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Epidemiological-Study Reanalyses and *Daubert*: A Modest Proposal to Level the Playing Field in Toxic Tort Litigation

Alexander J. Bandza*

Chemicals and their attendant risks are ubiquitous in modern life. The certainty with which exposure to a chemical can be linked to a suspected harm often determines whether liability against a manufacturer (and therefore recourse for a victim) is warranted. Problematically, for many chemicals that are suspected toxins, certainty is a nuanced and difficult construct for science and law. The resulting knowledge gap enhances the possibility of legal failure—legitimate victims suffering real harms will go uncompensated, and phantom risks will subject faultless corporations to potentially ruinous liability.

Many courts consider epidemiological studies to be the "gold standard" for linking exposure to allegedly toxic substances with harm, but these studies are not always available or favorable to one party. Expert witnesses may therefore attempt to reanalyze existing epidemiological studies. Trial courts, exercising their *Daubert*-mandated gatekeeping role, generally exclude these reanalyses. However, this Note argues that the premises for this restrictive view of epidemiological-study reanalyses are problematic, and, therefore, the strong judicial presumption of exclusion is ripe for review. For example, in 2011, the First Circuit implicitly endorsed this less restrictive view in *Milward v. Acuity Specialty Products Group, Inc.* when it found the trial court abused

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its discretion by excluding an expert’s causation opinion that contained epidemiological-study reanalyses.

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“Modern life, including good health as well as economic well-being, depends upon the use of artificial or manufactured substances, such as chemicals. And it may, therefore, prove particularly important to see that judges fulfill their Daubert gatekeeping function, so that they help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points towards the right substances and does not destroy the wrong ones.”

“Science lies not in discovering facts, but in discovering new ways of thinking about them.”

INTRODUCTION

No one really wins in toxic tort litigation. To one scholar, it is a miscarriage of justice—a system providing little, if any, recourse for victims harmed by toxic substances. To another, toxic tort litigation is a scientifically baseless juggernaut that plaintiffs’ attorneys unleash upon industry’s deep pockets, hoping to eventually strike it rich. Toxic tort litigation may produce one of two parties: a “Truly Deserving Victim” or a “Truly Blameless Manufacturer.”

The Truly Deserving Victim is a hypothetical person that used a manufacturer’s product and, as a result, suffered harm. The victim filed suit, claiming the manufacturer’s product caused harm, and introduced scientific testimony to establish causation. The victim obtained no compensation because the suit was dismissed. Later, the scientific community explicitly accepted the substance of the Truly Deserving Victim’s expert testimony. Therefore, the court’s incorrect determination to reject scientific testimony left the harm unredressed. The Agent Orange litigation brought by Vietnam War veterans against Dow, Monsanto, and other manufacturers of the defoliant exemplifies this scenario. Following exposure to Agent Orange, veterans suffered cancers and neurological illnesses, and their children had birth defects. In court, the

5. These two parties are meant to illustrate the extremes of toxic tort litigation. This illustration is not meant to convey that the Truly Deserving Victim and the Truly Blameless Manufacturer are the only outcomes in toxic tort litigation. Certainly, beneficial outcomes in between these extremes are possible.
veterans relied on animal toxicological studies to demonstrate causation, but the court demanded favorable epidemiological evidence.\footnote{8} As a result, the plaintiffs were forced to accept a controversially low settlement.\footnote{9} Today, Agent Orange is overwhelmingly linked with several cancers and birth defects.\footnote{10}

The Truly Blameless Manufacturer is a hypothetical corporation that manufactured a product used by a consumer who then suffered some harm and incorrectly attributed it to the product. The consumer filed suit, claiming the Truly Blameless Manufacturer’s product caused harm. The consumer introduced scientific testimony to establish causation. The consumer obtained compensation through a settlement or favorable judgment. Later, the greater scientific community rejected the substance of the consumer’s expert testimony. Therefore, the court’s incorrect determination to admit the scientific testimony harmed the Truly Blameless Manufacturer. A concrete example of the Truly Blameless Manufacturer scenario is the litigation surrounding silicone breast implants. There, Dow Corning and other manufacturers faced an avalanche of suits alleging their implants caused cancer and immune system damage.\footnote{11} The litigation redistributed billions of dollars from the corporations and their insurers to plaintiffs and their lawyers, forcing Dow Corning into bankruptcy.\footnote{12} However, the evidence today suggests that silicone implants do not cause cancer or immune system damage.\footnote{13}

Considerations of fairness flow from litigation involving either party. Is it fair to deny compensation to a Truly Deserving Victim if scientific evidence for causation has not yet been judicially branded “sound science”?\footnote{14} On the other hand, is it fair to demand compensation from a Truly Blameless Manufacturer if the greater scientific community ultimately rejects the scientific evidence for

\footnote{8} In re Agent Orange Prod. Liab. Litig., 611 F. Supp. 1223, 1231, 1238 (E.D.N.Y. 1985) (stating that “[e]pidemiological studies are the only useful studies having any bearing on causation”). In the absence of favorable epidemiological studies, the court held there was no question of fact because “Agent Orange cannot now be shown to have caused plaintiffs’ numerous illnesses.” Id. at 1241. The court hypothesized that even if the case went to the jury, a verdict for the plaintiffs likely would not have survived a posttrial motion for judgment notwithstanding the verdict. See In re Agent Orange Prod. Liab. Litig., 597 F. Supp. 740, 786 (E.D.N.Y. 1984).

Generally, toxicology involves exposing a population to a potentially toxic substance in order “to generate knowledge about the toxic effects” of a substance, whereas “[e]pidemiology is an observational science that seeks to identify and evaluate relationships between exposure to [potentially toxic substances] and the health status of the exposed populations.” William K. Boyes et al., Integrating Epidemiology and Toxicology in Neurotoxicity Risk Assessment, 26 Human & Experimental Toxicology 283, 283 (2007); see also discussion infra Part II.B.

\footnote{9} SCHUCK, supra note 6, at 171–72. Indeed, some companies in the Agent Orange litigation considered the settlement agreement a “bargain.” Id. at 197.


\footnote{12} Bernstein, supra note 11, at 457 n.1.

\footnote{13} See id. at 480–84; see also INSTITUTE OF MEDICINE, SAFETY OF SILICONE BREAST IMPLANTS 10–11 (1999).

\footnote{14} See discussion infra Part I.B.
causation as “bad science”\textsuperscript{15} Each scenario is problematic for different reasons.\textsuperscript{16} Many scholars suggest that toxic tort litigation tends to produce more Truly Deserving Victims than Truly Blameless Manufacturers.\textsuperscript{17}

This Note argues that the federal courts’ almost-categorical rejection of epidemiological-study reanalyses in toxic tort litigation creates more Truly Deserving Victims than necessary. Three confounding factors contribute to this surplus. First, as a threshold matter, the use of scientific testimony in legal proceedings is fraught with epistemological incongruities.\textsuperscript{18} Second, as a general matter, tort law is often ill equipped to deal with the scientific uncertainties inherent in linking toxic-substance exposure and harm—in other words, causation.\textsuperscript{19} Third, courts often demand epidemiological studies to prove causation.\textsuperscript{20} In many instances, if a plaintiff cannot present supportive epidemiological studies, a court will exclude his or her scientific testimony under \textit{Daubert v. Merrell Dow Pharmaceuticals, Inc.},\textsuperscript{21} effectively ending the case.

