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INTRODUCTION

Tort cases involving scientific uncertainty frequently present courts with a difficult causation issue. In the paradigmatic case, the available scientific evidence indicates that a substance might be hazardous, but does not establish that the substance is hazardous.[1]

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1. In a fundamental sense, any tort case involving science involves uncertainty, since "[s]cientists understand that there is simply no way to prove a theory true or even probable, as any theory may be subject to being disproved. So the most that can be said is that a particular theory has withstood criticism and provides the best explanation of the data." Erica Beecher-Monas, *The Heuristics of Intellectual Due Process: A Primer for Triers of Science*, 75 N.Y.U. L. REV. 1563, 1581 (2000) (citations omitted). My use of the term "scientific uncertainty" is limited to cases in which the available evidence provides scientific support for the plaintiff's claim, but the evidence is not sufficient to establish that the claim can "withstand criticism and provide the best explanation of the data." In addition to the paradigmatic example of such uncertainty de-

When presented with such evidence, courts must decide whether the plaintiff has adequately proven that her injury was tortiously caused by the substance.

This causal issue potentially arises whenever we do not fully understand how a substance interacts with the body and produces an adverse health outcome. We do not, for example, adequately understand the etiology of cancer.[2] To assess whether a substance may cause injuries with unknown etiology, we observe health outcomes in populations of animals exposed to large amounts of the substance, study the biochemical effects of the substance on cells, organs, and embryos, and compare the substance's chemical composition to other known health hazards.[3] Though informative, these studies usually cannot determine whether the substance is hazardous. That determination typically requires a large-scale study comparing the incidence of adverse health outcomes in groups of exposed and non-exposed individuals, or comparing the incidence of exposure across injured and healthy groups. These epidemiological studies are expensive, time-consuming, and require that a large number of people be exposed to the substance. Without such study, however, the hazardous properties of the substance often cannot be established with existing scientific methods. Consequently, substances are often introduced into the environment before there is conclusive scientific evidence regarding their health hazards. How should this scientific uncertainty affect the tort rights of an individual who has been exposed to such a substance and has the type of injury, such as cancer, that is plausibly attributable to the substance in light of the available scientific evidence?

After the United States Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[4] an increasing number of courts have held that causation must be established by epidemiological evidence showing that a population of individuals exposed to the substance faced at least twice the risk of suffering the injury in

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scribed in the text, other common tort examples include uncertainty over the degree of risk posed by a substance known to be hazardous, or the degree of risk a known hazard posed for a particular individual. Analysis of the paradigmatic form of uncertainty provides a basis for analyzing these other forms of uncertainty. *See infra* Part IV.

2. *See, e.g.*, CARL F. CRANOR, REGULATING TOXIC SUBSTANCES: A PHILOSOPHY OF SCIENCE AND LAW 18 (1993).

3. For descriptions of the scientific approaches to risk identification, see *id.* at 3-48; FEDERAL JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 121-220 (1994); MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 26-43 (1996).

4. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

question.[5] According to these courts, such epidemiological studies are the only reliable evidence showing that the substance more likely than not caused the plaintiff's injury.[6] Numerous commentators criticize this evidentiary requirement, arguing that it is inconsistent with fundamental tort principles, particularly when applied to substances that have not been subjected to epidemiological study.[7] According to these critics and others, the lack of conclusive scientific evidence, and the unfairness of placing the burden of factual uncertainty on plaintiffs, require the adoption of special rules, such as placing the burden on a defendant manufacturer to prove that its product is not hazardous.[8]

The vast majority of potentially hazardous substances have not been subjected to epidemiological study,[9] creating an evidentiary gap of potential concern to the tort system.[10] In some important contexts involving evidentiary gaps, application of ordinary rules would undermine tort norms, so the tort system has adopted

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5. *See* 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, 339 (1999). Not all courts have adopted this requirement. *See* David L. Faigman et al., *How Good Is Good Enough?: Expert Evidence Under* Daubert *and* Kumho, 50 CASE W. RES. L. REV. 645, 663 (2000) ("It is now clear that courts will not exclude causal opinions based on non-epidemiological evidence in situations where a body of such data does not exist."). For a description of the various approaches taken by the courts, with case citations, see Andrew See, *Use of Epidemiology Studies in Proving Causation*, 67 DEF. COUNS. J. 478, 479 (2000).

6. *See* Finley, *supra* note 5, at 349-52 (providing a non-exhaustive list of cases).

7. *See, e.g.*, Margaret Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2131-34 (1997); Finley, *supra* note 5, at 363-76; *see generally* Michael H. Gottesman, *Should Federal Evidence Rules Trump State Tort Policy? The Federalism Values* Daubert *Ignored*, 15 CARDOZO L. REV. 1837 (1994).

8. *See* Berger, *supra* note 7, at 2140-52 (proposing 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); Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 45 (1995) (proposing that, if plaintiff can demonstrate strong uncertainty regarding causation, the burden of proof should be shifted or plaintiffs should receive proportionate 50% recovery); Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773 (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 (1997) (arguing that the burden of proof on causation should be shifted to the defendant because the defendant created the factual uncertainty by exposing the plaintiff to the substance in question).

9. *See* CRANOR, *supra* note 2, at 4 (observing that, of the more than 55,000 commercial chemicals, only six or seven thousand had been subjected to chemical study as of the early 1990s); FEDERAL JUDICIAL CTR., *supra* note 3, at 193 ("It must be emphasized that less than 1% of the 60,000-75,000 chemicals in industrial commerce have been subjected to a full safety assessment, and only 10-20% have any toxicological data at all.").

10. The concept of an "evidentiary gap," and its relation to normative concerns, is identified by Jane Stapleton, *Legal Cause: Cause-in-Fact and the Scope of Liability for Consequences*, 54 VAND. L. REV. 941 (2001).

special rules to redress the inequity.[11] An important question, then, is whether cases of scientific uncertainty involve the type of problem that justifies a special evidentiary rule for establishing causation.

As Part I shows, the critics of the epidemiological evidentiary requirement have not justified a special rule for cases of scientific uncertainty. Part II then explains why there is no need to adopt new evidentiary rules in the products liability context. In the paradigmatic case involving cancer, for example, tort liability can be imposed on product sellers for not adequately warning about the scientific evidence suggesting that the product is carcinogenic. The issue of whether the product caused the plaintiff's cancer involves the extent of damages. This causal issue in the damages phase is already governed by a special evidentiary rule, which does not require epidemiological proof showing that the product is carcinogenic. In this context, the epidemiological evidentiary requirement is inconsistent with current doctrine and can be eliminated without adopting new rules.

Cases outside of the products liability context require different analysis, because the hazardousness of the substance determines the appropriateness of imposing any liability on the defendant. Part III shows that the appropriate tort norm supports a requirement of epidemiological proof. The tort norm, as reflected in the ordinary evidentiary standard, addresses the problem of factual uncertainty, and the associated problem of legal error, by giving equal weight to the competing interests of deserving plaintiffs and non-culpable defendants. By placing the initial burden of factual uncertainty entirely on plaintiffs, the requirement of epidemiological proof appears to be unfair. However, an equal apportionment of uncertainty is not attainable given the current state of scientific knowledge. Alternative evidentiary approaches, such as shifting the burden of proof to defendants, would place an even greater burden on non-culpable defendants, thereby violating the tort norm underlying the ordinary evidentiary standard.

