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Liability for Increased Risk of Harm: A Lawyer's Response to Professor Shafer

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LIABILITY FOR INCREASED RISK OF HARM: A LAWYER'S RESPONSE TO PROFESSOR SHAFER

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INTRODUCTION

Tort doctrine, which insists on proof of causation by a preponderance of the evidence, frustrates two of tort law's principal objectives—deterrence of harmful behavior and the facilitation of corrective justice—when applied to cases in which causation is extraordinarily difficult, if not impossible, to determine.[1] Causation problems are particularly complex in cases where plaintiffs allege that their injuries result from exposure to drugs or other chemicals. Professor Shafer's suggestion, which advocates allowing such plaintiffs to recover simply on a showing of increased risk of injury, is a provocative attempt to correct the inadequacies posed by current doctrine, and is an inspiring starting point for rethinking whether and to what extent tort doctrine must change.

I. THE CAUSATION REQUIREMENT

As a threshold matter, a plaintiff pressing a tort claim must prove that (1) the defendant owed plaintiff a duty to prevent reasonably foreseeable harm; (2) the defendant breached that duty; and (3) the breach of the duty caused harm to plaintiff. Even

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[1] There is broad recognition of this dilemma in legal scholarship, and scholars have suggested a wide range of solutions. *See, e.g.*, Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2122 (1997) (suggesting imposing upon manufacturers the duty to research and warn, the performance of which would constitute a complete defense to liability); Andrew R. Klein, *A Model for Enhanced Risk Recovery in Tort*, 56 WASH. & LEE L. REV. 1173 (1999) (proposing a doctrine that allows recovery for enhanced risk when plaintiff can show that exposure to the product has at least doubled plaintiff's risk of injury); Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773 (1997) (recommending a presumption of causation when manufacturers cannot show that they have performed minimal safety testing).

when tort claims do not involve toxic torts, the element of causation can be difficult. For example, suppose plaintiff sues a supermarket, claiming that the supermarket failed to clean a spill, that plaintiff slipped on the wet floor, and that she injured her back as a result.[2] In this example, plaintiff must clear two "causation" hurdles. First, plaintiff must show that the wet floor, and not some other factor beyond defendant's control, caused her to fall. Second, plaintiff must show that the fall, as opposed to something else, caused her back injury. Neither of these elements can be proven with total certainty. The law allows plaintiff to recover if plaintiff simply can establish both elements by a preponderance of the evidence.

To prove that plaintiff slipped because the floor was wet, plaintiff might call witnesses who will testify that they observed no other occurrence that likely caused the fall. Defendant will offer all possible evidence that tends to show a different cause for the fall. For example, defendant might offer evidence that plaintiff was wearing high-heeled shoes, talking on her cell phone, and reaching for an item on the top shelf when she fell. The jury will evaluate all the evidence in light of their own experience and knowledge of the world. Jurors will make an assessment about the reliability or credibility of each piece of evidence. In the end, the jury might determine that it was more likely than not that the wet floor caused the plaintiff to fall. It goes without saying that the jury does not, and never will, know for certain what caused the fall. But the system tolerates some amount of uncertainty.

To prove that the fall caused the plaintiff's back injury, plaintiff may produce an expert witness.[3] The witness will describe the plaintiff's injury and explain that such an injury can generally be caused only by a fall or sudden blow. The defendant will cross-examine the expert, trying to cast doubt on his credibility and conclusions. The defendant may also offer evidence of other factors that might have caused the plaintiff's injury. Based on all the evidence, including its assessment of the expert's credibility, the jury will make a determination. If the jury finds the defendant liable, it does not mean that the jury is absolutely sure that the plaintiff's story is accurate, but only that the jury believes that plaintiff's account is more likely to be true than not true.[4]

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[2] *See, e.g.*, Negri v. Stop & Shop, Inc., 480 N.E.2d 740 (N.Y. 1985).

[3] *See, e.g.*, FED. R. EVID. 702 (authorizing federal courts to allow expert witnesses to testify "[i]f scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue").

[4] *See* Ellen Relkin, *Some Implications of* Daubert *and Its Potential for Misuse: Misapplication to Environmental Tort Cases and Abuse of Rule 706(a) Court-Appointed Experts*, 15 CARDOZO L. REV. 2255, 2256 (1994).

Thus, the law as currently constructed tolerates a substantial amount of uncertainty, but it nonetheless works reasonably well in achieving the underlying objectives of tort law. First, the law helps deter harmful behavior; if a supermarket knows it can be sued for creating dangerous conditions, it will probably be more vigilant in maintaining the public areas of the store. Moreover, the system serves the objectives of corrective justice; although the relatively low burden of proof might result in overcompensation in some cases, it seems reasonable to believe that compensation is awarded correctly in the majority of cases.

Now examine toxic torts. When plaintiff claims that exposure to a chemical or drug caused her injury, the amount of uncertainty inherent in the adjudication process increases exponentially. In fact, it is fair to say that the law is so ill-equipped to deal with the uncertainties inherent in toxic tort cases that the application of common-law tort doctrine to such cases significantly undermines the objectives of the tort system.[5]

An injured plaintiff must prove causation in two senses; first, plaintiff must prove "general causation"—that is, that the drug or chemical was capable of causing the type of injury of which plaintiff complains.[6] The strongest and most reliable evidence of general causation is a well-designed epidemiological study[7] that shows an increased risk (against the background population) of harm from exposure to the drug or chemical.[8] Here, the strength of the association and the confidence interval are key factors in determining whether the study is admissible.[9] Some courts will allow a plaintiff to present to the jury any study that shows a relative risk of above one.[10] Some courts have drawn a hard line,

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5 *See* Berger, *supra* note 1, at 2122.