This Note therefore proposes a modest change to the courts’ use of \textit{Daubert}: relax the almost-categorical rejection of epidemiological-study reanalyses in toxic tort litigation. This proposal is warranted for three reasons. First, rejection is premised on overly simplistic assumptions about the import of publication and an underappreciation for science as a process.\textsuperscript{22} Second, there are valid reasons why on-point, published epidemiological studies may not exist, unrelated to the absence of actual causation.\textsuperscript{23} Third, epidemiological-study reanalyses may play a supporting role in an expert’s causation opinion, consistent with the weight-of-the-evidence methodology germane to scientific analysis.\textsuperscript{24} Furthermore, this proposal does not unduly deprive defendants of their ability to mount a defense, as existing evidentiary and procedural

\textsuperscript{15} See \textit{id.}

\textsuperscript{16} This Note does not address the ethical or moral arguments that the interests of social justice are likely better served when the legal system prioritizes reducing the number of Truly Deserving Victims.


\textsuperscript{18} See discussion \textit{infra} Part I. Epistemology is “[t]he theory or science of the method or grounds of knowledge.” \textit{OXFORD ENGLISH DICTIONARY} (2d ed. 1989).

\textsuperscript{19} See discussion \textit{infra} Part II.

\textsuperscript{20} See discussion \textit{infra} Part III.

\textsuperscript{21} 509 U.S. 579 (1993).

\textsuperscript{22} See discussion \textit{infra} Part IV.A.1.

\textsuperscript{23} See discussion \textit{infra} Part IV.A.2.

\textsuperscript{24} See discussion \textit{infra} Part IV.A.3.
protections remain available to guard against spurious reanalyses. This Note concludes by illustrating that *Milward v. Acuity Specialty Products Group, Inc.*, a recent First Circuit decision, implicitly recognizes the propriety of such a proposal.

I. THE “SHOTGUN MARRIAGE” OF LAW AND SCIENCE

A. Law Versus Science

Law and science share some similar objectives and methods and ultimately seek the same general outcome: rational conclusions free of prejudice and self-interest. However, the two disciplines differ in important ways that color any discussion of using scientific evidence in legal proceedings. Law’s primary objective, in theory, is justice. The legal process seeks a specific conclusion—the final resolution of an individualized controversy within a limited time period. Conversely, the objective of science is truth. The scientific process aims to advance society’s understanding of the way the world works through sound methodology, without a selective bias for specific conclusions. Accordingly, while scientific research may be directed at answering questions with pressing societal import, “[i]n the scientific search
for truth there are no time limits and no point at which a final decision must be made.”36

Law and science also treat facts differently. Law is concerned with finding “facts” only to the extent this facilitates the efficient adjudication of controversies.37 Law is generally backward looking38 and therefore the “facts” in law are rarely replicated.39 Conversely, science is focused on, as far as possible, “getting the ‘facts’ right.”40 Science is forward looking, as the “hallmark and guarantor of scientific acceptability” is replication.41

These differences ultimately influence how the lawyer and the scientist use scientific information. In litigation, the lawyer reveals and characterizes evidence narrowly to fit a favorable conclusion for the client and attempts to minimize (or avoid disclosing) weaknesses or alternative explanations.42 Conversely, the scientist probes evidence’s strengths and weaknesses and directly addresses opposing interpretations or explanations.43

36. Goodstein, supra note 28, at 81. However, scientists might feel compelled to generate results and conclusions as quickly as possible in order to answer important questions or to compete for limited resources. See, e.g., Joseph Ben-David & Teresa A. Sullivan, Sociology of Science, 1 ANN. REV. OF SOC. 203, 206 (1975) (highlighting “the apparent contradiction between the norm of communality which requires scientists to publish their results and regard them as the property of mankind, and their sensitivity and frequent selfishness concerning priority in discovery”); infra note 250.


38. Loevinger, supra note 30, at 328. This is not to say that law cannot have forward-looking impacts; indeed, some scholars and judges have considered these impacts desirable. See Richard Markovits, Liberalism and Tort Law: On the Content of the Corrective-Justice-Securing Tort Law of a Liberal, Rights-Based Society, 2006 U. ILL. L. REV. 243, 293 (noting several contemporary law professors and judges who “maintain that judges should decide cases to promote various . . . goals—i.e., should operate as goal-oriented social engineers”).

39. Bloembergen Amicus Brief, supra note 32, at 15–16 (noting that “the facts to be proved in the legal process arise out of situations that occurred in the past” so that “[t]he legal process rarely has the luxury of being able to repeat experimentally a disputed chain of causation to corroborate the proffered hypothesis, even if, in some cases, it might theoretically be possible”).

40. JASANOFF, supra note 37, at 9. Science takes specific data and creates and verifies general theories based on these data. See Loevinger, supra note 30, at 328.

41. Loevinger, supra note 30, at 328. Science is also forward looking in the sense that the formal organizations that support science—for example, universities, institutes, governments, and firms—can target research efforts and funds “mainly in the expectation of [future] economic [or societal] benefit.” Ben-David & Sullivan, supra note 36, at 210.

42. See Kritzer, supra note 31, at 50. Ultimately, the jury then weighs the evidence introduced by all parties to reach its judgment. The process of weighing individual pieces of evidence is analogous in many respects to the scientific process. See Sheldon Krimsky, The Weight of Scientific Evidence in Policy and Law, 95 AM. J. PUB. HEALTH S129, S131 (2005); see also discussion infra Part IV.A.3.

43. See Kritzer, supra note 31, at 50.
B. Science, “Sound Science,” and “Junk Science”

Fundamentally, science is a process and not an “encyclopedic body of knowledge about the universe.”44 Scientists propose and collectively refine explanations about the world, revising these explanations as new information comes to light.45 The scientific community accepts explanations “corroborated by experiments using accepted methodologies” that are “consistent with other accepted explanations.”46 Therefore, science is not simply observation but the explanation and clarification of relationships.47 “Valid science” represents a “convergence of well reasoned explanation with supporting observations or experimental results.”48

There is no “simple recipe” for science, although some generalizations are possible.49 It begins with a hypothesis—an educated guess.50 For a hypothesis to survive, it must be internally consistent, have explanatory value, and accurately predict observed results.51 Scientists test hypotheses through rigorous and continuous experimentation, attempting to prove it false.52 While it can never be proven to be true, with sufficient corroboration and consistency, a hypothesis may be recognized as generally valid.53 A generally valid hypothesis may become a scientific law or theory.54

Ultimately, science is a delicate dance of creativity and conservatism. Science is creative because it only advances when researchers propose and test new ideas.55 It is conservative because it is cumulative—it advances by building on past research—but continually seeks to shed false ideas.56 Importantly, there is no bright line between these qualities that easily “divides

45. Id. at 7–8; see also Loevinger, supra note 30, at 327 (explaining that “scientific statements or theories are never finally established and are always subject to revision or rejection” and that “this is true of such basic scientific theories as general relativity, quantum mechanics, and the Big Bang”).
46. Amicus Brief of AAAS and NAS, supra note 44, at 8.
47. Id. at 9.
48. Id.
49. Id. at 8.
50. Id.
51. Id.
52. Id. at 9; see also Bloemergen Amicus Brief, supra note 32, at 14 (stating that a “hypothesis can be falsified or disproved, but cannot, ultimately, be proven true because knowledge is always incomplete”).
53. Amicus Brief of AAAS and NAS, supra note 44, at 9.
54. Id. Scientific “laws are descriptive statements of relationships among observable phenomena,” and scientific “[t]heories, by contrast, are inferred explanations for observable phenomena or regularities in those phenomena.” Norm G. Lederman et al., Views of Nature of Science Questionnaire: Toward Valid and Meaningful Assessment of Learners’ Conceptions of Nature of Science, 39 J. OF RES. IN SCI. TEACHING 497, 500 (2002).
55. Amicus Brief of AAAS and NAS, supra note 44, at 7.
56. Id.
science, almost-science, and pseudo-science.”
Disagreement about an idea, without its subsequent rejection, does not represent a failure of science. Indeed, the freedom to disagree—really, the necessity of disagreement—is one of its strengths.