Part IV concludes by ascertaining the limits of the epidemiological evidentiary requirement. The requirement can be justified as long as non-epidemiological forms of proof would yield incorrect liability outcomes more than one-half of the time, so the requirement's validity necessarily depends on evolving approaches to risk

11. For a description of the various evidentiary rules pertaining to causation, see DAN B. DOBBS, THE LAW OF TORTS §§ 173-79 (2000).

assessment and the forms of non-epidemiological proof involved in the case. Another important limit pertains to the amount of risk that must be identified by epidemiological study. Although many courts require at least a doubling in risk, tort norms merely require that epidemiological proof identify an increase in risk sufficient to establish tortious conduct by the defendant. This conclusion stems from the nature of epidemiological proof and the range of plausible biological models for explaining the etiology of cancer and other chronic diseases, coupled with the important distinction between causal issues in the liability and damages phase of trial. Just as the necessity of epidemiological proof depends on context, the degree of increased risk that must be identified by epidemiological study is also context dependent.

I. CRITIQUES OF THE REQUIREMENT THAT CAUSATION BE PROVEN WITH EPIDEMIOLOGICAL STUDY

The epidemiological evidentiary requirement has been widely criticized for being inconsistent with tort principles.[12] These criticisms have merit, but they do not establish the claim that, in adopting the evidentiary requirement, courts have effectuated "substantive changes in causation law through the rubric of evidentiary admissibility decisions."[13]

The most obvious problem with the evidentiary requirement is that it provides inadequate incentives for manufacturers to fund epidemiological study. As between individual plaintiffs and manufacturers, the cost of epidemiological study is most easily borne by manufacturers. Manufacturers do not have an adequate incentive to incur the cost of epidemiological or other study, though, if plaintiffs bear the burden of producing such evidence, so manufacturers typically choose ignorance. In the mass tort litigations, for example, the manufacturer in each case "did not test its product adequately initially, failed to impart information when potential problems emerged, and did not undertake further research in response to adverse information."[14]

This problem undoubtedly is of great social concern. It does not, however, supply sufficient reason for altering ordinary tort rules. The best incentives for research are provided by a tort rule making manufacturers strictly liable for unknown or unforeseeable

12. These criticisms, with the appropriate attributions, are more fully described in Finley, *supra* note 5, at 363-76.

13. *Id.* at 336.

14. Berger, *supra* note 7, at 2135.

risks.[15] Nevertheless, tort liability is limited by the requirement that the defendant acted tortiously with respect to a foreseeable risk, and tortious conduct typically is defined in terms of negligence.[16] The tort system's reliance on a negligence standard for foreseeable risks implies that the attainment of optimal research incentives is not a sufficient reason for imposing tort liability on those who expose others to potentially hazardous substances.

To bolster the case against the epidemiological evidentiary requirement, critics argue that the requirement inappropriately relies on scientific norms rather than tort norms. Scientific norms do undoubtedly differ from tort norms.[17] For example, epidemiological studies tend to yield more reliable or informative results as the size of the sampled population increases. Larger sample sizes are also more costly. Animal studies tend to be less informative and less expensive than epidemiological studies.[18] And other methods of risk identification are even less informative and less expensive.[19] What is the appropriate relationship between the reliability or informativeness of any given mode of scientific inquiry and cost considerations? Scientists need not trade off reliability and cost considerations in the same manner as the tort system, so the relevant scientific norms differ from tort norms. Due to this difference, the fact that scientists use only epidemiological proof to infer causation does not mean the tort system must also rely on such proof to infer causation. The difference in scientific and tort norms accordingly reveals the need to determine independently whether tort norms require causal proof by epidemiological study; it does not show that a tort norm is violated by the evidentiary requirement.

What, then, is the relevant tort norm? Here the critics point to the unfairness of placing the entire burden of uncertainty on

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15. *See* Steven Shavell, *Liability and Incentive to Obtain Information About Risk*, 21 J. LEGAL STUD. 259, 260 (1992).

16. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2 b)-(c) (1998) [hereinafter PRODUCTS LIABILITY] (limiting liability for design and warning defects to the lack of reasonable care in reducing or avoiding foreseeable risks of harm).

17. A point extensively developed by CRANOR, *supra* note 2.

18. "It is much easier, and more economical, to expose an animal to a chemical or to perform in vitro studies than it is to perform epidemiological studies." FEDERAL JUDICIAL CTR., *supra* note 3, at 194-95. But, "[i]n the absence of an understanding of the biological and pathological mechanisms by which disease develops, epidemiological evidence is the most valid type of scientific evidence of toxic causation." *Id.* at 126.

19. In vitro studies, for example, are conducted in the laboratory and are less expensive and less reliable than animal studies. *See* GREEN, supra note 3, at 36-37. For a ranking of the various types of scientific evidence in terms of relevance for causation, see Beecher-Monas, *supra* note 1, at 1604-26.

plaintiffs, the outcome produced by the epidemiological evidentiary requirement. As before, the criticism identifies a relevant concern while begging the underlying question. In what way does the requirement of epidemiological proof violate the tort norm regarding the allocation of factual uncertainty? The ordinary evidentiary standard, based upon a preponderance of the evidence, allows for the possibility that some non-culpable defendants will incur liability. The standard also allows for the possibility that some deserving plaintiffs will not be compensated. Such errors are inevitable in a world of limited information. How the risk of legal error, or the burden of factual uncertainty, should be allocated between the parties is the normative issue most obviously addressed by an evidentiary standard. The norm underlying the ordinary evidentiary standard places at least some burden of factual uncertainty on plaintiffs. Even if the norm strives to equally apportion the burden between plaintiffs and defendants, such a sharing of the burden may not always be possible—one party or the other may have to bear the entire burden. The mere fact that one party bears the entire burden of uncertainty under an evidentiary rule, such as the one requiring epidemiological proof, therefore does not necessarily violate a tort norm of equality.

Thus, the critics of the epidemiological evidentiary requirement have raised valid concerns, but have not persuasively shown that the requirement violates tort norms. The issue requires more analysis. For reasons that will become apparent, the problem is usefully analyzed by distinguishing between products liability cases and other tort cases.

II. SCIENTIFIC UNCERTAINTY AND EVIDENTIARY REQUIREMENTS IN THE PRODUCTS LIABILITY CONTEXT

To analyze the epidemiological evidentiary requirement, we will consider the following products liability case. The plaintiff-consumer has cancer and claims that a defect in the defendant manufacturer's product caused the injury. The alleged defect involves the manufacturer's failure to warn about the risk of cancer. To support the allegations, the plaintiff relies on scientifically valid studies showing that the product contains a chemical known to be an animal carcinogen. The plaintiff also relies on other scientifically valid laboratory studies supporting the hypothesis that the chemical is a human carcinogen. Finally, the plaintiff has evidence, such as the expert opinion of medical doctors, showing that her cancer was probably not caused by exposure to other known carcinogens. The plaintiff, however, does not have epidemiological evi-

dence, because no such studies have been conducted. The question is whether the plaintiff should be able to recover for her cancer on the basis of the foregoing evidence.

Defining the problem in this manner may seem puzzling. Causation is an element common to all tort claims, and causal issues in products liability cases are governed by general tort principles.[20] In the products liability context, however, the issue of whether the product caused the cancer is mostly relevant for determining the extent of damages rather than the appropriateness of imposing liability on the defendant. Outside of the products liability context, the causal issue is fundamental to the question of whether *any* liability is appropriate. Proof of carcinogenicity therefore serves different purposes in the two contexts, implying that each context may require different types of evidence.