6 *Id.*; Daniel A. Farber, *Toxic Causation*, 71 MINN. L. REV. 1219, 1227 (1987).

7 Even this evidence, however, can be fatally flawed.

8 This assumes a confidence interval that puts the probability of causation at greater than fifty percent. A confidence interval is a number that represents a range of values to allow for random variations in the data. *See* Gerald W. Boston, *A Mass-Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience*, 18 COLUM. J. ENVTL. L. 181, 257-58 (1993).

9 For an excellent and accessible explanation of the various types of epidemiological studies, see *id.* at 231-41.

10 *See, e.g.*, Landrigan v. Celotex Corp., 605 A.2d 1079, 1087 (N.J. 1992) (rejecting the defendant's argument that a relative risk of two was necessary for a determination that the product more likely than not caused the plaintiff's illness, and holding that a study showing a relative risk of 1.55 was "one piece of evidence, among others, for the court to consider in determining whether the expert has employed a sound methodology in reaching his or her conclusion"); Grassis v. Johns-Manville Corp., 591 A.2d 671 (N.J. Super. Ct. App. Div. 1991) (holding that an epidemiological study with a risk ratio of less than two was admissible if the plaintiff's expert could "factor out other known risk factors such as family history, diet, alcohol consumption, smoking . . . or other factors which might enhance the remaining recognized risks").

barring evidence of increased risk unless it is greater than two.[11] To those courts, a relative risk of less than two is not helpful to plaintiff, because it cannot establish that the product was more likely than not the cause of plaintiff's injury.[12] If epidemiological studies have not been performed, plaintiffs might offer different types of evidence, including animal studies, structure activity analysis,[13] or, in the case of nonlatent injuries, adverse reaction reports.

Plaintiffs also must prove "specific causation."[14] That is, the plaintiff must establish that she was exposed to the product and must show, by a preponderance of the evidence, that the product, and not some other factor, caused plaintiff's injury. Where epidemiological studies show that those exposed to the product have an increased risk of greater than two, and it is therefore more likely than not that this particular plaintiff's injuries were caused by exposure to the product, most courts also require plaintiff to introduce evidence establishing that other known potential causes, such as cigarette smoking or obesity, did not cause the particular plaintiff's injury.[15] Here, plaintiff is likely to call a medical expert who will employ differential diagnosis to establish the lack of other contributing factors.[16]

Where an epidemiological study shows that those exposed to the product suffered a greater incidence of injury than those in the background population, but that the relative risk is only between one and two, proof of specific causation is crucial. Plaintiff must establish that the presence or absence of other factors, such as an unusually high level of exposure or the absence of family history of the disease, make causation more likely than not. When the other

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11 *See, e.g.*, DeLuca v. Merrell Dow Pharm., Inc., 911 F.2d 941, 958 (3d Cir. 1990) (holding that, on remand, the plaintiffs would have to establish a relative risk of greater than two to survive summary judgment); *In re* Joint E. & S. Dists. Asbestos Litig., 827 F. Supp. 1014, 1028 (S.D.N.Y. 1993) (vacating the jury verdict because relative risk of cancer shown by study was less than two), *rev'd*, 52 F.3d 1124 (2d Cir. 1995).

12 *See* Berger, *supra* note 1, at 2126 (stating that "as an abstract proposition, unless the ratio is at least 2.0, no plaintiff will be able to prove that his or her disease was more likely than not attributable to the defendant's product").

13 As Professor Berger explains, plaintiffs tend to rely on one or more of four types of scientific evidence to prove general causation: structure-activity analysis, in vitro analysis, in vivo analysis, and epidemiological analysis. *See id.* at 2123 (citing Susan R. Poulter, *Science and Toxic Torts: Is There a Rational Solution to the Problem of Causation?*, 7 HIGH TECH. L.J. 189, 217-26 (1992)).

14 Berger, *supra* note 1, at 2122; Farber, *supra* note 6, at 1228.

15 *See* Berger, *supra* note 1, at 2122 n.18.

16 *See id.* For an excellent discussion of how courts should deal with the differential diagnosis method, see Note, *Navigating Uncertainty: Gatekeeping in the Absence of Hard Science*, 113 HARV. L. REV. 1467 (2000) [hereinafter *Navigating Uncertainty*].

possible causes of plaintiff's specific injury are unknown, proving specific causation can be an uphill battle.[17]

Because both types of causation must be proved by scientific evidence, the uncertainties inherent in the tort system generally are substantially increased. First, juries may be relatively less capable of evaluating scientific evidence than other types of evidence.[18] Unlike jurors in ordinary torts cases, most jurors assessing scientific evidence cannot refer to their life experience and general knowledge in assessing the evidence's validity. Furthermore, cross-examination may not serve its function, because the jury might not be able to understand the points being made. Finally, because scientific experts are usually expertly prepared and extraordinarily polished, jurors might find it more difficult to evaluate a particular expert's credibility.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[19] the United States Supreme Court attempted to address the increased uncertainties inherent in toxic tort cases by laying out a process to ensure that only scientifically reliable evidence could reach the jury. The *Daubert* Court concluded that the trial court (as opposed to the jury) is responsible for determining whether the scientific expert's conclusions were supported by reasoning or methodology that is scientifically valid,[20] and whether the proffered scientific study has bearing on the particular issues raised by plaintiff's claim.[21]

As a result of *Daubert*, courts hearing toxic tort claims routinely hold pretrial hearings to determine the admissibility of scientific evidence. Because both plaintiffs' and defendants' experts might have to testify twice (at the hearing and at trial), Daubert hearings greatly increase the costs of cases that go to trial. In addition, some courts, under authority of Federal Rule of

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17 *See* Berger, *supra* note 1, at 2120-21. Berger notes that toxic torts present unusually difficult causation problems because:

> [P]roof of causation rarely consists of a direct explanation of a causal process, both because we do not yet fully comprehend the biological mechanisms that produce birth defects and illnesses such as the cancers and auto-immune diseases for which plaintiffs seek compensation, and because exposure to defendant's product is usually not a necessary cause of the [plaintiff's] particular disease.