Despite the reality of science-as-process, the public perception of science is often more rigid and definitive. This restrictive conception means ongoing debate about a scientific finding leaves it vulnerable to public criticism that it has not yet ripened into so-called “sound science.” As a result, critics often employ the terms “sound science” and “junk science” to advance particular interests by framing a scientific conclusion as something either worth believing or not.

The “sound science” movement divides and characterizes evidence, sometimes dismissing it based on this characterization. Demanding this rigid view of sound science could potentially raise the evidentiary bar so high as to preclude prophylactic measures in regulation or liability in litigation. This result aligns with the interests of “sound science” proponents—typically members of industry—desiring less stringent regulation and reduced liability exposure. The “sound science” movement effectually characterizes findings to achieve a particular outcome, which seems difficult to distinguish from the adversarial use of facts in legal disputes. Indeed, although not always framed using these terms, the spirit of the “sound science”/”junk science” divide haunts the use of scientific evidence in legal proceedings.

58. See id.
59. See id.
61. Id.
62. “Junk science” is a characterization meant to seize upon the public perception of science-encyclopedic in order to cast doubt on unfavorable claims against an entity or industry. Thomas McGarity, Our Science Is Sound Science and Their Science Is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-producing Products and Activities, 52 U. Kan. L. Rev. 897, 901 (2004) (arguing that “[s]tripped of their rhetorical flourish, ‘junk science’ means ‘their science,’ and ‘sound science’ means ‘our science’”). The term “junk science” is generally credited to Peter Huber. See Huber, supra note 4, at 2 (maintaining that “[t]he pursuit of truth, the whole truth, and nothing but the truth has given way to reams of meaningless data, fearful speculation, and fantastic conjecture” and consequently “[c]ourts resound with elaborate, systematized, jargon-filled, serious-sounding deceptions that fully deserve the contemptuous label used by trial lawyers themselves: junk science” (footnote omitted)).
63. See Doremus et al., supra note 60, at 7-505.
65. See id.
66. See McGarity, supra note 62, at 901.
67. Cf. id. (describing “[b]oth the demand for ‘sound science’... and the call for the elimination of ‘junk science’... [as] artfully framed appeals to scientific objectivity that carefully avoid the appearance of self-interest” (footnote omitted)).
C. Science in the Courtroom: Frye, Daubert, and Why It Matters

“Law lags science; it does not lead it.”68 With the distinct paradigms of law and science in play, courts and commentators have long struggled with getting them to “play nice.” Many have expressed serious doubts about the possibility of reconciliation.69 However, in many areas of civil litigation, like toxic torts, using scientific testimony is unavoidable,70 and expert testimony provides little real insight unless it is reliable.71 Accordingly, the judiciary has grappled with defining standards for admitting scientific testimony into the courtroom. The widely held belief that jurors are unsophisticated and susceptible to the “mystic infallibility”72 they purportedly ascribe to science has historically led to a conservative approach to judicial admission of scientific testimony.73

The “general acceptance” standard outlined in Frye v. United States74 held sway for decades until Daubert v. Merrell Dow Pharmaceuticals, Inc. overruled it in 1993.75 Under the Frye standard, scientific testimony could not be admitted unless it had “gained . . . standing and scientific recognition,” or general acceptance, in the relevant scientific community.76 A number of states continue to employ the Frye standard.77

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74. 293 F. 1013, 1014 (D.C. Cir. 1923). The famous passage from Frye reads:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.

Id. (emphasis added).
76. Frye, 293 F. at 1014.
Daubert held that Federal Rule of Evidence 702—which governs the admissibility of expert testimony—overruled the Frye standard. Importantly, Daubert compels the trial court to serve as the “gatekeeper” to ensure all proffered scientific testimony is both relevant and reliable. The relevancy inquiry asks whether the scientific testimony is tied closely enough to the case’s facts to be helpful in resolving a factual dispute. The reliability inquiry is much more challenging. It asks whether scientific testimony is “ground[ed] in the methods and procedures of science.” To assist in this inquiry, Daubert outlined a nonexhaustive four-factor analysis. Per Daubert, the trial court should examine whether the reasoning or methodology underlying the scientific testimony (1) has been tested, (2) has been peer reviewed or published, (3) has “a known or potential rate of error,” and (4) has been accepted within the general discipline. However, these four factors are neither necessary nor sufficient. The essence of the reliability requirement is to ensure “an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”

Broadly, then, Daubert requires courts to focus on methodology, not an expert’s conclusions. As long as expert testimony rests on “good grounds,” it should be admitted for the jury to consider. However, the judicial presumption to admit an expert’s conclusions is not absolute; it ends where the

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78. The rule states:
If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

FED. R. EVID. 702.
79. Daubert, 509 U.S. at 589.
80. Id. at 590, 597.
81. Id. at 591.
83. See Daubert, 509 U.S. at 593–94.
84. Id. At least two scholars have suggested that the “Supreme Court did not know exactly what to do with the ‘known or potential rate of error’ factor” and actually mislabeled it. Mark Haug & Emily Baird, Finding the Error in Daubert, 62 HASTINGS L.J. 737, 741 (2011) (noting, however, the factor does have a “strong whiff of the ‘stuff’ of science”). The “known or potential rate of error factor” is also misleading considering error is endemic to the scientific endeavor. Id. at 751, 753.
85. Kumho Tire, 526 U.S. at 141.
86. Id. at 152 (emphasis added).
87. See Daubert, 509 U.S. at 593–94.
88. Id. at 590, 596.
methodology, data, and conclusions are connected “only by the ipse dixit of the expert.”89

Commentators have extensively debated the import of Daubert versus Frye.90 Daubert’s primary legacy may not be doctrinal. According to a leading treatise, “relatively few toxic tort case admissibility rulings actually turn on the difference between Daubert and Frye.”91 Empirical analyses are consistent with this conclusion.92 Rather, Daubert seems to have emboldened lawyers and courts to scrutinize scientific testimony more closely.93 Since Daubert, lawyers have been more likely to seek exclusion of expert testimony,94 judges have been less likely to admit expert testimony,95 and judges have granted more summary judgment motions (most against plaintiffs).96 In other words, post-Daubert plaintiffs face greater scrutiny at several litigation stages when relying on expert testimony.

II. LAW AND SCIENCE IN TOXIC TORT LITIGATION

A. The Law of Toxic Torts

1. Torts and the Issue of Causation

The “essence” of tort is that “a person should be subject to liability for carelessly causing harm to another.”97 An action in tort for damages determines whether to transfer money from the defendant to the plaintiff.98 To effectuate a transfer, the plaintiff must prove, among other things, that it is more likely than

93. See, e.g., McGeary, supra note 66, at 909 (arguing that after Daubert, the Supreme Court left hardly “any doubt” that “lower courts were to exercise their gatekeeper roles aggressively to screen out anything that smacked of ‘junk science’”).
95. Id. at 15.
96. DIXON & GILL, supra note 92, at xvi.
98. See, e.g., Wright v. Willamette Indus., Inc., 91 F.3d 1105, 1107 (8th Cir. 1996).
not that the defendant caused his or her harm.99 Here, causation encompasses cause-in-fact and proximate cause.100 These two distinct requirements are often folded “uncomfortably together” and termed, simply, “causation.”101

Cause-in-fact describes the “actual connection” between a defendant’s actions and a plaintiff’s injury.102 In most cases, cause-in-fact is considered easier to satisfy than proximate cause and is not genuinely in dispute.103 For example, a cause-and-effect relationship is “obvious” where “A’s vehicle strikes B, injuring him; a bottle of A’s product explodes, injuring B; [or] water impounded on A’s property flows onto B’s land, causing immediate damage.”104

Proximate cause presupposes cause-in-fact and asks whether—in “logic, fairness, policy, and practicality”—the defendant should still be liable to the plaintiff.105 In other words, proximate cause determines whether the defendant’s actions and the plaintiff’s injury are “too remote” from one another.106 Proximate cause generally is the “more elusive concept”107 because it is “little more than a swirling maelstrom of policy, practicality, and case-specific fairness considerations.”108

2. The Special Challenge of Proving Causation in Toxic Torts

Toxic torts are unique in comparison to most tort actions. Toxic torts are a subset of products liability law.109 Products liability concerns the “set of rules governing a product seller’s legal responsibility for harms caused by his products.”110 A toxic tort is “any injury attributable to exposure to a toxic

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99. Id. In order to recover, a plaintiff in tort must prove duty, breach, cause-in-fact, proximate cause, and harm. Owen, supra note 97, at 1686.