In the case under consideration, the plaintiff alleges that the defendant manufacturer is liable for failing to warn that the product might cause cancer. This allegation can take two forms. The plaintiff could allege that the warning is defective for not disclosing that the product is in fact carcinogenic. Alternatively, the plaintiff could allege that the warning is defective for not stating that the product *might* be carcinogenic. The distinction between the two allegations is crucial. For the first allegation, the plaintiff must demonstrate that the product is carcinogenic, a showing that may well depend on epidemiological proof. For the second allegation, the plaintiff need only demonstrate that the manufacturer should have warned consumers about the scientific evidence of carcinogenicity, a showing that does not require epidemiological proof.

For allegations of the second type, the plaintiff claims that the product warning should have let consumers know there is a reasonable scientific basis for concluding that the product might be carcinogenic, even though the evidence is inconclusive. To establish this claim, the plaintiff must first show that the requested disclosure involves a foreseeable risk.[21] The risk involves the possibility that the product is carcinogenic. This risk is foreseeable, even though there is not conclusive scientific evidence of carcinogenicity. The plaintiff can show that the product contains a chemical known to be an animal carcinogen and has other properties suggestive of human carcinogenicity. This evidence provides a sufficient foundation for the administrative regulation of the product as a human

20. *See* PRODUCTS LIABILITY, *supra* note 16, § 15.
21. *See id.* § 2 (b)-(c).

carcinogen.[22] The non-epidemiological evidence therefore provides a reasonable basis for inferring that the product might be carcinogenic, satisfying the requirement of foreseeability.

The plaintiff must next show that the product warning should have disclosed the possibility or risk that the product is carcinogenic. The rationale for disclosure, as formulated by the *Restatement (Third) of Torts: Products Liability*, is worth careful consideration:

> 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.[23]

As this provision indicates, the manufacturer must disclose the possibility that the product is carcinogenic if the disclosure would be material to the consumer's decision of whether to purchase or use the product. To see why this disclosure can be material, compare the following bets.[24] The first bet involves coin *A*, which you have been able to examine. Suppose you confidently believe the coin is fair because it comes up heads or tails with approximately equal frequency. The second bet involves coin *B*, which you have never seen and cannot examine prior to the bet. You do not know if coin *B* is two-headed, two-tailed, or otherwise fair. Without any further information about coin *B*, you might decide that each of these coin configurations is equally likely, so you impute a 0.5 probability of heads or tails to coin B (the equally likely two-headed and two-tailed coins cancel one another out, leaving the fair coin). You also impute the same probabilities to coin *A*. Do you think the bets involving the two coins are identical, and does that make a difference?

You have much more confidence in your probability assessment of coin *A* than in your assessment of coin *B*. The difference is irrelevant if you must bet now, for in that case you form a best estimate and bet accordingly. The best estimate for the two coins is

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22. *See, e.g.*, Alon Rosenthal et al., *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269, 270 (1992).

23. PRODUCTS LIABILITY, *supra* note 16, § 2 cmt. m.

24. The example is drawn from JACK HIRSHLEIFER & JOHN G. RILEY, THE ANALYTICS OF UNCERTAINTY AND INFORMATION 10-11 (1992).

the same and hence there is no relevant difference between them in this setting. The difference in your confidence of these estimates is relevant, though, if you have the option of obtaining more information prior to making the bet. When this option is available, you should be more willing to invest effort or money to obtain information about coin *B* than about coin *A*. For example, if you can observe a toss of coin *B*, and the outcome is heads, you can rule out the possibility that the coin is two-tailed. Observing the identical outcome from a toss of coin *A*, by contrast, is unlikely to change your opinion that the coin is fair. Hence "greater prior doubt (lesser degree of confidence) makes it more important to acquire additional evidence before making a terminal move [such as placing a bet]."[25]

Now consider how this reasoning applies to the consumer's decision of whether to purchase a product that might be carcinogenic. Absent a warning, the consumer can be confident that the product is not carcinogenic. By contrast, a consumer who is aware of the animal studies and other indicators of carcinogenicity would have much lower confidence in her assessment of the product risk. The difference in confidence may not matter if the consumer must make the consumption decision right now, but typically that is not the case. Consumers usually have the option of waiting to consume or use a product. Delayed consumption is costly for the consumer (as she cannot derive any present benefit from the product), but the cost of delayed consumption can be less than the benefit of waiting to find out whether the product actually is a carcinogen. Information about possible carcinogenicity, therefore, can influence the consumer's decision whether to purchase or use the product. Such a disclosure would reduce the consumer's confidence about the product's safety, and may induce her to wait until further study has been done. In these cases, the seller can be liable for not warning about the potential that the product might be carcinogenic, despite the lack of epidemiological evidence.

At this point in the tort inquiry, causal questions become relevant, but not in a manner that requires epidemiological proof. A warning defect can injure the plaintiff only if she would not have purchased or used the product had she been adequately warned. This causal issue is resolved in two different ways by the vast majority of courts. "A great many jurisdictions have adopted the heeding presumption in failure-to-warn cases,"[26] which presumes

25. *Id.* at 11; *see also id.* at 167-208 (developing the analytics of informational decisions).
26. Coffman v. Keene Corp., 628 A.2d 710, 719 (N.J. 1993).

that the plaintiff would have heeded or followed the warning had the defendant given one. Virtually all other jurisdictions rely on a subjective standard for establishing causation, which the plaintiff can satisfy by testifying that she would not have purchased or used the product had she been given an adequate warning.[27]

As I have argued elsewhere, the heeding presumption is more defensible than the subjective standard.[28] Suppose the disclosure about the potential carcinogenicity of the product would increase by 5% the average consumer's estimate of the cost of current consumption as compared to delayed consumption. A 5% increase in cost is material to the consumer's decision whether to purchase the product now, yet a 5% increase in cost is unlikely to cause the *average* consumer to forego purchasing the product.[29] For most products, a 5% increase in price will cause *some* consumers to forego the purchase, but how can the plaintiff show that she is one of these "marginal" consumers? Whether an individual is a marginal consumer largely depends on the intensity of her preferences for the product. The intensity of the plaintiff's preferences is inherently subjective, and typically there is no objectively verifiable evidence on the matter. In most cases, then, the only evidence on causation consists of the plaintiff's testimony that she would not have purchased the product had she known it might be carcinogenic. For this reason, the plaintiff's testimony is sufficient to satisfy the subjective standard in the jurisdictions that take this approach. But since the plaintiff will almost always testify to that effect (otherwise why bring the lawsuit?), these jurisdictions are doing nothing other than presuming causation, the same outcome more defensibly achieved by the heeding presumption.

As this discussion indicates, under either the heeding presumption or the subjective standard, the plaintiff will often be able to establish that she would not have purchased the product had she known it might be carcinogenic. At this point, the plaintiff has established a tortious invasion of her autonomy interest—the right to make "an informed decision not to purchase or use the product at

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27. *See* Michael S. Jacobs, *Toward A Process-Based Approach to Failure-to-Warn Law*, 71 N.C. L. REV. 121, 162-63 (1992).

28. *See* Mark Geistfeld, *Inadequate Product Warnings and Causation*, 30 U. MICH. J.L. REFORM 309, 337-49 (1997).