Id.

18 Professor Boston emphasizes that a strong educational background and keen intelligence are necessary to enable one to properly evaluate epidemiological evidence. He explains that "[a]ppreciating the philosophies of epidemiological science, the concepts of hypothesis testing, confidence intervals, confounding, and misclassification are critical to making an informed assessment of the value and weight to be assigned to any particular study." Boston, *supra* note 8, at 273-75.

19 509 U.S. 579 (1993).

20 *See id.* at 589-92.

21 *See id.* at 591.

Evidence 706,[22] empanel their own independent panels of experts. The process of identifying qualified and independent experts who are willing to serve as expert witnesses can add months, even years, to a case. The process also increases costs, because the parties must depose and ultimately cross-examine the court's experts in addition to one another's. The consequences of the increased costs are serious: on one hand, the increased cost of litigation might deter plaintiffs from bringing meritorious cases. On the other, defendants that must defend meritless suits will pass on the increased costs of litigation to the public, either by raising prices or by developing fewer products.

Moreover, following *Daubert*, courts' views of the proper standard of admissibility are far ranging. First, many courts view epidemiology as the sine qua non of scientific evidence.[23] In those courtrooms, if a sufficiently reliable epidemiological study shows that those exposed to defendant's product are at no greater risk of injury than those who are unexposed to the product, plaintiff is barred from presenting any other type of scientific evidence.[24] As a result, unless a plaintiff also presents an epidemiological study that counters defendant's, the plaintiffs will lose on summary judgment.

Though there are often solid reasons for preferring epidemiological studies to other types of scientific evidence, a few courts have gone farther, awarding summary judgment to defendants when *no* reliable epidemiological studies have been performed, but plaintiff has other medical evidence of causation.[25]

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22 FED. R. EVID. 706.

23 *See, e.g.*, Berger, *supra* note 1, at 2125.

24 *See, e.g.*, Raynor v. Merrell Pharms. Inc., 104 F.3d 1371, 1375 (D.C. Cir. 1997) (stating that "the only way to test whether data from non-human studies can be extrapolated to humans" would be to conduct the same experiments on humans or by epidemiological studies); Allen v. Penn. Eng'g Corp., 102 F.3d 194, 197 (5th Cir. 1996) (affirming the trial court's exclusion of plaintiffs' nonepidemiological evidence of causation because "the most useful and conclusive type of evidence in a case such as this is epidemiological studies"); Elkins v. Richardson-Merrell, 8 F.3d 1068 (6th Cir. 1993) (affirming trial court's award of summary judgment for defendant because defendant presented epidemiological evidence casting doubt on causation); Lynch v. Merrell-Nat'l Labs., 830 F.2d 1190, 1193-97 (1st Cir. 1987) (affirming summary judgment for defendants, where plaintiffs had no epidemiological evidence to counter defendants' studies); *In re* "Agent Orange" Prod. Liab. Litig., 611 F. Supp. 1223, 1231 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d. Cir. 1987) (rejecting the plaintiff's animal studies because they rest "on surmise and inapposite extrapolation," and concluding that epidemiological studies were "the only useful studies having any bearing on causation").

25 *See, e.g.*, Moore v. Ashland Chem. Inc., 151 F.3d 269 (5th Cir. 1998) (upholding the trial court's rejection of the plaintiffs' clinical medical experts, who applied accepted clinical medical methodology to determine that plaintiff's exposure to the chemical Toluene caused an immediate injury to plaintiff, because the expert's testimony was not premised on "hard science"); Glastetter v. Novartis Pharms. Corp., 107 F. Supp. 1015,

A few other courts have held that plaintiffs cannot survive summary judgment unless they present an epidemiological study that shows a risk of greater than two.[26] Both of these approaches are problematic.

First, a rule that does not let plaintiffs present evidence establishing a relative risk between one and two arguably frustrates the principles of corrective justice and deterrence that inform tort law. Suppose an epidemiological study shows that, in the general population (those not exposed to defendant's drug), five out of every one hundred people experience plaintiff's symptoms, but that nine out of every one hundred people exposed to defendant's drug, experience plaintiff's symptoms. Assuming that the study takes proper account of other risk factors, no plaintiff could prove causation, even though the study strongly indicates that defendant's product caused four people to become ill. So long as the defendant knows that only a few people will be injured by its product, it will not internalize the costs associated with the product's production.

Second, courts' insistence on epidemiology, though understandable, frustrates the tort system's goal of deterring harmful conduct. Plaintiffs can rarely, if ever, fund and generate epidemiological studies.[27] Such studies are tremendously expensive,[28] and a plaintiff, or class of plaintiffs, will probably be unable to obtain funding. Moreover, epidemiological studies take years to complete. Therefore, even if a plaintiff could fund such a study, the results might not be available before the case has run its course.[29] Thus, unless the federal government steps in, the only party in a position to undertake an epidemiological study is the

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1042-44 (E.D. Mo. 2000) (awarding summary judgment to defendant where defendant's own epidemiological study was too flawed to be relevant, and "[p]laintiffs' experts admit that the absence of such [epidemiological] evidence severely limits their ability to reach a conclusion as to general causation").