101. Owen, supra note 97, at 1673.

102. Id. at 1680.

103. Eggen, supra note 100, at 895.


105. Owen, supra note 97, at 1681.

106. Id. at 1671.

107. Eggen, supra note 100, at 895.

108. Owen, supra note 97, at 1682.


substance where injury is not immediately manifest.” 111 This latency—the lag between injurious exposure to the product (the toxic substance) and the injury’s manifestation—is the sine qua non of toxic torts.112

Toxic torts arise in a variety of exposure contexts, including occupational, environmental, and consumer products.113 Occupational exposures take place at work and result from producing the toxic substance, fabricating products that contain the toxic substance, or otherwise working with the toxic substance.114 Environmental exposures occur outside of work and result from public contact with contamination via air, water, or land.115 Consumer product exposures involve harm caused by a manufacturer’s product introduced into the marketplace for consumer use.116 Given the ubiquitous presence of many toxic substances in our lives today, a single substance may give rise to all three exposure types.117

Due to the delay between exposure and the recognition of harm, toxic torts invert the causation difficulties germane to most tort actions. In contrast to the relative ease with which a plaintiff can establish cause-in-fact in most tort actions, cause-in-fact becomes the paramount controversy in toxic torts.118 Conversely, proximate cause carries minimal significance in toxic torts.119

A toxic-tort plaintiff must prove factual causation in two ways. First, a plaintiff must demonstrate general causation—that the toxic substance is generally capable of causing the injury in question.120 This form of proof is “all-or-nothing” (either the toxic substance is capable of causing the injury in question or not).121 Second, a plaintiff must prove specific causation—that the toxic substance caused the specific injury at issue in the litigation.122 Given that the inability to prove general causation renders moot any specific-causation inquiry, the failure to prove general causation is “often fatal” to toxic tort

111. Schwartz & Means, supra note 110, at 1094.
112. See id.
113. Id.
114. Id.
115. Id. at 1096.
116. Id. at 1097. 
117. See id. at 1094 n.26.
118. See Eggen, supra note 100, at 896.
119. Danielle Conway-Jones, Factual Causation in Toxic Tort Litigation: A Philosophical View of Proof and Certainty in Uncertain Disciplines, 35 U. RICH. L. REV. 875, 887–88 (2002). The use of proximate cause in traditional tort actions—a means “to contract or extend the liability of an actor . . . to achieve the tort goals of corrective justice, deterrence, or compensation”—is accepted because cause-in-fact is often certain. See id. at 887, 892 n.78. On the other hand, the use of proximate cause is generally “absent or eroded” in the toxic tort context because cause-in-fact remains uncertain. Id. at 888, 892 n.78. Indeed, one scholar has noted that cause-in-fact in toxic torts “has eclipsed the public policy and social justice principles embedded in proximate causation.” Id. at 888.
121. Gerald Boston, A Mass-exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience, 18 COLUM. J. ENVTL. L. 181, 202–03 (1993) (stating that “resolution tends to be all-or-nothing, at least in a scientific sense—either Bendectin is capable of causing birth defects or it is not; either cigarette smoking is capable of causing lung cancer or it is not; either DES is capable of causing vaginal adenocarcinoma or it is not”).
122. Bernstein, supra note 120, at 52.
causation becomes a complex and highly contested issue involving extensive use of expert witnesses to proffer scientific causation opinions.\textsuperscript{124} The challenges associated with general and specific causation in toxic torts are legion.\textsuperscript{125} First, the scientific evidence needed to support causation may be uncertain or nonexistent.\textsuperscript{126} For example, evidence to establish general causation for a particular type of cancer may be inconclusive or associational at best, and a specific plaintiff has no way to “reverse engineer” general causation through clinical evidence of his or her injury.\textsuperscript{127}

Second, toxic torts often involve injuries that are also found in the nonexposed general population, increasing the indeterminacy of specific causation.\textsuperscript{128} For example, asbestos exposure can lead to asbestosis, mesothelioma, lung cancer, and pleural plaques.\textsuperscript{129} Asbestosis and mesothelioma are “signature diseases”—“rare diseases associated with exposure to a particular [toxic] substance that rarely occur in the non-exposed population”—of asbestos exposure.\textsuperscript{130} However, lung cancer is not—other toxic substances, including common substances like tobacco smoke, can also cause it.\textsuperscript{131}

Third, a long latency period—several decades for some substances, such as asbestos\textsuperscript{132}—can make identifying a toxic substance’s manufacturer difficult, if not impossible.\textsuperscript{133} For example, by the early 1980s, various manufacturers in different geographic locations had produced more than 3000 types of asbestos-containing products.\textsuperscript{134} Each product poses unique risks based on the probability it will release asbestos fibers,\textsuperscript{135} and different types of

\begin{thebibliography}{99}
\bibitem{123} Eggen, \textit{supra} note 100, at 896. Toxic torts “are won or lost on the strength of the scientific evidence presented to prove causation.” Rider v. Sandoz Pharm. Corp., 295 F.3d 1194, 1197 (11th Cir. 2002).
\bibitem{124} See Bert Black & David Lilienfeld, \textit{Epidemiologic Proof in Toxic Tort Litigation}, 52 \textit{FORDHAM L. REV.} 732, 738 (1984); Amicus Brief of AAAS and NAS, \textit{supra} note 44, at 6 (explaining that because “in a toxic tort case, science can provide unique insights into the likelihood that exposure to a certain chemical caused the injury at issue . . . [expert witness] testimony may provide the sole foundation for determining whether a plaintiff can satisfy a causation requirement” (emphasis added)).
\bibitem{125} \textit{Cf.} Eggen, \textit{supra} note 100, at 896–97 (“Nowhere has the bifurcation of the standard of causation proof between general causation, based on probabilities, and specific causation, based on individualized factual connections, been as pronounced as it is in the toxic tort case.”).
\bibitem{126} See id. at 890.
\bibitem{127} See id. at 896.
\bibitem{128} See id. at 890.
\bibitem{129} Katherine O’Reilly et al., \textit{Asbestos-Related Lung Disease}, 75 \textit{AM. FAM. PHYSICIAN} 683, 684 tbl.1 (2007).
\bibitem{130} Boston, \textit{supra} note 121, at 203.
\bibitem{131} See id. at 197.
\bibitem{132} See Schwartz & Means, \textit{supra} note 110, at 1095 n.31.
\bibitem{133} Eggen, \textit{supra} note 100, at 890; Schwartz & Means, \textit{supra} note 110, at 1097.
\bibitem{135} \textit{Id.}
\end{thebibliography}
asbestos fibers present different risks. Even when product-level ambiguities can be avoided because the toxic substance at issue is narrowly defined and chemically unique, a long latency period is likely to compromise the victim’s memory and manufacturers’ records to such an extent that failure to identify the specific manufacturer (assuming the actual manufacturer is still in business) might limit or preclude recovery.