29. The seller in these circumstances must warn about the potential hazard. *See* PRODUCTS LIABILITY, *supra* note 16, § 2 cmt. i ("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.").

all"[30]—without having to rely on epidemiological proof. Whether the product tortiously caused the plaintiff's cancer therefore involves a question of damages rather than of liability.

Causal issues in the damages context—did the defendant cause the full extent of harm underlying plaintiff's damages claim?—are often subjected to standards of proof less demanding than those required for causal issues concerning liability—did the defendant tortiously cause any harm to the plaintiff?[31] A relaxed evidentiary standard for damages can be justified, according to the U.S. Supreme Court, "[w]here the tort itself is of such a nature as to preclude the ascertainment of the amount of damages with certainty," because in these cases "it would be a perversion of fundamental principles of justice to deny all relief to the injured person, and thereby relieve the wrongdoer from making any amend for his acts."[32] This rationale for relaxing the demands of the ordinary evidentiary standard has been applied in various tort contexts, such as tortious interference with prospective economic advantage and the intentional spoilation of evidence.[33] The rationale is particularly persuasive in cases of scientific uncertainty. The tortious conduct consists of the failure to let consumers and users know about the scientific uncertainty, so it would be perverse if the defendant could rely on the uncertainty to escape liability in the damages phase.

Of course, a less demanding evidentiary standard does not eliminate the plaintiff's burden of proving with reasonable certainty that her cancer was caused by exposure to the product. Reasonableness depends on what can fairly be demanded of the plaintiff in light of the defendant's tortious conduct. Hence, the plaintiff must establish a reasonable scientific basis for concluding that the product is carcinogenic, such as the animal and laboratory studies in the context presently analyzed. Moreover, the plaintiff must introduce evidence of specific causation that sufficiently eliminates the possibility that her cancer was caused by some other carcinogen and not the defendant's product. Reasonable proof, however, does not involve epidemiological studies, for it is the absence of epidemiological evidence, coupled with the indicators of carcinogenicity, that

30. *Id.* § 2 cmt. i.

31. *See* RESTATEMENT (SECOND) OF TORTS § 912 cmt. a (1979).

32. Story v. Paterson Parchment Paper Co., 282 U.S. 555, 563 (1931).

33. *See generally* Pati Jo Pofahl, Smith v. Superior Court: *A New Tort of Intentional Spoilation of Evidence*, 69 MINN. L. REV. 961 (1985) (discussing the relaxed evidentiary requirements for causal questions in cases of prospective economic advantage and the intentional spoilation of evidence).

creates the scientific uncertainty in the first instance. The plaintiff's right to know about the uncertainty was violated by the defendant, so the defendant should not be able to escape liability by relying on the uncertainty in the damages phase.

An alternative approach is to treat the damages for cancer as punitive in nature. Punitive damages are often justified as a way to provide the appropriate incentives for defendants to behave non-tortiously.[34] If the defendant manufacturer were not liable for the plaintiff's cancer, it would not have an adequate incentive to warn about the possibility that the product is a carcinogen. Why give consumers bad news about the product if there is no downside to keeping the information secret? Once the manufacturer is liable for the cancer, it assumes responsibility for the worst case scenario that can be reasonably inferred from the current scientific understanding of the product. Rather than face liability for the worst case scenario, a manufacturer would find it more cost-effective to behave non-tortiously by disclosing the uncertainty to consumers and users. Disclosure of the uncertainty, in turn, increases consumer estimates of product cost, giving the manufacturer an incentive to engage in further research to clear up the uncertainty.[35]

III. SCIENTIFIC UNCERTAINTY AND EVIDENTIARY REQUIREMENTS OUTSIDE OF THE PRODUCTS LIABILITY CONTEXT

Cases involving scientific uncertainty have been concentrated in the products liability area. Products liability cases can be analyzed differently than other tort cases. The product seller's failure to adequately warn consumers of scientific uncertainty creates a basis for liability that does not depend on epidemiological proof. Tort cases in other contexts do not involve contractual relationships or a right to informed consent that can be effectively enforced in cases of scientific uncertainty.[36] In these contexts, the plaintiff can-

34. DOBBS, *supra* note 11, § 381 at 1063 ("Courts usually emphasize that punitive damages are awarded to punish or deter .... The idea of deterrence ... is that a sufficient sum should be extracted from the defendant to make repetition of the misconduct unlikely.").

35. Sellers might choose to warn about the uncertainty and not engage in further research. Such research could find the substance to be carcinogenic, forcing the seller to warn consumers that the product is a carcinogen. As compared to a warning that the product might be carcinogenic, a warning that the product is carcinogenic is likely to reduce consumer demand. This cost of research has the potential to undermine the seller's incentive to study the hazards posed by the product.

36. Medical malpractice cases are the closest analog to products liability cases, but there is an important difference. Like products liability cases, malpractice cases involve a duty of disclosure (the doctrine of informed consent), so, for the same reasons given in Part II, a plaintiff could

not establish liability by showing that the defendant's failure to apprise her of scientific uncertainty violated her right to informed decision-making. For these contexts, an analysis of the epidemiological evidentiary requirement must directly address the issue of whether the requirement violates tort norms.

A tort norm based on corrective justice, which makes causation an essential predicate of liability, provides an obvious basis for evaluating an evidentiary requirement pertaining to causation. (The efficiency rationale for tort liability is discussed later.) As a matter of corrective justice, the need for the plaintiff to establish causation does not become any less important once the plaintiff has already established duty and breach by the defendant.[37] If proof of duty and breach, when coupled with factual uncertainty, fully satisfied the plaintiff's burden of proof, then there would be no good reason for giving the plaintiff the initial burden of proving causation. The burden of proof reflects an underlying norm concerning the appropriate allocation of factual uncertainty between the parties, so the mere existence of factual uncertainty cannot be a sufficient reason for shifting the burden of proof on causation.[38] Instead, the plaintiff needs to show why the factual uncertainty is "extraordinary" in the sense that the norms underlying the ordinary burden of proof justify a special rule for shifting the burden in the case at hand.

A special rule can be justified if the plaintiff, by satisfying ordinary evidentiary standards, shows that the defendant completed a tort. By proving that the defendant's tortious conduct more likely than not caused *some* harm, the plaintiff establishes her right in corrective justice to receive some compensation. If that right cannot be adequately protected by ordinary rules, the court is em-

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establish a breach of the duty without relying on epidemiological proof. But, unlike products liability cases, the causal question in malpractice cases—would the plaintiff-patient have foregone the prescribed treatment had she been adequately informed?—is governed by an objective standard. *See generally* 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. The objective standard effectively bars recovery for inadequate disclosure in all but the most extreme cases. *See generally id.*; *see also* Geistfeld, *supra* note 28, at 339-41 (explaining why the objective standard would bar recovery in most cases of inadequate disclosure). Hence, the tort right of informed consent is unlikely to be of much help to plaintiffs in malpractice actions involving scientific uncertainty.

37. See Arthur Ripstein & Benjamin C. Zipursky, *Corrective Justice in an Age of Mass Torts*, *in* MORAL PHILOSOPHY AND THE U.S. LAW OF TORTS (Gerald Postema ed., forthcoming 2001).

