivation of 'the option to accept or reject a parental relationship with the child.'"<sup>136</sup> On this count the court overruled the trial court's grant of summary judgment for defendant and remanded for a new trial.

It should be obvious that the crucial distinction is not between informed consent and wrongful birth. As noted earlier, both claims seek to vindicate the right to self-determination and autonomy. The reason that the court found that the informed consent case fails and that the wrongful birth case can succeed is that the plaintiff in the informed consent case seeks damages for the physical injury caused by the failure to provide the information (injury-causation); whereas in the wrongful birth case the plaintiff eschews seeking damages for the birth defect and seeks only to vindicate the right to informed choice (decision-causation). It is interesting that in the wrongful birth case the court allows recovery both for the deprivation of the right to choose and the special medical expenses of raising a child with a congenital impairment. Allowing for these special expenses, however, logically follows from the conclusion that the mother would have aborted the fetus and would thus not have had to encounter these expenses. Having established decision-causation, her entitlement to special damages is unexceptional.

The analogy from the wrongful birth case to our paradigm case is almost exact. Just as a woman is entitled to recover for her "own mental and emotional anguish" for having lost the opportunity to decide whether she wished

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131. *Id.*

132. *Id.*

133. *Id.* at 818.

134. *Id.* at 813-14.

135. *Id.*

136. *Id.* at 819 (citations omitted).

to give birth to a child who could possibly be afflicted with a physical abnormality, so she should be entitled to recover for the emotional damages for having lost the opportunity to decide whether she wishes to take an anti-nausea drug that might cause serious birth defects or an anti-lactation drug that has a material risk of causing a stroke. That medical causation cannot be established should not be dispositive in either case. We thus advocate a cause of action for negligent infliction of emotional distress when plaintiff is deprived of an informed choice about material risk even if the causation of the actual physical injury cannot be established with the certainty demanded by traditional causation norms. We would expect that the greater the materiality of the risk, the greater the damages assessed against the defendant. And we would also expect that greater damages would be assessed if it were found that a defendant acted in bad faith in refusing to reveal material risk information. The sense of betrayal and hurt suffered by a plaintiff deprived of meaningful choice cannot be divorced from the conduct of the defendant who was responsible for the deprivation.<sup>137</sup>

We are mindful that the tort of negligent infliction of emotional distress is not universally recognized. Although most courts allow for the action without requiring proof of physical manifestations arising from the emotional harm,<sup>138</sup> some courts still demand some form of physical harm as a necessary element of the cause of action.<sup>139</sup> Two very strong arguments lead us to believe that even the minority should recognize such a cause of action in the case of informed choice. First, unlike general negligence, which is not targeted to a specific right, the duty to provide information for informed choice is very specific and will not be protected unless damages for emotional distress are granted. General negligent conduct regularly results in physical harm. Defendants cannot plan on avoiding exposure to liability. Drug manufacturers can, however, rely on the inability of plaintiffs to establish the very high causation threshold to escape liability. A credible deterrent must be put in place. Second, those courts that require objective symptomology do so because they fear that emotional distress is too easily feigned.<sup>140</sup> In the cases we address, plaintiffs suffer very substantial physical

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137. The authors would limit the right to recovery for mental distress to cases in which the unwarned-of risk actually materializes. Although, theoretically, the dignitary right to informed choice ought to be protected whether or not the risk materializes, there are good reasons for limiting recovery for mental distress to cases in which a plaintiff suffers actual harm. The cause of action for negligent infliction of emotional distress has traditionally been bounded by limited-duty rules to assure that it does not spread so wide a net that plaintiffs with marginal claims are allowed to recover. Thus, for example, many courts limit recovery to cases in which mental distress is manifested by physical symptoms. Bystander claims for mental distress are limited by courts to either persons in the zone of danger or those who witnessed the event. See DOBBS, *supra* note 60, §§ 308–12.

138. See, e.g., *Taylor v. Baptist Med. Ctr.*, 400 So. 2d 369 (Ala. 1981); *Molien v. Kaiser Found. Hosps.*, 616 P.2d 813 (Cal. 1980); *Culbert v. Sampson's Supermarkets, Inc.*, 444 A.2d 433 (Me. 1982).

139. See, e.g., *Wilson v. Sears, Roebuck & Co.*, 757 F.2d 948, 950 (8th Cir. 1985) (applying Nebraska law); *Dailey v. LaCroix*, 179 N.W.2d 390, 394 (Mich. 1970).

140. See, e.g., *Payton v. Abbott Labs.*, 437 N.E.2d 171, 181 (Mass. 1982); *Reilly v. United States*, 547 A.2d 894, 896 (R.I. 1988).

injury. The question is not whether the injury is real. That plaintiffs would suffer emotional distress from having been denied the right to avoid a devastating injury does not raise the verifiability problems that attend many of the cases of negligent infliction of emotional distress.