B. The Science of Toxic Torts

To establish or refute a causal link between exposure to a toxic substance and an alleged injury, an expert witness may provide different types of scientific evidence in a causation opinion. Scientific evidence related to causation may be broadly classified as a human-based study, a non-human-based study, or some other type of evidence. Each class of evidence has benefits and limitations.

1. Human-Based Studies

Human-based studies include randomized clinical trials, epidemiological studies, and case reports. Randomized clinical trials randomly assign a set of individuals to one of two groups: one group exposed to the substance in question, and one nonexposed (control) group. After a sufficient period of time has passed, researchers evaluate study participants for the development of any effects. Done correctly, randomized clinical trials are considered the “gold standard” for determining the relationship between exposure and injury. However, ethical considerations—knowingly exposing humans to substances suspected to be harmful—limit their use for potentially toxic substances. Therefore, randomized clinical trials are generally limited to substances considered to be beneficial to human beings.

Epidemiology is the statistical study of disease determinants within human populations. Epidemiologists use statistics to look for unusually high disease incidence within segments of a study population and, more broadly, to determine whether disease incidence correlates with specific potential risk factors.

137. See Kircher, supra note 134, at 1123.
138. See CRANOR, supra note 3, at 94.
139. See id. at 95.
141. Id.
142. Id.
144. Green et al., supra note 140, at 338.
145. Boston, supra note 121, at 213.
Of particular interest in toxic tort litigation, an epidemiologist compares a population subgroup exposed to a specific substance with a subgroup similar in as many respects as feasible that lacks this exposure. Data may be derived from surveys, death certificates, or clinical and medical observations. Well-designed epidemiological studies that corroborate other scientific causation evidence provide the strongest support for causation. But in order to cross the line from an association/correlation to scientific causation, one needs more than just statistical evidence.

Case reports describe clinical events involving one or a few individuals. They can help identify potentially toxic substances for further controlled study. However, standing alone, case reports provide the weakest support for causation of all human-based studies because they consist of anecdotal evidence without reference to a control group.

2. Non-Human-Based Studies

Non-human-based studies include in vivo and in vitro studies. In vivo studies commonly entail exposing animals—usually rats or mice—to a potentially toxic substance in order to observe its effects. The benefits of in vivo studies are numerous. For example, researchers can tightly control exposure as well as the non-exposure dimensions of the subject animals’ lives, ethical limitations are less of a concern, and postexperimental dissection and tissue analysis may reveal additional information. However, in vivo studies have two significant drawbacks that affect their probative value in toxic tort litigation. First, extrapolating from animals to humans may not always be possible or may be based on inaccurate assumptions. Second, the high dosages given to animals to induce effects may not be comparable to those

147. See Green et al., supra note 140, at 339.
148. Dore, supra note 146, at 431.
152. See id. at 474.
153. Id. at 232.
154. Id. at 203.
155. Id. at 218.
156. See Green et al., supra note 140, at 345.
157. Id. at 346. Some scholars consider the criticism of extrapolation myopic. See Haug & Baird, supra note 84, at 753 (noting the criticism “often draws attention to the differences between the animal and the human—the sole source of bias in a well-designed animal study—while largely ignoring the many biases attendant to the alternative”).
involved in occupational, environmental, or consumer-product exposures to humans.158

In vitro studies involve exposing cells, bacteria, tissues or organs to a toxic substance in order to observe biochemical effects.159 The primary benefits of in vitro studies are that they can be carried out relatively rapidly and cheaply, and they do not generally implicate serious ethical concerns.160 However, their probative value in toxic tort litigation has been questioned based on the inferential leap required to apply isolated-tissue-derived findings to human beings.161

3. Other Types of Evidence

Other evidence with relevance to causation includes structure-activity relationships and genetic data.162 Structure-activity relationships recognize that a substance’s chemical structure may be related to its biological effects.163 Certain structures regularly appear in potentially toxic substances.164 Industry and regulatory agencies alike regularly use structure-activity relationships to identify potentially toxic substances.165 But structure-activity relationships are merely qualitative and therefore garner limited judicial appreciation.166

The field of toxicogenomics analyzes the genetic predisposition for harm and whether exposure to a substance can modify genetic material to induce harmful effects.167 Molecular epidemiology translates these genetic modifications to disease incidence in human populations.168 Some have extolled toxicogenomics as heralding “a new era of certainty” in understanding exposures and harmful effects.169 However, limitations on its utility include the field’s emerging nature, the astounding complexity of the human genome, and

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158. See Green et al., supra note 140, at 346.
159. Boston, supra note 121, at 218.
160. See id. at 220. However, the stem-cell debate is a salient example of an ethical controversy surrounding in vitro research. See Melissa Little, Wayne Hall & Amy Orlandi, Delivering on the Promise of Human Stem-Cell Research: What Are the Real Barriers?, 7 EMBO REP. 1188, 1188 (2006).
161. See Green et al., supra note 140, at 339; see also, e.g., Wade-Greaux v. Whitehall Labs., Inc., 874 F. Supp. 1441, 1480 (D.V.I. 1994), aff’d, 46 F.3d 1120 (3d Cir. 1994) (finding that “the notion that one can accurately extrapolate from [in vivo and in vitro studies] to humans to prove causation without supportive positive epidemiologic studies is scientifically invalid because it is inconsistent with several universally accepted and tested scientific principles”).
162. Cranor, supra note 3, at 111.
163. Id.
164. Id.
165. Id.
166. See id. at 112.
168. Id. at 390.
169. See id. at 369.
the wide variety of potential genomic interactions with the human environment.\footnote{170}

\section*{III. EPIDEMIOLOGY AND ITS REANALYSIS}

\subsection*{A. Epidemiological Studies in the Courtroom}

Epidemiological studies have played a starring role in a litany of toxic tort litigation regarding asbestos, Bendectin, benzene, electromagnetic radiation, silicone breast implants, tobacco, and many other substances.\footnote{171} However, they serve as a “two-edged sword” for the toxic-tort plaintiff.\footnote{172} If on-point epidemiological studies demonstrate an association between exposure and the type of injury suffered by a plaintiff, the plaintiff can rely on this evidence to establish general causation.\footnote{173} Conversely, if such studies are lacking or fail to find a clear association, then establishing causation (and therefore obtaining recourse) can be exceedingly difficult for the toxic-tort victim.\footnote{174}

Courts have consistently expressed a preference for epidemiological studies as proof of causation.\footnote{175} This widespread preference is premised on the belief that epidemiological studies minimize systematic biases in the available scientific data.\footnote{176} For example, the preference for epidemiology over animal studies exists because “uncertainty stemming from interspecies extrapolation is far larger than the uncertainty resulting from uncontrolled bias or errors in exposure information in epidemiological studies.”\footnote{177} However, few courts have outright mandated the use of epidemiological evidence to prove causation.\footnote{178}

When multiple epidemiological studies exist but fail to demonstrate general causation, courts may be unwilling to entertain nonepidemiological