38. For this reason, it is hard to defend the claim made by Porat & Stein, *supra* note 8, that the burden can be shifted merely because the defendant is responsible for creating the uncertainty by exposing the plaintiff to the substance.

powered to protect the right by adopting special rules. If, however, the defendant has not completed a tort, then the plaintiff has not established her right to compensation and the corresponding need to have the right protected by a special rule.[39]

This justification explains why courts have adopted relaxed evidentiary standards regarding damages,[40] since those rules apply to cases in which the plaintiff has first proven that the defendant completed a tort. This justification, though, would not permit alteration of the ordinary evidentiary rules merely because the case involves scientific uncertainty. In the paradigmatic case, the plaintiff may be able to establish that the defendant failed to exercise reasonable care by not conducting further research in light of a reasonable basis, such as animal studies, for concluding that the substance might be hazardous to human health. But what harm has the plaintiff or anyone else suffered? Without establishing that the substance is in fact hazardous, the plaintiff cannot show that she has been harmed in any way by the defendant's failure to conduct further testing. Without such a showing, there may be no justification for altering the ordinary burden of proof on causation.

Even if the plaintiff has not established a completed tort, in some contexts a special evidentiary rule possibly could be justified on the basis of the norm for the ordinary evidentiary rule. The norm requires that plaintiffs ordinarily bear the burden of proof on causation, but the norm could also require that plaintiffs be relieved of that burden in special contexts, and those contexts may include the paradigmatic case of scientific uncertainty. If, however, the norm supports the requirement that plaintiffs establish causation by epidemiological proof, then tort principles do not require a special rule in cases of scientific uncertainty.

What is the appropriate evidentiary norm? Consider the preponderance of the evidence rule, which is often called the "more-likely-than-not" standard. Suppose the plaintiff establishes all elements other than causation. If the evidence shows there is a 50.1% chance that the defendant caused the harm, the plaintiff can recover even though there is a 49.9% chance that the defendant did not cause the harm (a false positive). And if the evidence shows there is a 50.1% chance that the defendant did not cause the harm, the plaintiff cannot recover even though there is a 49.9% chance that the defendant did cause the harm (a false negative). This standard, therefore, gives equal weight to the chance of a false positive

39. *See generally* Ripstein & Zipursky, *supra* note 37.
40. *See supra* notes 31-32 and accompanying text.

and a false negative, a weighting that presumably reflects the normatively acceptable allocation of factual uncertainty.

The same weight given to false positives and false negatives reflects a normative position that gives equal weight or concern to (1) the interest of a non-culpable defendant in avoiding liability judgments based on limited factual information, and (2) the interest of a victim who does not receive her rightful compensation due to limited factual information. These competing interests appear to be normatively equivalent, so giving them equal weight seems to conform to the norm of equality. On this view, the norm underlying the ordinary evidentiary standard in tort law strives to apportion equally the burden of factual uncertainty (or erroneous legal determinations) between deserving plaintiffs and non-culpable defendants.[41]

The norm, however, requires further elaboration. The ordinary evidentiary standard allows the jury to conclude that a fact has been established if the evidence, when viewed in a light most favorable to the plaintiff, would enable a reasonable juror to conclude that the fact more likely than not exists.[42] The standard, therefore, may give the jury some latitude in choosing a version of the facts before it must apply the more-likely-than-not standard. The courts have not adequately addressed the appropriate relationship between the jury's selection of facts and the more-likely-than-not standard.[43] This relationship can be analyzed in terms of the betting problem described earlier in Part II. The problem involves an individual who must assess the probabilities of heads or tails without knowing whether the coin is fair. The coin could be two-headed, two-tailed, or fair. If the individual assigned equal probabilities to each configuration, he would conclude that the probability of heads or tails is 0.5, the same probability imputed to a

41. *Cf.* John Kaplan, *Decision Theory and the Factfinding Process*, 20 STAN. L. REV. 1065, 1072 (1968) (demonstrating that a probability of 0.5 is the optimal point for cases in which "the consequences of an error in one direction are just as serious as the consequences of an error in the other"). A similar, though different conceptualization of the burden of proof is set forth in David Kaye, *The Limits of the Preponderance of the Evidence Standard: Justifiably Naked Statistical Evidence and Multiple Causation*, 1982 AM. B. FOUND. RES. J. 487. Like the analysis here, Kaye conceptualizes the burden of proof as giving equal weight to false positives and false negatives. Unlike the approach here, Kaye relies on a norm of cost minimization. The norm of equality relied upon here is identical to a norm of cost minimization if the cost of false positives equals the cost of false negatives, as Kaye assumes. The two norms will not be the same, however, whenever the costs of the two types of error are not the same, as is frequently the case.

42. *See, e.g.*, DOBBS, *supra* note 11, § 150 at 360.

43. *See* Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 YALE L.J. 376, 387-88 (1986).

fair coin. The same probability estimate for the two types of coins does not mean the individual thinks the unknown coin is fair, because he is much more confident about the probability estimate of a fair coin than of an unknown coin. The distinction between a probability estimate and the degree of underlying confidence often occurs when juries evaluate factual allegations. That distinction, in turn, explains why the evidentiary norm includes the requirement of reasonableness in the more-likely-than-not standard.

Consider the following case. The plaintiff shows that the defendant was negligent for not providing life-saving equipment on a boat. To establish causation, the plaintiff must show that, had the defendant provided life-saving equipment, the decedent would not have drowned. The causal inquiry is counterfactual, and the jury will often not know the exact factual context in which the life-saving equipment would have been used.[44] Suppose a reasonable juror could consider three contexts without having any basis for concluding that one is more likely than any other: (1) the life-saving equipment would have made a difference in most cases; (2) the equipment would have made a difference in many cases; or (3) the equipment would have made no difference. Without any information concerning the relative likelihood of the three scenarios, the jury could decide that each scenario is equally likely, implying that the life-saving equipment had less than a 50% chance of preventing the drowning. The jury, in other words, would find that the plaintiff did not satisfy the burden of proof on causation. The ordinary evidentiary standard, however, does not obviously compel the jury to reach that conclusion. If the evidence is viewed in the light most favorable to the plaintiff, a reasonable juror could adopt context (1), in which there is a greater than 50% chance that the equipment would have prevented the drowning. The ordinary evidentiary standard appears to sanction such a finding, particularly since the finding supports the rationale for a duty to provide life-saving equipment.[45] Hence, the plaintiff would not necessarily lose such a case.[46]

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44. *See, e.g.*, Reyes v. Vantage S.S. Co., 609 F.2d 140, 144 (5th Cir. 1980) (holding that the factfinder "must be prepared to determine whether there was time for a crew member to go to the hypothetical storage location, obtain the hypothetical line-throwing appliance, move it to the appropriate firing location, and fire the appliance—all before [the decedent] went limp in the water").

45. *See* Wex S. Malone, *Ruminations on Cause-in-Fact*, 9 STAN. L. REV. 60, 61-88 (1956) (arguing that courts will let juries determine cause-in-fact for cases of substantial factual uncertainty over causation if dismissal of the case would undermine the reason for the tort duty). A more refined version of Malone's thesis is that the nature of the tort duty can create certain factual presumptions applicable to a causation inquiry involving inherent factual uncertainty.