One lawyer/scientist has suggested that differential diagnosis should, in certain circumstances, be admissible on causation when epidemiology is absent. *See Navigating Uncertainty*, *supra* note 16. One judge has suggested that many judges lack the scientific training necessary to enable them to evaluate scientific evidence, which may explain courts' discomfort with evidence other than epidemiology. *See* Cynthia Stevens Kent, Daubert *Readiness of the Texas Judiciary: A Study of the Qualifications, Experience, and Capacity of the Members of the Texas Judiciary to Determine the Admissibility of Expert Testimony Under the* Daubert, Kelly, Robinson, *and* Havner *Tests*, 6 TEX. WESLEYAN L. REV. 1 (1999).

[26] *See, e.g.*, DeLuca v. Merrell Dow Pharm., Inc., 911 F.2d 941, 958 (3d Cir. 1990) (holding that, on remand, plaintiffs would have to establish a relative risk of greater than two to survive summary judgment).

[27] *See* Wagner, *supra* note 1, at 774-75.

[28] *See* Berger, *supra* note 1, at 2128.

[29] *See* Wagner, *supra* note 1, at 776, 791; *see also* Berger, *supra* note 1, at 2128 (noting that manufacturers often do not begin studies until after litigation has commenced).

defendant corporation.[30] Studies have shown that corporations are notoriously reluctant to fund studies that might reveal the harmful effects of their products.[31]

One might speculate that, because an epidemiological study showing no increased risk to those exposed is a defense to liability, the system does in fact create incentives for manufacturers to fund such studies. However, examine the question from the perspective of a manufacturer who has invested substantial sums in research, development, and marketing of a product that is now on the market. Epidemiological studies are extraordinarily expensive. A manufacturer aware of scattered reports of harmful effects of its product will undertake such a study only if it believes that the study will show no increased risk of harm to those exposed. If there is any chance that the study will reveal an increased risk of harm, a rational manufacturer might refrain from funding a study to preserve a vigorous market for the product. This is especially true when, absent such a study, the defendants will likely prevail in any future litigation.[32]

It makes economic sense for a company to remain willfully uninformed of possible adverse consequences of its product, generate significant short-term profits, and later take one of two possible courses of action: either fight to the death to escape liability if and when the company is eventually sued, or fund and design an epidemiological study that the company can later disavow if it turns out to prove evidence of causation.[33] Until then,

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[30] *See, e.g.*, Boston, *supra* note 8, at 241 (establishing that "[p]articularly for cases involving environmental exposures, there are often no epidemiological studies reported in the literature").

[31] *See* Berger, *supra* note 1, at 2135 (citing evidence that the manufacturers of Agent Orange, asbestos, bendectin, breast implants, the Dalkon Shield, thalidomide, and tobacco did not test products adequately, declined to inform the public when evidence indicating a possible adverse reaction surfaced, and did not engage in further research in response to adverse reaction reports).

[32] *See* Berger, *supra* note 1, at 2137-38 n.93 (establishing that a cost-benefit analysis might lead "rational" corporate decision makers to refrain from funding expensive tests).

[33] Explore two recent examples of this type of corporate behavior. First, the Consumer Products Healthcare Organization (an organization comprised of manufacturers of products containing phenylpropanolamine ("PPA")) funded a study to explore a possible association between PPA and stroke after the Food and Drug Administration ("FDA") pressured them to do so. The study was designed in conjunction with Yale scientists and the FDA. The Association expected that the study would confirm PPA's safety. When it revealed a connection between PPA and stroke, the Association quickly set out to discredit the study on various grounds, among them that the study's design was flawed. *See Safety of Cold Remedies Disputed*, NEWSDAY, Oct. 21, 2000, at A7; *see also* Gay Stolberg, *F.D.A. Ban Sought on Chemical Used for Cold Remedies*, N.Y. TIMES, Oct. 20, 2000, at A1 (revealing that, after the study's completion, the Association hired a "panel of prominent scientists" to challenge the studies findings). And in *Glastetter v. Novartis Pharmaceuticals Corp.*, 107 F. Supp. 1015, 1042-44 (E.D. Mo. 2000),

the company is secure in the knowledge that it has failed to generate evidence that might hurt it later. Thus, as Professors Margaret Berger and Wendy Wagner have emphasized, the current system creates a disincentive for manufacturers to investigate the possible harm caused by their products.[34]

Of course, not all courts insist that plaintiffs produce epidemiology to get to the jury. At the other end of the spectrum, some courts might take the view that any evidence that is relied upon by the scientific community, government, or corporate establishment in decision making should be submitted to a jury.[35] Such an approach might present its own problems. For example, adverse reaction reports are, in effect, a form of epidemiological study. However, a random gathering of such reports lacks the controls and data necessary to make a reliable association regarding causation. Or, a particular animal study might involve such a large dose of the drug at issue that it is not probative of whether the same drug, in much smaller doses, would produce the same response in humans. Yet, if a jury is unable to understand the cross-examination because jurors lack the requisite scientific knowledge to make sense of the proceedings, the reports may prejudice the jury, which might find for the plaintiff even if the science does not warrant such an outcome. If so, these cases create a risk that some defendants might be held liable for damages that they did not cause.[36] Such a result would be antithetical to the ideals of corrective justice and would frustrate the goal of optimal deterrence.