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\begin{itemize}
\item \footnote{170}{\textit{See id.} at 370, 396. Complicating factors include the sheer “numbers of exposures to different chemicals, radiation, viruses, and particles; numbers of genes involved in the pathway to disease; numbers of polymorphisms at each gene; numbers of epigenetic factors; [and] numbers of different manifestations of disease.” \textit{Id.} at 396.}
\item \footnote{171}{\textit{See FAIGMAN ET AL., supra note 91, § 23:1.}}
\item \footnote{172}{\textit{Id.}}
\item \footnote{173}{\textit{See id.}}
\item \footnote{174}{\textit{See id.}}
\item \footnote{175}{\textit{See, e.g., In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998), aff’d, 289 F.3d 1193 (10th Cir. 2002) (stating that “[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” (citation omitted)); Raynor v. Merrell Pharm. Inc., 104 F.3d 1371, 1375 (D.C. Cir. 1997) (asserting that “where sound epidemiological studies produce opposite results from nonepidemiological ones, the rate of error of the latter is likely to be quite high”); Brock v. Merrell Dow Pharm., Inc., 874 F.2d 307, 311 (5th Cir. 1989) (maintaining that epidemiological studies are, “[u]ndoubtedly, the most useful and conclusive type of evidence”).}}
\item \footnote{176}{\textit{FAIGMAN ET AL., supra note 91, § 23:1.}}
\item \footnote{177}{\textit{Irv Hertz-Picciotto, \textit{Epidemiology and Quantitative Risk Assessment: A Bridge from Science to Policy,} 85 AM. J. PUB. HEALTH 484, 485 (1995).}}
\item \footnote{178}{\textit{See In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 800–01 (N.D. Ohio 2004) (discussing pre- and post-Daubert cases that declined to recognize a judicial mandate for epidemiological studies).}}
\end{itemize}
causation evidence. For example, in *Brock v. Merrell Dow Pharmaceuticals, Inc.*, the court held that animal-based studies concluding Bendectin caused birth defects were insufficient to prove general causation because several available epidemiological studies failed to demonstrate a correlation. Similarly, in *Lynch v. Merrell-National Laboratories, Division of Richardson-Merrell, Inc.*, the court held that animal-based studies in combination with structure-activity evidence could not overcome the fact that the available epidemiological studies had failed to find an association.

However, courts are sometimes willing to relax their preference in scenarios where little to no epidemiological evidence is available. Indeed, at least one court has recognized the injustice of barring recovery to individuals harmed during the time period after a product’s marketplace entrance but before cultivation of epidemiological evidence. Some courts have even been willing to relax the preference when the available epidemiological studies fail to find an association but are limited in number. To be sure, some alternative source of scientific causation evidence is needed if epidemiological studies are not (or cannot be) used.

### B. Reanalysis of Epidemiological Studies

Reanalysis occurs “when a person other than the original investigator obtains an epidemiologic data set and conducts analyses to evaluate the quality, reliability or validity of the dataset, methods, results or conclusions reported by

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179. FAIGMAN ET AL., *supra* note 91, § 23:1; see, e.g., Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005). The Norris court stated:

We are not holding that epidemiological studies are always necessary in a toxic tort case. We are simply holding that where there is a large body of contrary epidemiological evidence, it is necessary to at least address it with evidence that is based on medically reliable and scientifically valid methodology.

*Id.*

180. 874 F.2d 307 (5th Cir. 1989).


182. 830 F.2d 1190 (5th Cir. 1987).

183. *See id.* at 1194–97.


185. *See Bloomquist v. Wapello Cnty*, 500 N.W.2d 1, 5 (Iowa 1993). The Third Restatement of Torts also recognizes and discusses the potential for this injustice. *RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL HARM* § 28, cmt. c, subsec. (3) (Proposed Final Draft May 2005) (explaining that “[a]s a consequence of the [long latency period], some plaintiffs may be forced to litigate long before epidemiologic research is available”).


187. FAIGMAN ET AL., *supra* note 91, § 23:1; see, e.g., Ashburn v. Gen. Nutrition Ctrs., Inc., 533 F. Supp. 2d 770, 774–75 (N.D. Ohio 2008) (excluding plaintiff’s scientific testimony because, although epidemiological evidence was not required, “other types of evidence upon which plaintiff might reasonably rely [were] equally absent”).
the original investigator.” 188 Today, the practice is fairly common in science and litigation, and its use is expected to increase going forward. 189

There is nothing inappropriate per se about reanalysis. 190 It enables further use of preexisting data, refines prior results and interpretations based on accumulated knowledge, and potentially helps ferret out errors and inaccuracies in data and prior interpretations. 191 But because reanalysis is a process that, by definition, might modify the conclusions of an original study, when done in the context of litigation, it engenders (and, perhaps, warrants) considerable skepticism. 192 Further, it can have a chilling effect on research affecting well-funded stakeholders by imposing burdens on the original authors. 193

Notably, epidemiological-study reanalysis is treated differently inside and outside of the courtroom.

1. Courtroom Treatment of Reanalysis

Plaintiffs in toxic tort litigation often turn to reanalysis when, although their claim is supported by other types of evidence, they face difficulties proving causation because existing epidemiological studies do not indicate an association between the type of harm suffered by the plaintiff and the potentially toxic substance at issue. 194 Plaintiffs must respond to unfavorable epidemiological studies and often attempt to do so through reanalysis. 195

However, courts have not been very receptive to the practice. Reanalyses devoid of methodological explanation are rightfully ripe for rejection. 196 However, courts often reject even seemingly transparent reanalyses—if not peer reviewed or published—produced during, or in anticipation of,
litigation.\(^{197}\) According to the Ninth Circuit’s opinion in *Daubert* on remand, a plaintiff employing a reanalysis “must come forward with other objective, verifiable evidence that the testimony is based on ‘scientifically valid principles.’”\(^{198}\)

Given the limited, extraordinary scenarios in which courts have so far admitted an expert’s causation opinion containing reanalyses, adequate “other objective, verifiable evidence” is apparently out of reach for most plaintiffs. For example, in *Ruff v. Ensign-Bickford Industries, Inc.*,\(^{199}\) the court allowed the plaintiffs’ expert to reanalyze a study by grouping together two previously distinct cancer outcomes to generate a statistically significant result.\(^{200}\) However, the court’s decision to admit this evidence relied on the fact that the expert had proposed the same reanalysis method in a prelitigation publication.\(^{201}\) Notably, the court in *Ambrosini v. Labarraque*\(^{202}\) admitted an expert’s unpublished reanalysis, reasoning that, since the litigation concerned a banned product, failure to publish should not be determinative because the product was of limited future interest (and, therefore, unlikely to be the subject of further study or publication).\(^{203}\)

2. Treatment of Reanalysis Outside the Courtroom

While reanalysis may not be widely accepted in toxic tort litigation, it is a common practice in the context of regulation, often advanced by stakeholders seeking to influence new regulatory efforts.\(^{204}\) Parties for whom the results of existing studies have negative implications have strong incentives to closely scrutinize these studies.\(^{205}\) Published reanalyses emerging in this context have included industry reanalyses of government studies on the effects of beryllium, chromium, and benzene.\(^{206}\) Each of these industry reanalyses suggested that the unfavorable conclusions of prior studies were overstated or nonexistent.\(^{207}\) A company certainly has the right to vindicate its interests against regulation and litigation based on weak evidence, but there is no bright line separating

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\(^{197}\) See, e.g., *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317–18 (9th Cir. 1995) (rejecting a reanalysis because it had not been subject to peer review or publication and was produced for litigation); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936, 945 (D. Minn. 2009); *Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706, 726–27 (Tex. 1997).

\(^{198}\) *Daubert*, 43 F.3d at 1318.


\(^{200}\) *Id.* at 1284–87.

\(^{201}\) *Id.* at 1285.

\(^{202}\) 101 F.3d 129 (D.C. Cir. 1996).

\(^{203}\) See *id.* at 135–37 (quoting *Daubert v. Merrell Dow Pharm.*, Inc., 509 U.S. 579, 593 (1993)).

\(^{204}\) Neutra et al., *supra* note 188, at 335.