On this view, the ordinary evidentiary standard addresses two aspects of factual uncertainty: the uncertainty associated with known probabilities (will a fair coin come up heads or tails?); and the deeper uncertainty or degree of confidence associated with any given probability estimate (is the coin fair or not?).[47] Cases involving known probabilities can be readily evaluated in terms of the more-likely-than-not standard. Cases in which probability estimates are not confidently held, by contrast, are much more difficult to evaluate in terms of the more-likely-than-not standard. For such cases, the evidentiary rule can require that any given probability

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Predicting how individuals might behave in a counterfactual world, for example, is particularly fraught with uncertainty. Adopting presumptions of behavior derived from the duty of care eliminates the uncertainty in a defensible manner, as illustrated by the heeding presumption in products liability. *See supra* note 26 and accompanying text; *see also* Mark Geistfeld, *Tort Law and Criminal Behavior (Guns)*, 43 ARIZ. L. REV. (forthcoming 2001) (arguing for a behavioral presumption in the causal inquiry consistent with the behavioral presumption adopted by the tort duty). All of the cases discussed by Malone can be rationalized on this ground, as the cases involve contexts in which the factual uncertainty consists of the lack of knowledge regarding how the accident victim or someone else would have acted if the defendant had exercised reasonable care. Whether one adopts Malone's conceptualization of the cause-in-fact inquiry, or an inquiry based on factual presumptions derived from the duty of care, each conceptualization yields the type of evidentiary norm discussed in the text.

46. *See Reyes*, 609 F.2d at 144 (finding for the plaintiff on remand, even though the decedent was drunk while in the water and struggling against a strong current); Kirincich v. Standard Dredging Co., 112 F.2d 163, 164 (3d Cir. 1940) (remanding case in which the deceased, who may have been unable to swim, was carried away by the falling tide while "shipmates tried to save him with inadequate equipment"); Zinnel v. United States Shipping Bd. Emergency Fleet Corp., 10 F.2d 47, 49 (2d Cir. 1925) ("Nobody could, in the nature of things, be sure that the intestate would have seized the rope, or, if he had not, that it would have stopped his body . . . . [W]e think it a question about which reasonable men might at least differ . . . . "). *But see* Skinner v. Square D Co., 516 N.W.2d 475, 480 (Mich. 1994) ("Nor is it sufficient to submit a causation theory that, while factually supported, is, at best, just as possible as another theory.").

47. These aspects of the causal inquiry are identified in Neil B. Cohen, *Confidence in Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U. L. REV. 385, 404-05 (1985); Gold, *supra* note 43. In statistical terminology, the probability estimate is a "point estimate," and the decision-maker's confidence in that estimate is represented by the "confidence interval." According to Cohen, all point estimates within the confidence interval must exceed 50% to satisfy the plaintiff's burden of proof. *See* Cohen, *supra*, at 398-404. This interpretation of the burden of proof is more demanding than my interpretation, and is inconsistent with the cases. *See supra* note 26 (heeding presumption); note 46 (rescue cases). Gold, by contrast, assumes the confidence dimension significantly reduces the plaintiff's burden of proof so that epidemiological proof is not required, but he never adequately explains the relationship between the confidence interval and the plaintiff's burden of proof. *See generally* Gold, *supra* note 43. Like Gold, I assume that not all point estimates in the confidence interval must exceed 50%. Unlike Gold (and Cohen), I claim that a point estimate within the confidence interval only satisfies the plaintiff's burden of proof if that estimate satisfies the reasonableness requirement of the evidentiary standard. Reasonableness can be determined by reference to the rationale for the relevant tort duty, see *supra* note 45, and presumably can depend on other factors. *Cf.* Malone, *supra* note 45, at 85 (observing that the jury "could fairly be permitted a wide range of speculation at [defendant's] expense" when "the defendant's conduct was so obviously open to condemnation").

estimate be based on a reasonable degree of confidence—that is, the estimate must be based on something more than mere speculation or conjecture, while accounting for all undisputed facts. Beyond the minimal requirement of reasonableness, it often will be difficult to regulate the appropriate relationship between probabilities and the underlying confidence. Thus the ordinary evidentiary rule: the jury can conclude that a fact has been established if the evidence, when viewed in a light most favorable to the plaintiff, would enable a reasonable juror to conclude that the fact more likely than not exists.

For these reasons, an evidentiary norm based on the equal treatment of deserving plaintiffs and non-culpable defendants can allow for a greater range of evidence than might be suggested by a narrow interpretation of the more-likely-than-not evidentiary standard. Nevertheless, the norm supports the epidemiological evidentiary requirement.

In the paradigmatic case of scientific uncertainty, we do not adequately understand the etiology of the disease or injury, like cancer. Due to the lack of such knowledge, we infer causal relationships entirely on the basis of associational relationships, such as those identified by valid epidemiological study. If individuals exposed to the substance have a higher incidence of cancer, we assume this association means there is a causal relation, even though we do not fully understand the causal mechanism. The causal relationship is expressed probabilistically: exposure to the substance increases the risk of cancer by $x\%$. This probability is an estimate, so there is a degree of confidence associated with the estimate. However, the degree of confidence is a statistical property that can be quantified in a non-controversial manner.[48]

So too, because we do not fully understand the etiology of cancer, we rely on the results of animal studies or chemical analyses to provide some guidance as to carcinogenicity. Like epidemiological studies, the guidance depends entirely on associational relationships. The nature of the associational relationship is different, however. The fact that the substance increases the risk of cancer for mice does not mean it poses the same risk, or any risk, for humans. To be relevant, the associational relationship identified by nonepidemiological proof, like animal studies, must be of the following type: after adjusting for differences in dose levels, a substance that is an animal carcinogen will cause the same type of cancer in hu-

48. The appropriate degree of confidence is related to the amount of increased risk that must be identified by epidemiological study, an issue discussed in Part IV below.

mans y% of the time, or a different type of cancer in humans z% of the time.

Now consider the requirement of epidemiological proof in light of the previously identified evidentiary norm. We have been assuming the plaintiff has various types of non-epidemiological evidence tending to show that her cancer was caused by exposure to the defendant's substance. Suppose such evidence correctly identifies a human carcinogen 30% of the time. This evidence does not show that the substance more likely than not caused the plaintiff's cancer. Moreover, the jury does not have much latitude in choosing another number. Unlike other types of cases in which the jury may have discretion in choosing the context and the associated probability estimate, it typically will not have such discretion in cases of scientific uncertainty. Absent an understanding of the cause of cancer, probabilities derived from associational relationships are the only available evidence of carcinogenicity. To reject such a probability estimate in favor of some other number requires the jury to make implicit assumptions about the cause of cancer. These assumptions would seem to be nothing other than mere conjecture or speculation given our lack of knowledge on the matter.

The reasonableness constraint on jury decision-making, which allows for greater discretion in contexts of factual uncertainty such as the drowning example, therefore limits the jury's discretion in the paradigmatic case of scientific uncertainty. Unless the non-epidemiological evidence correctly identifies the substance as a sufficiently potent human carcinogen at least 50% of the time, that evidence does not provide a reasonable basis for the jury to conclude that the substance more likely than not caused the plaintiff's cancer.[49] Whenever non-epidemiological evidence is unable to satisfy this condition, the evidentiary rule can require epidemiological evidence for satisfying the plaintiff's burden of proof.

But what about the aspirational aspect of the evidentiary norm that strives to apportion equally the burden of factual uncertainty between plaintiffs and defendants? The epidemiological evidentiary requirement systematically disadvantages plaintiffs, because no individual plaintiff will find it cost-effective to undertake such studies in light of the high cost and low probability of identifying the substance as a human carcinogen. This systematic unfair-

49. Merely because a substance is a human carcinogen does not mean that the substance more likely than not caused the plaintiff's cancer. The potency of the carcinogen—the degree to which it increases the risk of cancer—is an additional factor that must be identified to make non-epidemiological proof relevant. *See infra* Part IV.

ness suggests that the epidemiological evidentiary standard cannot be justified if the alternative evidentiary rule would not unfairly disadvantage non-culpable defendants. In the present state of science, this outcome does not seem to be attainable.