Admittedly, courts have generally been reluctant to broaden products liability-related mental distress claims. Thus, for example, in *Metro-North Commuter Railroad v. Buckley*,<sup>141</sup> the U.S. Supreme Court refused to recognize a claim under the Federal Tort Claims Act based on a plaintiff's exposure to asbestos when the plaintiff had exhibited no physical manifestation of any asbestos-related injury. The fear that an asymptomatic plaintiff might develop asbestosis at some time in the future was not sufficient to support recovery for mental distress. But the refusal of most courts to allow recovery for asymptomatic asbestos plaintiffs is predicated in large part on their right to recovery when and if they contract some actual asbestos-related disease.<sup>142</sup> In our informed choice paradigm case there is no tomorrow. The plaintiff who was denied informed choice suffers from the very harm not warned against. The risk was sufficiently material so that it warranted a warning. The right to choice has been inalterably denied. The causal connection remains clouded because of the inability to establish causation with sufficient clarity to satisfy traditional tort causation norms. Absent recovery for mental distress, the plaintiff remains forever without a remedy and drug companies need not look forward to a day of reckoning for their failure to provide the information necessary for autonomous choice.

Similarly, the reluctance of some courts to allow mental distress recovery for those who have been placed in fear of contracting HIV/AIDS should not stand in the way of recognizing a mental distress cause of action for informed choice.<sup>143</sup> Two factors characterize the fear of AIDS cases. First, courts have refused to feed AIDS phobia by giving legitimacy to the view that any contact whatsoever with an HIV-infected person can result in transfer of the HIV virus. Second, whatever mental distress is present is transient since blood tests can determine whether the plaintiff has contracted the HIV virus. In the informed choice case in which we propose recovery for mental distress, the materiality of the risk has been substantiated and the defendant has failed to provide the requisite information to the patient. The risk is anything but transient. Plaintiffs live daily with the unwarned-about consequences and will do so for the remainder of their lives.

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141. 521 U.S. 424, 428-32 (1997).

142. For a comprehensive discussion of why courts have been reluctant to allow recovery for asymptomatic exposure to asbestos, see James A. Henderson & Aaron D. Twerski, *Asbestos Litigation Gone Mad: Exposure-Based Recovery for Increased Risk, Mental Distress, and Medical Monitoring*, 53 S.C. L. REV. 815, 816-35 (2002).

143. Some courts have refused to allow recovery for mental distress arising from possible exposure to the HIV virus whether the action is brought as an intentional tort (battery): *Brzoska v. Olson*, 668 A.2d 1355 (Del. 1995); *Funeral Servs. by Gregory, Inc. v. Bluefield Cmty. Hosp.*, 413 S.E.2d 79 (W. Va. 1991), or negligence: *Majca v. Beekil*, 701 N.E.2d 1084 (Ill. 1998); *Carroll v. Sisters of St. Francis Health Servs., Inc.*, 868 S.W.2d 585 (Tenn. 1993).

The addition of an action for informed choice would affect the method of resolving *Daubert* challenges. Currently most *Daubert* challenges in toxic tort cases come before the trial court in the form of in limine motions to bar a plaintiff's expert from testifying about causation. Trial judges preside over extensive *voir dire* of the experts and then decide whether plaintiffs have adduced sufficient admissible evidence to warrant a trial on the merits.<sup>144</sup> As is discussed above, courts have found, in many instances with considerable justification, the expert opinions too weak to support traditional causation.

If courts were to recognize an action for informed choice, the same testimony offered on causation would be relevant to establishing the risk potential of the drug and whether the uncertain risk should have been warned against. There is little likelihood that plaintiffs' experts could be successfully challenged on their ability to assess risk. A review of the cases indicates that experts have rarely been challenged on their academic credentials.<sup>145</sup> Therefore, it would be far more cost-effective and efficient for a trial court to defer ruling on the *Daubert* motion with regard to the causation issue until trial.<sup>146</sup> If, at the close of plaintiffs' case, the trial judge believed that the *Daubert* criteria were not met with regard to the case for injury-causation, the court would grant a directed verdict for defendants on that issue. Plaintiffs would then be free to use the testimony of their experts to support their claims for lack of informed choice.

Recognition of a causation-free informed choice cause of action in which the damages would be for the infliction of mental distress raises the possibility that plaintiffs could successfully prosecute class actions. The major stumbling block to class certification in product liability personal injury actions has been that evidence of causation is so peculiar to the individual plaintiff that common issues of fact do not predominate.<sup>147</sup> If every case requires extensive testimony as to whether the defendant's product caused the plaintiff's harm, there are few economies of scale to be gained by class certification. However, once medical causation is removed as an issue from drug cases, the only individual issue is the degree and

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144. See, e.g., *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434 (W.D. Pa. 2003) (143-page opinion reviewing expert testimony); *Eve v. Sandoz Pharms. Corp.*, No. IP 98-1429-C-Y/S, 2001 U.S. Dist. LEXIS 4531 (S.D. Ind. March 7, 2001) (extensively rehearsing the testimony of experts who testified in many other cases dealing with Parlodel).