\(^{205}\) *Id.*

\(^{206}\) *Id.*

\(^{207}\) *Id.*
legitimate vindication from bad-faith criticism undertaken purely to support a certain posture in regulation or litigation.208

A famous example of reanalysis done right involved the “Harvard Six Cities Study,”209 a sixteen-year study linking exposure to airborne particulate matter with lung cancer and cardiopulmonary disease.210 The study played a critical role in supporting the creation of a national ambient air quality standard pursuant to the Clean Air Act211 for particulate matter having a diameter of 2.5 micrometers or less (PM$_{2.5}$).212 Due to the large projected economic impact of a PM$_{2.5}$ standard, industry representatives and members of Congress urged the original investigators to produce the underlying data for reanalysis.213 The Health Effects Institute organized an independent reanalysis conducted by leading experts in epidemiology, exposure assessment, biostatistics, public health, and medicine, which confirmed the original data’s quality and the original conclusions’ validity.214

Some reanalyses have sparked significant controversy. For example, in 1987, Dr. Zhang JianDong published a study associating elevated cancer rates in Jinzhou, China with the discharge of 300,000 tons of effluent containing hexavalent chromium into the local groundwater supply.215 A California community used the study as evidence in litigation against Pacific Gas & Electric Co. (PG&E), a large user of hexavalent chromium.216 In a 1997 reanalysis, later revealed to have been instigated by PG&E, Dr. Zhang appeared to backtrack on his earlier findings.217 Whether Dr. Zhang was ever given the chance to read a final version of the reanalysis prior to publication is unclear.218 However, several U.S. agencies cited it in abandoning their efforts

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208. See Neil Pierce, Corporate Influences on Epidemiology, 37 Int’l J. Epidemiology 46, 49 (2008).
210. Id. at 1753; Neutra et al., supra note 188, at 336.
213. Id.
214. Id. at 341.
216. Egilman, supra note 215, at 171. This litigation was featured in the film Erin Brockovich. Id. at 169.
218. Waldman, supra note 215.
to regulate hexavalent chromium. The journal retracted the 1997 reanalysis in 2006.

Interestingly, authors may delay publishing a reanalysis in order to avoid the taint associated with litigation. For example, in the 1970s, intrauterine contraceptive devices were introduced as a safer alternative to the birth control pill. The Dalkon Shield, manufactured by A.H. Robins Co., was the most popular device. The manufacturer faced an avalanche of suits alleging a link between its product and pelvic inflammatory disease (PID), which ultimately forced it into a $2.5 billion bankruptcy. The Women’s Health Study—a data set behind multiple epidemiological studies that linked the devices to PID—played an integral role in establishing causation. However, an expert witness for A.H. Robins and his colleagues waited until after the conclusion of the litigation before publishing their reanalysis of the data set (which concluded the devices did not lead to an increased risk of PID) because they feared the appearance of bias would preclude “a fair reading” of their work by fellow scientists.

IV. COURTS SHOULD RETHINK THEIR ALMOST-CATEGORYICAL REJECTION OF EPIDEMIOLOGICAL-STUDY REANALYSES

A. The Premises for Rejecting Epidemiological-Study Reanalyses Are Problematical

Federal courts’ frequent rejection of epidemiological-study reanalyses is unfounded. There are three reasons that justify relaxing the courts’ strong presumption against admitting epidemiological-study reanalyses. First, rejection is premised on overly simplistic assumptions about the import of publication and an underappreciation for science as a process. Second, rejection ignores legitimate reasons, which do not include the absence of actual causation, why on-point, published epidemiological studies may not exist. Third, rejection implicitly rules out using the weight-of-the-evidence methodology often appropriate for, or even necessary to, scientific analysis of potentially toxic substances.

222. Id. at 626.
223. Id. at 626–27.
225. See id.
1. Rejection Is Premised on an Inaccurate, Monolithic Conception of Peer Review

Publication in a peer-reviewed journal is an explicit Daubert factor.\(^227\) Whether or not a theory or technique has been published in a peer-reviewed journal is a “relevant, though not dispositive” consideration for the trial court,\(^228\) and many courts have been hostile to nonpublished evidence “manufactured” for litigation. For example, on remand from Daubert, the Ninth Circuit castigated plaintiffs’ experts for relying on nonpublished evidence, admonishing that “a scientist’s normal workplace is the lab or the field, not the courtroom or the lawyer’s office.”\(^229\)

This binary judicial inquiry (whether the reanalysis has been published or not) stems from a narrow and misplaced conception of peer review. The idea that “publication” and “peer-review” are synonymous is incorrect: publication does not necessarily entail peer review, and peer review is not necessarily limited to the context of publication.\(^230\)

“True peer review” is part of the stuff of science—the “time-honored and fundamental” process of scrutiny and replication by which scientists vet hypotheses and methods of supporting them.\(^231\) In the broadest sense, true peer review occurs whenever one scientist scrutinizes the results or conclusions of another.\(^232\) These scientists might work in academia, for a government agency, in the research arm of a corporation or industry group, or at a think tank.\(^233\) The exchange of results and conclusions among scientists might occur in the laboratory, at a conference, or in a scientific journal.\(^234\) Publication in a scientific journal rapidly broadcasts scientific findings, allowing scrutiny of those findings by other, more widely dispersed scientists in future publications.\(^235\) Therefore, journal publication is but one discrete activity in the ongoing, and more influential, peer review process.\(^236\)

Since the 1950s, publication in a scientific journal has commonly required submission to “editorial peer review.”\(^237\) This process typically involves two (or more) referees from the relevant field reviewing the article and advising the

\(^{228}\) Id.
\(^{229}\) Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995) (describing “[o]ne very significant fact to be considered [a]s whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying”); see also Perry v. United States, 755 F.2d 888, 892 (11th Cir. 1985) (asserting that, given the generally close association of expert witnesses with a party’s lawyers, “examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine”).
\(^{230}\) Cf. Chan, supra note 70, at 100.
\(^{231}\) Id. at 100, 113.
\(^{232}\) See id. at 100.
\(^{233}\) See id. at 113.
\(^{234}\) Id.
\(^{235}\) Id. at 113–14.
\(^{236}\) See id.
\(^{237}\) Id. at 101, 116.
editor whether or not to publish the article. While editorial peer review is an entirely voluntary undertaking by a journal, and review practices vary across journals, a journal’s prestige roughly correlates with the perceived quality of its editorial peer review process.

Editorial peer review does not adjudge the truth of scientific claims. Rather, it promotes the publication of plausibly supported articles in order to introduce them to the wider scrutiny of true peer review. Referees do not perform experiments or attempt to replicate results (on the contrary, they assume the accuracy of presented data). Instead, they focus their efforts on scrutinizing the reasoning—from methodology and data to conclusions—and assessing the article’s potential import. Therefore, publication in a scientific journal is a poor proxy for reliability. Indeed, treating publication in this way transforms editorial peer review into “something no scientist or journal editor ever meant it to be: a litmus test for scientific truth.”

Some argue that the primary advantage of editorial peer review over the adversarial process in law is that it is carried out by individuals who are “truly disinterested in the outcome of a particular litigation, the prospects of a particular product, the financial success of a particular industry, or even ‘justice.’” However, editorial peer review truly shines when a theory produces results that are repeatedly accepted for journal publication. While this type of cumulative editorial peer review begins to approach true peer review, reliance on any single incidence of publication to establish validity is misplaced.

Furthermore, editorial peer review is not a completely disinterested process. In fact, science can be a minefield of potential conflicts of interest.