To summarize, the most reliable evidence in toxic tort cases are sound, well-designed epidemiological studies. Yet the system, as currently designed, perversely discourages the development of that evidence. Moreover, the current landscape creates huge risks of overcompensation, undercompensation, and less than optimal deterrence. Clearly, a new approach to toxic torts is necessary.

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the defendant corporation successfully discredited an epidemiological study it had funded itself.

34 *See* Berger, *supra* note 1, at 2119, 2135-40; *see also* Wagner, *supra* note 1, at 774-75 (noting that "if manufacturers face virtually no penalty for remaining ignorant about the latent health risks of potentially toxic products, but risk crushing liability if they learn of long-term hazards, it is only rational for manufacturers to choose ignorance").

35 *See* Berger, *supra* note 1, at 2125.

36 One of the more famous examples of this is the litigation regarding the drug Bendectin, which was alleged to have caused birth defects, and which resulted in numerous jury verdicts for plaintiffs in the early 1980s. Since that time, numerous epidemiological studies have failed to establish any causal connection between Bendectin and birth defects. For an excellent exploration of the Bendectin cases, see Boston, *supra* note 8, at 271-91.

II. RECOVERY FOR INCREASED RISK: CURRENT DOCTRINE

With his proposal, Glenn Shafer joins the list of scholars[37] and judges[38] debating the merits of a doctrine that would impose liability for increased risk of disease. Shafer recommends that we reduce the high level of uncertainty in toxic tort cases by radically changing tort law doctrine to recognize a theory of liability based solely on increased risk. To understand the impact of his proposal, it is helpful first to explore how courts have dealt with the question of increased risk.

At first glance, a tort theory that awards damages even absent proof of present injury seems to run contrary to conventional tort doctrine.[39] However, there is some precedent for awarding damages based on the increased risk created by exposure to a product. A brief description of how recent courts have grappled with the unique difficulties of toxic tort cases provides a helpful background for evaluating Shafer's proposal.

First, some courts have allowed plaintiffs to go before a jury with a claim that the defendant should be held liable for causing an increased risk of injury, provided that the plaintiff can show, through the use of epidemiological evidence, that the plaintiff's exposure to the defendant's product increased the plaintiff's chance of sustaining the injury. Most, but not all, courts

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[37] *See, e.g.*, E. Donald Elliott, *Why Courts? Comment on* Robinson, 14 J. LEGAL STUD. 799 (1985); Farber, *supra* note 5; Joseph H. King, Jr., *Causation, Valuation and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences*, 90 YALE L.J. 1353 (1981); Klein, *supra* note 1, at 1173; Glen O. Robinson, *Probabilistic Causation and Compensation for Tortious Risk*, 14 J. LEGAL STUD. 779 (1985); David Rosenberg, *The Causal Connection in Mass Exposure Cases: A Public Law Vision of the Tort System*, 97 HARV. L. REV. 849 (1984).

The benefits and difficulties presented by a theory of liability for increased risk has been a favorite topic among student scholars. *See, e.g.*, Note, *An Analysis of the Increased Risk Cause of Action*, 33 VILL. L. REV. 437 (1988); David P.C. Ashton, Comment, *Decreasing the Risks Inherent in Claims for Increased Risk of Future Disease*, 43 U. MIAMI L. REV. 1081 (1989); Brent Carson, Comment, *Increased Risk of Disease from Hazardous Waste: Proposal for Judicial Relief*, 60 WASH. L. REV. 635 (1985); Note, *The Inapplicability of Traditional Tort Analysis to Environmental Risks: The Example of Toxic Waste Pollution Victim Compensation*, 35 STAN. L. REV. 575 (1983); Brent Carson, Comment, *Increased Risk of Disease from Hazardous Waste: A Proposal for Judicial Relief*, 60 WASH. L. REV. 635 (1985); Keith W. Lapeze, Comment, *Recovery for Increased Risk of Disease in Louisiana*, 58 LA. L. REV. 249 (1997); Note, *Latent Harms and Risk-Based Damages*, 111 HARV. L. REV. 1505 (1998); Barton C. Legume, Note, *Increased Risk of Cancer as an Actionable Injury*, 18 GA. L. REV. 563 (1984); Diane Schmauder, Note, *An Analysis of New Jersey's Increased Risk Doctrine*, 25 RUTGERS L. REV. 893 (1994).

[38] *See, e.g.*, Mauro v. Raymark Indus. Inc., 561 A.2d 257, 269-70 (N. J. 1989) (Handler, J., dissenting).

[39] *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 30, at 165 (West 5th ed. 1984) (stating that "[t]he threat of future harm, not yet realized," is inadequate justification for the imposition of liability).

recognizing such a claim require that the plaintiff's increased risk of injury be "reasonably probable,"[40] or "reasonably certain."[41]

These cases are simply an extension of well-accepted tort principles that an injured plaintiff may recover damages for the injury actually suffered as well as any related injury that is reasonably probable to occur. The key to plaintiff's recovery for increased risk of injury is that the plaintiff currently manifests injury from exposure to the defendant's product. If present symptoms are shown, the doctrine of increased risk is useful because it allows the injured plaintiff to prove all damages at once, thereby preventing the need for a second trial years later, if and when the latent injuries manifest. For example, courts have allowed plaintiffs suffering from asbestosis to recover for the increased risk of cancer posed by the disease.[42]