145. See, e.g., *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1354-56 (N.D. Ga. 2001) (holding that plaintiff's experts were well-qualified by education and experience to opine as to whether Parlodel caused plaintiff's stroke; however, their opinions did not meet *Daubert* criteria); *Nelson v. Am. Home Prods. Corp.*, 92 F. Supp. 2d 954, 968 (W.D. Mo. 2000) (holding that while plaintiff's expert was a highly qualified professor, his opinion as to whether Cordarone caused plaintiff to lose his eyesight did not meet *Daubert* criteria).

146. See *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (holding that a court has discretion "to avoid unnecessary 'reliability' proceedings . . . [when] the reliability of an expert's methods is properly taken for granted").

147. See, e.g., *In re Fibreboard Corp.*, 893 F.2d 706 (5th Cir. 1990) (holding that individual medical causation issues destroy commonality and hence prevent class certification); *Liggett Group Inc. v. Engle*, 853 So. 2d 434, 444-46 (Fla. Dist. Ct. App. 2003) (holding that medical causation is inherently individualized and thus not subject to class certification).



extent of the plaintiff's mental upset. Once liability for failure to warn is established, remand of the issue of damages alone for individual trials will not undermine the predominance requirement. The damages issue is so narrow and focused that even if the cases are not settled, the trials are likely to be short and subject to quick resolution.

### CONCLUSION

The current state of *Daubert* drug litigation is intolerable. Cases in which plaintiffs fall short of being able to meet the demanding criteria established for the admissibility of expert testimony on causation are deemed to have no merit whatsoever. That a toxic drug cannot be proven to have definitively caused a harm does not mean that plaintiffs should be deprived of the right to choose whether they wish to subject themselves to the material risk of that harm actually taking place. When the undisclosed risk actually occurs, plaintiffs have a legitimate claim that they must live their lives with a result that might have been avoided had they been properly informed. The sense of betrayal is greatest when a drug is prescribed not for therapeutic purposes, but rather, for aesthetic or palliative relief.

We are aware that there is no bright line that can be drawn between lifestyle and therapeutic drugs.<sup>148</sup> Nonetheless, the distinction is important as a beginning point in recognizing a cause of action for informed choice. In the former, the issue of decision-causation, that is, whether the plaintiff would have chosen against taking the drug if informed of the possible serious side effects, is much clearer. The decision-causation question is much more difficult in the case of drugs that have important therapeutic properties.<sup>149</sup> At this stage, we need not resolve the outer reaches of a causation-free informed choice drug case. It is sufficient that we outline the broad strokes of such a

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148. How, for instance, should the COX-2 inhibitors be classified? They do not cure underlying disease but alleviate pain and perhaps outperform other considerably cheaper drugs in preventing annoying, but sometimes extremely dangerous, perhaps fatal, gastrointestinal effects. It is possible that a combination of considerably cheaper and safer drugs would have had the same beneficial effects. There will certainly be issues about causation—not only over which COX-2 inhibitors can cause cardiovascular harm, but also about the circumstances in which they do so. Questions about dosage, latency, and underlying disease will certainly be raised even with regard to Vioxx, which Merck took off the market for causing an excess of strokes and heart attacks. It appears that neither physicians nor consumers were provided with adequate information to make an informed choice about using other drugs to relieve pain without the danger of gastrointestinal distress.

149. Where a drug has significant therapeutic value, the question of whether a patient properly informed of uncertain risks would have taken the drug if warned of them is highly complex. One of the authors has explored this issue at length in Twerski & Cohen, *supra* note 80. In that article, the authors examine decision-causation in the context of medical malpractice informed consent and conclude that there exists no credible model for determining what decision a patient would have made if informed of difficult choices between different therapeutic interventions, each presenting countervailing risks and benefits. It is for this reason that we have chosen to limit our proposal to lifestyle drugs where the decision-causation issue is more easily subject to resolution. Thus, we have little doubt that a woman in her first trimester of pregnancy faced with choosing between the discomfort of nausea and the uncertain risk of birth defects from a drug that would alleviate the symptoms would choose not to take the drug.

cause of action. Mrs. Mekdeci was right.<sup>150</sup> Whether Bendectin caused her child's limb reduction will never be known. But she has had to live with the agony that her child's deformity might have been avoided had she not taken Bendectin in the first trimester of her pregnancy. It was her choice to decide whether she wished to suffer the discomfort of nausea or take the chance that her child might be born with a birth defect caused by the drug. That choice was unjustly taken from her. No one has responded to her anguished cry that she was betrayed. We now do so.

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150. See Mekdeci Deposition, *supra* note 1.