Suppose the plaintiff can satisfy the burden of proof by relying solely on non-epidemiological evidence, including animal studies or laboratory indicators of carcinogenicity.[50] The defendant cannot rebut until the epidemiological studies have been completed, so the defendant will typically lose. Is this outcome acceptable in light of the tort norm that strives to apportion equally the burden of factual uncertainty?

As before, suppose that in 30% of cases involving only animal studies and other non-epidemiological evidence, the substance turns out to be a human carcinogen. If the plaintiff can satisfy the burden of proof with this evidence, then 70% of these cases will result in the defendant being liable for a non-carcinogen—the chance of a false positive is 70%.[51] This rate of false positives must be compared to the rate of false negatives produced by the alternative rule that requires epidemiological evidence. This rule means that some deserving plaintiffs will not recover. In the example, 30% of the cases based entirely on non-epidemiological evidence will involve human carcinogens. Hence, the evidentiary rule requiring epidemiological evidence lets culpable defendants escape liability in 30% of the cases—the rate of false negatives.

Ideally, an evidentiary standard should balance the rates of false positives (the interests of non-culpable defendants) and false negatives (the interests of deserving plaintiffs), the type of balancing reflected in the more-likely-than-not standard. Such a balance cannot be achieved in this context. The choice in the example is between a rule not requiring epidemiological proof with a 70% rate of false positives and an alternative rule requiring epidemiological proof with a 30% rate of false negatives. The error rates cannot be balanced, implying that one set of interests will suffer disproportionately by bearing the entire burden of factual uncertainty. If the choice is made by reference to a norm that gives equal weight to each set of interests, then the choice should minimize the burden that must be imposed on one set of interests. As between a 70% rate of false positives and a 30% rate of false negatives, a rule creating the latter burden is fairer. The burden the rule places on deserving

50. This sort of burden is proposed in many of the sources cited at *supra* note 8.

51. This number conservatively favors the plaintiff, because it omits consideration of potency. *Cf. supra* note 49.

plaintiffs is less than the burden that would be placed on non-culpable defendants by the alternative rule. The equal weight given to each set of interests therefore justifies the requirement of epidemiological proof, despite the disproportionate burden placed on plaintiffs.

IV. LIMITS OF THE EPIDEMIOLOGICAL EVIDENTIARY REQUIREMENT

Although the epidemiological evidentiary requirement is consistent with tort norms, we must still consider whether courts have properly formulated the requirement. According to some courts, epidemiological proof is required in all cases and is relevant only if it shows that the substance at least doubles the risk of injury.[52] This strong form of the evidentiary requirement is inconsistent with tort law. The most defensible form of the requirement is limited to contexts in which non-epidemiological proof is not sufficiently reliable, and even in those contexts the epidemiological proof need not show a doubling of risk to establish causation.

The epidemiological evidentiary requirement is necessarily dependent on the current state of science and the types of non-epidemiological proof proffered by the plaintiff. The prior analysis shows that the epidemiological evidentiary requirement is justified whenever the causal evidence consists solely of non-epidemiological proof that would yield incorrect liability findings (false positives) more than one-half of the time. Non-epidemiological proof, such as animal studies, will become more reliable with advances in scientific knowledge. Animal studies are likely to become better predictors of human risk as scientists determine the mechanisms by which families of chemicals act on the environment and human health.[53] Similarly, advances in genetic knowledge and the manipulation of genes have the potential to greatly increase the reliability of animal studies.[54] Because animal studies and other forms

52. *See supra* notes 5-6 and accompanying text.

53. The chemical industry is funding such a study. "Many scientists think [the study] will provide the means to determine when it does or does not make sense to extrapolate from epidemiological studies and animal tests to assessments of a chemical's human health risks." Claudia H. Deutsch, *Chemical Industry to Spend $1 Billion to Assess Product Safety*, N.Y. TIMES, Jan. 27, 1999, at A14.

54. For example, the new field of toxicogenomics involves the laboratory testing of animals or cells to determine the pattern of gene activity involved upon exposure to a potentially hazardous substance. "This pattern of gene activity, at least in theory, should indicate whether the chemical is toxic, much as DNA fingerprints are used to judge the guilt or innocence of criminal

of non-epidemiological proof may become sufficiently reliable to satisfy the plaintiff's burden of proof for cases in which epidemiological proof is unavailable, the epidemiological evidentiary requirement must acknowledge this possibility and be limited accordingly.

Another important limitation of the evidentiary requirement involves the degree of risk that must be identified by epidemiological study. Epidemiological proof showing a doubling in risk is a superficially appealing requirement. Given the extreme uncertainty and the associated limitation on the jury's discretion, epidemiological proof showing a doubling of risk would seem to be the only non-speculative evidence showing that the substance more likely than not caused the plaintiff's injury. A requirement that epidemiological proof must always show at least a doubling in risk, however, is inconsistent with tort norms.

Epidemiological study can determine whether a substance increases the incidence of a given disease or injury within a population of sufficiently homogenous individuals. Epidemiological proof therefore identifies *per capita* risk for a population rather than the risk faced by each *individual* member. Due to the difference between per capita population risk and individual risk, the doubling-in-risk requirement cannot be defended for diseases with unknown etiology, such as cancer.

Consider a case in which the defendant tortiously exposed the female plaintiff to radiation, and the plaintiff subsequently develops bone cancer. Suppose valid epidemiological proof shows the baseline or background risk of bone cancer in the population of non-exposed women is two in one thousand by age forty-five, whereas the risk of bone cancer in the population of exposed women is three in one thousand by age forty-five. Suppose the plaintiff has all the relevant characteristics of other members of the studied population, so the per capita population risk is relevant for determining the risk faced by the plaintiff. According to the doubling-in-risk requirement, this epidemiological evidence is not admissible and the

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suspects." Andrew Pollack, *DNA Chip May Help Usher In a New Era of Product Testing*, N.Y. TIMES, Nov. 28, 2000, at F2. Another significant development, based on recombinant DNA techniques, involves "transgenic mice" whose genes have been manipulated to greatly increase our "understanding how interactions between individual genes and the environment affect human health." Mitch Eddy, *The Use of Transgenic Mice for Environmental Health Research, in* INNOVATIONS, ENVIRONMENTAL HEALTH PERSPECTIVES, Vol. 101, No. 4 (Sept. 1993), *available at* http://ehpnet1.niehs.nih.gov/docs/1993/101-4/innovations.html. For a description of various transgenic models, and their relation to human risk assessment, see *Taconic Animal Models*, Taconic Transgenic Models, *available at* http://www.taconic.com/anmodels/transgenic%20model%20list%202001.htm (last visited Feb. 5, 2001).

plaintiff must lose the case because the evidence shows that her bone cancer more likely than not was caused by the background risk and not the radiation exposure. The conclusion is unsound, however, because it inappropriately assumes that the cases of bone cancer caused by the background risk (two in one thousand) are independent of the cases of bone cancer caused by the radiation exposure. As two epidemiologists explain:

> [I]t is possible that exposure interacts with background factors to advance the incidence time of all bone cancer cases. This would happen if the cancer is the endpoint of a pathologic process whose rate is accelerated by radiation exposure. Thus, it could be that the two background cases (the two women who would have gotten bone cancer at age 45 even without exposure) instead got their cancer years earlier because of exposure; while the three cases that occurred at age 45 would not have occurred until years later absent the exposure. In fact, it could be that exposure causally contributed to *all* cancers at *all* ages by accelerating *all* the incidence times.[55]

Because we do not fully understand the etiology of cancer, we cannot determine the etiology of any individual case of cancer. Of the various plausible models of cancer or other important chronic diseases, none rule out the type of scenario in which exposure facilitates the onset of injury in all exposed individuals rather than merely creating injuries additional to those caused by the background risk.[56] As a result, the per capita population risk identified by epidemiological study is likely to underestimate the degree of risk faced by any individual.[57]

Whereas our limited understanding of the etiology of cancer justifies the epidemiological evidentiary requirement, that same lack of knowledge undermines the doubling-in-risk requirement. Suppose the epidemiological proof identifies an increase in per capita population risk of 1.9. Because the per capita population risk is likely to underestimate the degree of individual risk, a jury (if given the appropriate biological evidence on how exposure might facilitate the disease) could reasonably conclude that the exposure increased individual risk by at least a factor of two, enabling it to find that

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55. Sander Greenland & James M. Robins, *Epidemiology, Justice, and the Probability of Causation*, 40 JURIMETRICS J. 321, 327 (2000). For other criticisms of the assumption that the per capita risk equals the individual risk, see Mark Parascandola, *What Is Wrong with the Probability of Causation?*, 39 JURIMETRICS J. 29, 35-41 (1998).

56. *See* Greenland & Robins, *supra* note 55, at 325.

57. *See generally id.*; *see also* Louis A. Cox, Jr., *Statistical Issues in the Estimation of Assigned Shares for Carcinogenesis Liability*, 7 RISK ANALYSIS 71, 72-73 (1987); Sander Greenland & James M. Robins, *Conceptual Problems in the Definition and Interpretation of Attributable Fractions*, 128 AM. J. EPIDEMIOLOGY 1185, 1192-93 (1988); James M. Robins & Sander Greenland, *Estimability and Estimation of Excess and Etiologic Fractions*, 8 STAT. MED. 845, 850-51 (1989).

the exposure more likely than not injured the plaintiff. This conclusion is most compelling for risk increases slightly less than two, but the logic applies more generally to any risk increase sufficient to establish tortious conduct by the defendant.

Reconsider the case in which the defendant exposed the female plaintiff to radiation, thereby increasing the per capita population risk from two in one thousand to three in one thousand. Suppose this epidemiological proof, in conjunction with the other relevant evidence, shows an increase in risk sufficient to establish that the defendant acted tortiously. If the plaintiff could introduce expert testimony showing that the exposure facilitated her injury according to a plausible biological model, she would not conclusively prove that her cancer was facilitated by the radiation. The defendant cannot conclusively disprove the point. Importantly, though, the causal question facing the jury is essentially similar to the causal question courts frequently submit to juries in the rescue cases discussed earlier.[58] The defendant has breached a duty of care to the plaintiff. Whether the breach caused harm (failure to rescue) is very plausible but impossible to determine. Nevertheless, as long as the facts permit a reasonable juror to find causation, courts submit the causal question to the jury. By contrast, courts that adopt the doubling-in-risk evidentiary requirement would not submit the cancer case to the jury, even though the defendant's breach quite plausibly harmed the plaintiff. The causal inquiry is not fundamentally different than the rescue cases.

To be sure, the cancer case involves tortious conduct that facilitated the injury, whereas the rescue cases do not necessarily involve injuries of that type (either the decedent would have drowned or not). Such distinction is irrelevant, however. The facilitation of injury is compensable in tort (wrongful death, for example, is merely facilitation of the inevitable).[59] As long as the jury can reasonably conclude that the defendant's tortious conduct more likely than not facilitated the injury, the question of how much harm the defendant caused—how greatly was the cancer facilitated?—is one of damages, and it is therefore governed by an evidentiary standard that does not require epidemiological proof.[60]

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58. *See supra* notes 44-46 and accompanying text.

59. For a discussion of these issues, and the supporting citations, see David A. Fischer, *Successive Causes and the Enigma of Duplicated Harm*, 66 TENN. L. REV. 1127, 1134-60 (1999).

60. *See supra* notes 31-32 and accompanying text. As this statement suggests, the facilitation theory may require a damages claim based on the assumption that the plaintiff would have gotten cancer at a later date.

Courts often let juries decide highly uncertain causal questions in contexts that are indistinguishable from the cancer case under discussion.[61] Hence, tort law does not support the requirement that epidemiological proof is admissible only if it identifies at least a doubling in risk. The only requirement is that epidemiological proof must identify an increase in risk sufficient to establish that the defendant acted tortiously. Any other limitations on the proof must be context dependent, involving the nature of the injury, the type of epidemiological study, and so on.

CONCLUSION

Cases involving scientific uncertainty should be resolved on the basis of the appropriate tort norm for allocating the burden of factual uncertainty. This norm does not require epidemiological proof in the products liability context, because such proof is primarily relevant for damages rather than causation. For damage issues, the tort norm allocates the burden of factual uncertainty to the defendant. In other contexts, epidemiological evidence is primarily relevant for causation, and the requirement of epidemiological proof is consistent with a tort norm of equality. The requirement, however, is limited by various contextual considerations, including the current state of science, and the epidemiological proof need not always show at least a doubling in risk.

The epidemiological evidentiary requirement illustrates the importance of causation in a system of corrective justice, although it can also be justified in terms of allocative efficiency. The primary economic problem posed by cases of scientific uncertainty is to identify the most cost-effective means of attaining the optimal level of research. Unlike most tort issues, the problem is particularly suitable for the centralized solutions offered by administrative regulation.[62] Research on chemicals and other substances yields information that is a public good, so the amount of research will probably be sub-optimally under-supplied by individual actors responding to

61. *See* DOBBS, *supra* note 11, § 173 at 420-22 (collecting cases supporting the conclusion that courts are "avowedly liberal with causation issues" whenever "the defendant's conduct is deemed negligent for the very reason that it creates a core risk of the kind of harm suffered by the plaintiff"); *see also supra* notes 45-47 (providing rationales for this approach to the cause-in-fact inquiry).

62. *See generally* Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357 (1984) (providing a general discussion of the economic factors relevant to the choice between adminstrative and tort regulation).

the incentives of tort liability.[63] More research will also improve the scientific procedures of risk identification, but individual actors responding to the incentives of tort liability would not account for these social benefits, again leading to a problem of under-supply. Inadequate research is the most troubling problem posed by cases of scientific uncertainty, but the appropriate solution is more aggressive administrative regulation rather than relaxing the causal requirement in tort law.[64]

63. *See* Susan Rose-Ackerman, *Market-Share Allocations in Tort Law: Strengths and Weaknesses*, 19 J. LEGAL STUD. 739, 745-46 (1990).

64. *Compare* Mark Geistfeld, *Reconciling Cost-Benefit Analysis with the Principle that Safety Matters More Than Money*, 76 N.Y.U. L. REV. (forthcoming 2001) (showing how cost-benefit methodology supports the aggressive administrative regulation of potentially hazardous substances in non-contractual settings pursuant to the precautionary principle).