The increased risk doctrine eliminates some difficulties for plaintiffs, most notably the need for the plaintiff to prove specific causation at a later date. For example, a plaintiff with asbestosis must show only general causation; she is relieved from having to prove later that exposure to asbestos, and not some other factor, was the cause of her particular case of cancer. But the doctrine, as it stands, does little to eliminate the serious problems created by tort doctrine as a whole. First, courts generally allow an increased risk claim only when the plaintiff can prove, as a threshold matter, that she has sustained some other, more immediate injury as a result of exposure to the defendant's product.[43] At least one court has emphasized that the requirement of current injury is necessary to comport with the ideals of corrective justice. But because the increased risk doctrine is inapplicable if the product creates only latent injuries, the doctrine fails to address the more problematic causation cases.[44] Moreover, to the extent that courts require a

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[40] *Mauro*, 561 A.2d at 261 (affirming the trial court's refusal to allow the jury to consider a theory of recovery based on the plaintiff's alleged increased risk of cancer from exposure to asbestos because the plaintiff did not present scientific evidence that established that the risk of cancer was "reasonably probable").

[41] Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1204 (6th Cir. 1988) (holding that the plaintiffs could not recover for the increased risk of cancer from exposure to toxin unless the cancer was "medically reasonably certain to follow from the existing present injury").

[42] *See, e.g.*, Iaconelli v. Johns-Manville, No. 82-2685, bench op. (D.N.J. Nov. 12, 1985) (allowing plaintiff to present the theory of increased risk of cancer because plaintiff was presently suffering from pleural asbestosis).

[43] *See* Klein, *supra* note 1, at 1179; *see also Iaconelli*, No. 82-2685, bench op.

[44] As Professor Klein points out, when the period between exposure and manifestation of injury is long, a plaintiff may have difficulty proving the connection between exposure to a particular toxin and the plaintiff's injury. *See* Klein, *supra* note 1, at 1173. Klein also notes that the statute of limitations and the "single cause of action" rule may bar the plaintiff's claim if injury is latent, which results in underdeterrence. *Id.* at 1181-82.

"substantial probability" of later injury, the same doctrine could lead to undercompensation and underdeterrence. For example, if the probability of causation is forty percent, defendants will escape liability for at least some of the injury that they cause.

Finally, and most importantly, the increased risk doctrine does not strike at the heart of the problems caused by toxic tort cases. By requiring the plaintiffs to provide epidemiological evidence of increased risk, it ignores the most difficult issue: plaintiffs' inability to generate such evidence. The increased risk doctrine, therefore, exacerbates the perverse incentive problem; if manufacturers are forced to overcompensate for increased risk of injury, there is an even greater incentive to avoid funding studies to discover risks posed by their products. Other attempts to require defendants to compensate for increased risk caused, such as medical monitoring and recovery for negligent infliction of emotional distress, are imbued with the same difficulties because they are predicated on the plaintiff's ability to prove increased risk through the use of epidemiology.

III. SHAFER'S THEORY OF LIABILITY FOR INCREASED RISK

Shafer's proposal takes several radical steps away from the traditional doctrine allowing recovery for increased risk of injury, and solves some of the crucial difficulties presented by current doctrine. First, Shafer would not require a showing of present injury to sustain a claim based on increased risk. As a result, plaintiffs who are able to show simply that the defendant's product increased the risk of injury would be relieved of showing specific causation. Additionally, some plaintiffs who make claims based solely on the possibility of latent injuries would be able to litigate their claims while evidence regarding exposure is fresh. Moreover, because plaintiffs would have a cause of action before an actual injury has manifested, it would be easier to try cases as class actions and, thus, defendants would not face the possibility of an unknown number of cases extending into the future.

Second, Shafer's suggestion that plaintiffs should be able to recover for increased risk when the epidemiological study shows *any* increased risk of causation, better serves the objectives of corrective justice and optimal deterrence. Defendants would no longer escape liability for certain injuries that they cause, as they

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However, many jurisdictions have relaxed these rules to accommodate toxic tort claims. *See, e.g.*, *Mauro*, 561 A.2d at 262 (noting that, in New Jersey, neither the statute of limitations nor the single controversy rule will bar a plaintiff with a latent injury from pursuing a toxic tort claim).

currently can if the chance of causation is less than fifty percent.[45] To illustrate, explore a recent example that made front-page news. Recent studies performed by scientists at Yale University revealed an association between ingestion of phenylpropanolamine ("PPA") and the incidence of hemorrhagic stroke.[46] The association between occurrence of such a stroke within three days of exposure to PPA from cold remedies was given an adjusted odds ratio of 1.23. Thus, although PPA caused some of the strokes examined, the cause of strokes for most of the subjects was some other, undetermined factor.

If those exposed to PPA through ingestion of cold medication sue PPA manufacturers, some courts will bar plaintiffs from introducing the Yale study as evidence of causation because the study does not prove that PPA more likely than not caused a particular plaintiff's stroke.[47] The same courts are also likely to exclude the case reports that created concerns regarding PPA's safety, on the theory that case reports are not valid science and therefore must be excluded under *Daubert.* Even if courts allow the study, plaintiffs will have a difficult time proving specific causation, because medical science cannot explain why those *not* exposed to PPA might experience a stroke. Thus, although the study strongly suggests that the drug caused a percentage of the strokes, the companies will not have to pay for the injuries caused.

Now, suppose Shafer's proposal was adopted and the tort system was changed so that liability could be premised on increased risk caused. First, the epidemiological study would be admissible in any court because it bears directly on the issue of increased risk. Second, specific causation would no longer be relevant. It would be inevitable that the drug companies would face liability for the risk created. Courts that previously excluded studies showing a relative risk less than two but greater than one, would now view such studies as relevant to show that the product created an increased risk of harm.[48]

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[45] *See* Klein, *supra* note 1, at 1197-98.

[46] *See Phenylpropanolamine & Risk of Hemorrhagic Stroke: Final Report of The Hemorrhagic Stroke Project*, May 10, 2000 [hereinafter "*Final Report*"] (on file with FDA and with author).

[47] Some courts might admit it as relevant when combined with other evidence, particularly if there is evidence of a potential for significant underreporting. The study excluded all stroke victims who died as a result of the stroke or who were unable to communicate within thirty days of experiencing the stroke. *See id.* at 7.

[48] *See* Farber, *supra* note 6, at 1239 (noting that allowing plaintiffs proportional recovery for increased risk of injury creates "a powerful economic incentive to avoid imposing . . . harm," and that absent proportional recovery, the difficulties in proving causation would allow manufacturers to escape liability for harms they create); *see also*

A third way in which Shafer's proposal would alleviate current problems with the system lies in his suggestion that toxic tort cases be tried as class actions. Under his proposal, class actions suits would be possible, because eligibility would be premised only on exposure and not injury. Thus, one could determine all class members at an earlier point in time than is currently possible. Manufacturers would be liable for all increased risk caused but would not find themselves in the position of having to fend off an infinite number of separate lawsuits. The class action requirement would ensure that the maximum amount of liability equals the total increased risk. The result would go a long way toward correcting the overdeterrence problem currently inherent in some toxic tort cases. Moreover, to the extent that courts are reluctant to embrace a doctrine of increased risk due to fears of overwhelming the court system,[49] the class action requirement is responsive to those concerns.[50]

Finally, Shafer's suggestion might reduce the costs of litigation. If plaintiffs no longer have to prove specific causation, Daubert hearings will involve fewer experts, resulting in lower costs to litigants and the judiciary. In addition, there would be less scientific evidence for the jury to evaluate, which would allow it to focus more intently on evaluating the evidence relevant to increased risk.

Although Shafer's suggestion resolves many difficulties inherent in the present system, there are several crucial issues that would have to be worked out before it can be viewed as a workable replacement for current doctrine. The following paragraphs focus on four of the most crucial issues: (1) the difficulty that science may have in reducing risk assessment to a certain numerical value; (2) the latent injury problem; (3) the frustration of corrective justice principles; and (4) the "perverse incentive" problem.[51]

Rosenberg, *supra* note 37, at 861-76 (1984) (arguing that a proportionality rule in mass exposure cases would optimize deterrence).

[49] *See* Mauro v. Raymark Indus. Inc., 561 A.2d 257 (N.J. 1989) (rejecting a claim of enhanced risk where the plaintiff failed to present proof that the risk of cancer was reasonably probable, in part out of fear of overwhelming the court system with cases).

[50] Of course, it is possible that a theory of liability premised on the creation of increased risk would expand exponentially the number of potential plaintiffs who file cases, because the number of potentially toxic chemicals and drugs to which people are exposed is substantial. *See* Klein, *supra* note 1, at 1193. But the problem is not as great as Klein fears; if plaintiffs can recover only upon *proving* increased risk, they cannot get very far unless the relevant epidemiological testing has been performed. Thus, this evidentiary requirement would bar most frivolous claims, and even many claims that may later prove to be valid.

[51] Daniel Farber addresses and rejects other arguments against proportional recovery for increased risk. *See* Farber, *supra* note 6, at 1240-44.

First, Shafer's faith in science's ability to establish increased risk with certainty may be too strong. In Professor Boston's words, the "belief that scientists will be able to arrive at a specific numerical value that can function as a proper proportion for application of a proportionality rule, appears to be inconsistent with current scientific methodology."[52] Vern Walker's theory of uncertainty provides a useful tool for understanding the various ways in which epidemiological evidence can be unreliable.[53] Epidemiological studies are hard to design because scientists cannot always control contributing factors that might skew the data.[54] Participants who do not experience any symptoms may forget that they took the product ("recall bias");[55] if there is a genetic component to a disease, constructing a random sample may be difficult;[56] and the latency period can make reporting inaccurate.[57] Other difficulties may include inability to measure exposure correctly (especially in the case of environmental toxins), misclassification, distortion produced by confounding, and less than rigorous application of scientific standards.[58] Finally, studies may be too undersized or underpowered to be reliable.[59] In short, the very act of attempting to represent the risk created by reducing the evidence to a simple number might ultimately prove to be as problematic as establishing causation currently is.

The second and closely related difficulty with Shafer's proposal is that he assumes that, at the time of trial, the court can determine the exact level of the increased risk. In fact, there is no research examining the toxicity of more than eighty percent of commercially available chemicals.[60] Moreover, even those studies that have been performed may be incapable of assessing risk adequately.

In the example he gives (spraying causes a cold), Shafer assumes a relatively short period between exposure and illness. In such cases, there is no need to compensate those who do not manifest injury by the time of the lawsuit. In fact, doing so would

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52 Boston, *supra* note 8, at 365.

53 *See* Vern R. Walker, *Theories of Uncertainty: Explaining the Possible Sources of Error in Inferences*, 22 CARDOZO L. REV. 1523 (2001). Walker suggests a methodology that helps us identify the different ways in which methodology may be unreliable. He catagorizes the types of possible uncertainty as "concept uncertainty," "measurement uncertainty," "calculation uncertainty," "mathematical modeling uncertainty," and "causal uncertainty." *Id.* at 1544-55.

54 *See* Berger, *supra* note 1, at 2127.

55 *See* Boston, *supra* note 8, at 233.

56 *See* Berger, *supra* note 1, at 2128.

57 *See id.*

58 *See* Boston, *supra* note 8, at 247-49.

59 *See id.* at 259-61.

60 *See* Wagner, *supra* note 1, at 774.

overcompensate those plaintiffs alleging increased risk. The better course in such cases would be to limit the plaintiff class to those who have actually suffered injury, and assess damages based on the probability that exposure to the chemical at issue actually caused the plaintiff's illness.

In cases that allege latent injury, however, existing studies may not determine whether an increased risk of injury persists beyond the time period of the study.[61] So, determination of a plaintiff's increased risk may be impossible. For example, suppose the latency period is thirty years from time of exposure to manifestation of injury. If the drug has been on the market for less than thirty years, an epidemiological study would fail to assess the risk of injury accurately. Or, suppose that we know that five years after exposure to a specific chemical there is a ten percent increased risk of harm, which rises to twenty percent ten years after exposure. Assessing risk with certainty would be difficult, if not impossible.

Third, although Shafer's proposal furthers the objectives of achieving optimal deterrence, it does so at the expense of concerns for corrective justice. A plaintiff who becomes seriously ill after the termination of the lawsuit will have been compensated only for the value of the increased risk, rather than the potentially enormous costs of actual injury. On the other hand, plaintiffs who never manifest injury would have received a windfall.[62] Either scenario undermines the objectives of corrective justice theory.[63]

Scholars evaluating increased risk proposals have addressed these concerns. Some have argued that there is no undercompensation problem, because plaintiffs can use the proceeds from the lawsuit to ensure against the possibility that they will later become ill.[64] This would be true, however, only if none of the plaintiffs had manifested signs of illness at the suit's termination. Plaintiffs who had become ill by this time would find it impossible to obtain insurance. Another answer might be to hold a separate posttrial damage hearing to allocate the damages among plaintiffs.[65] Plaintiffs who actually

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[61] *See* Berger, *supra* note 1, at 2128 (noting that when a study generates an inconclusive or negative result, it "may mean only that not enough time has elapsed to detect a significant effect").

[62] *See* Mauro v. Raymark Indus. Inc., 561 A.2d 257, 266 (N.J. 1989) (noting that the less likely and more speculative the chance of increased risk of disease, "the more difficult would be the juries' burden of calculating fair compensation. Inevitably, damage awards would be rendered for diseases that will never occur, exacting a societal cost in the form of higher insurance premiums and higher product costs").

[63] *See* Klein, *supra* note 1, at 1179.

[64] *See, e.g.*, *id.* at 1202-03; David Rosenberg, *Individual Justice and Collectivizing Risk-Based Claims in Mass Exposure Cases*, 71 N.Y.U. L. REV. 210, 219 (1996).

[65] *See* King, *supra* note 37, at 1384-85 (suggesting a test that would allow courts to

become ill could receive a larger award than those that do not. This solution, however, creates a logistical nightmare—a court would have to refrain from divvying up the proceeds until all of the plaintiffs had died!

The overcompensation problem could be remedied by limiting increased risk claims to drugs or chemicals alleged to cause only latent remedies. For example, if a stroke occurs as a result of exposure to PPA, it occurs within forty-eight hours of exposure. It would be antithetical to the objectives of corrective justice to allow exposed individuals who had manifested no symptoms at the time of a later occurring trial to recover damages for increased risk. Only where later injury is still a possibility would requiring compensation for enhanced risk be justifiable. Any serious exploration of an increased risk theory would have to come to terms with the corrective justice problem.

The fourth important shortcoming inherent in Shafer's proposal is its failure to address the most problematic result of the current system—the disincentive to fund and perform sound scientific studies. Because sound scientific studies are both necessary and sufficient bases for Shafer's proposal, liability for increased risk would exacerbate the perverse incentive problem. A study showing even a slight increase in injury to those exposed would be the basis for liability. As a result, corporations could be even less willing to fund studies until they had more than recouped their investment in research and development. Moreover, because liability could be imposed for even a small increase in risk, there would be even stronger temptations to design the study in such a way that it could later be disavowed, if necessary. Thus, a theory of liability for increased risk must be refined to overcome this serious policy concern.[66]

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calculate specific odds of eventual injury to each plaintiff).

[66] The idea might be combined with aspects of a proposal by Professor Margaret Berger to create a doctrine that might bring us closer to achieving the goals of the tort system. Professor Berger proposes that we impose a duty of care on manufacturers to engage in research to discover possible harms caused by their products. *See* Berger, *supra* note 1, at 2140-52. Her proposal "conditions culpability on the failure to develop and disseminate significant data needed for risk assessment." *Id.* at 2140-52. If a manufacturer shows it has complied with this duty by performing necessary studies, such a showing would constitute a complete defense to an injured plaintiff's claim. *See id.* at 2143. If the defendant breached the duty, then the burden is on defendant to show that its product could not have caused plaintiff's injury, or alternatively, the defendant can argue for a reduction in damages by proving that plaintiff's injury had other contributing causes. *See id.* at 2144-45. Her proposal would simplify the plaintiff's case and reduce costs because it would eliminate the general causation requirement. But despite its attractiveness, the proposal also has drawbacks because it requires the plaintiff to manifest injury, and because the existence of studies would constitute a complete defense to liability for injuries of unsuspecting plaintiffs.