239. Id.; see also Chan, supra note 70, at 117.
241. Chan, supra note 70, at 119.
242. Id.
243. Childs, supra note 238, at 655.
244. Chan, supra note 70, at 121.
245. Childs, supra note 238, at 658.
246. Amicus Brief of Physicians, Scientists, and Historians of Science, supra note 2, at 3.
247. Bloembergen Amicus Brief, supra note 32, at 11.
248. Id. at 11–12.
249. Id. at 12.
250. These potential conflicts may be specific and obvious but are sometimes broad and indirect. For example:

[T]he potential for conflict of interest can exist regardless of whether an individual believes that [a] relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, and paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.
Journal referees are often competing with an article’s author for similar limited resources, such as journal publications, government research funding, fellowships, and faculty positions. Further, the imprimatur Daubert places on published findings has led savvy counsel, representing both plaintiffs and defendants, to encourage their expert witnesses to try to publish their findings in advance of litigation. Notwithstanding these issues, scholars have suggested that editorial peer review might best be thought of like “democracy: a system full of problems but the least worst we have.”

2. Rejection Ignores Legitimate Reasons Why On-Point, Published Epidemiological Studies May Not Exist

There are two major reasons why on-point published epidemiological studies may not exist, despite true causation: resource constraints and lack of scientific interest. First, epidemiological studies can be expensive and time-consuming to undertake. Some larger studies may cost in excess of $100 million. As a result, epidemiological studies do not exist for the vast majority of substances used in commerce. For example, less than one quarter of the toxic substances known to be carcinogenic in 1992 had been the subject of an epidemiological study. For substances causing diseases with long latency periods, epidemiological studies may not begin to reveal correlations for decades after exposure begins. This may result in a nontrivial time period during which plaintiffs are forced to rely on causation evidence that courts deem inferior, such as the results of non-human-based studies or structure-activity evidence.

Similarly, the rarity of the disease at
issue dictates the sample size (and, hence, the feasibility) of a reliable epidemiological study. For example, an epidemiological study capable of detecting 200 excess cancers (cases of cancer above the background rate) per 100,000 individuals would require over one million study participants. For these reasons, occasionally neither plaintiffs nor defendants have access to epidemiological evidence.

Second, on-point published epidemiological evidence may not exist because the greater scientific community dismisses as banal a particular scientific question deemed critical to the legal community. For example, a complex, site-specific environmental contamination dispute may generate litigation-based interest in pursuing scientific analyses, although the dispute involves nothing novel enough to warrant investigation by the general scientific community. Alternatively, a drug voluntarily withdrawn from the market because a regulatory body suspects it may cause harm may garner less scientific attention going forward. Daubert contemplated this second problem—the notion that some scientifically valid studies may go unpublished or may never happen at all because of “limited interest.”

3. Rejection Implicitly Ignores the Weight-of-the-Evidence Methodology Appropriate for the Scientific Analysis of Potentially Toxic Substances

Plaintiffs’ experts may base their causation opinions on multiple lines of evidence, including animal studies, structure-activity relationships, and epidemiological-study reanalyses. However, in many instances, courts have excluded the entirety of an expert’s opinion because each line of evidence the expert relied upon, when examined individually, was purportedly insufficient to establish causation. In other words, courts have frequently declined to look at the totality of general causation evidence. The judicial hesitation over
“combining” lines of evidence implicitly rejects the possibility that an epidemiological-study reanalysis could play even a minor, supporting role in a causation opinion.268

This mindset is especially problematic because a single experiment or line of evidence is unlikely to be causation-determinative for potentially toxic substances.269 Randomized controlled trials might come close, but they are often not available for potentially toxic substances because of ethical concerns.270 Therefore, it becomes necessary to group together diverse lines of evidence to identify an association between exposure and harm.271 For example, human epidemiological studies might be most on-point, but animal toxicological studies could shed light on the biological mechanisms that lead to actual injury.272

The weight-of-the-evidence methodology is a process “in which all scientific evidence that is relevant to the status of a causal hypothesis is taken into account.”273 Judgments about the association between exposure and harm are made based on the totality of the scientific evidence—both positive and negative.274 This methodology generally requires subjective and qualitative determinations about the relative import and quality of various data by individual scientists.275 One scholar wryly observed that the methodology is imbued “with a sense of mystery—[the first line of evidence] doesn’t make the case for causation, [the second line of evidence] doesn’t make the case, . . . but put them all together and somehow—presto!—the job is done.”276

But the subjectivity inherent in the weight-of-the-evidence methodology is not the “junk science” Daubert was meant to protect against.277 National and international regulatory agencies commonly use the weight-of-the-evidence methodology to analyze potentially toxic substances,278 and the U.S.

268. Cf. Susan Haack, Warrant, Causation, and the Atomism of Evidence Law, 5 EPISTEME 253, 263 (2008) (explaining that, “[b]ecause the conjunction of [several lines of evidence] may warrant the causal conclusion to a higher degree than, i.e., be more reliable than, any of its components, Daubert can actually impede the process of arriving at the conclusion most warranted by the evidence proffered”).
269. Krimsky, supra note 42, at S129.
270. See id.
271. Id.
272. Id. at S130.
273. Id. at S129.
274. Id.
275. See id. (explaining that “weight of the evidence” may “refer[] to nothing more than a subjective assessment on the part of a reviewer who takes relevant data from a given body of published research into consideration in order to ascertain whether a hypothesis is more likely to be true than false”); see generally Douglas Weed, Weight of Evidence: A Review of Concept and Methods, 25 RISK ANALYSIS 1545, 1546–52 (2005) (describing the varied permutations of the weight-of-the-evidence methodology).
276. Haack, supra note 268, at 256; Amicus Brief of Physicians, Scientists, and Historians of Science, supra note 2, at 9–10.
Environmental Protection Agency employs the methodology extensively. Indeed, this methodology is germane to science itself, and not an idiosyncrasy of the scientific analysis of potentially toxic substances for litigation purposes. Curiously, the weight-of-the-evidence methodology admonished by courts when used in expert causation opinions is, in fact, hardly different from the jury’s task of weighing the credibility and relevancy of evidence presented in court.

B. Allowing Greater Use of Epidemiological-Study Reanalyses Would Not Deprive Truly Blameless Manufacturers of the Ability to Mount an Adequate Defense

Relaxing the presumptive rejection of epidemiological-study reanalyses would not create a glut of Truly Blameless Manufacturers for two reasons. First, existing evidentiary and procedural safeguards in federal courts can protect defendants from spurious epidemiological-study reanalyses. Second, the development of a “soft” literature on reanalysis, proven useful in other contexts, can help courts determine whether reanalyses rest on “good grounds.”

279. See EPA Final Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 33,996 (1986). The EPA’s approach is as follows:

Evidence of possible carcinogenicity in humans comes primarily from two sources: long-term animal tests and epidemiologic investigations. Results from these studies are supplemented with available information from short-term tests, pharmacokinetic studies, comparative metabolism studies, structure-activity relationships, and other relevant toxicologic studies. The question of how likely an agent is to be a human carcinogen should be answered in the framework of a weight-of-evidence judgment. Judgments about the weight of evidence involve considerations of the quality and adequacy of the data and the kinds and consistency of responses induced by a suspect carcinogen. There are three major steps to characterizing the weight of evidence for carcinogenicity in humans: (1) Characterization of the evidence from human studies and from animal studies individually, (2) combination of the characterizations of these two types of data into an indication of the overall weight of evidence for human carcinogenicity, and (3) evaluation of all supporting information to determine if the overall weight of evidence should be modified.

Id.

280. See Haack, supra note 268, at 255. For example:

Mary Leiko marshals textual, archeological, etc., evidence to show that Socrates and Cleopatra were not of African descent, and the philosophy of ancient Greece could not have been derived from Egyptian mysticism; [and] Dr. David MacKay of the Johnson Space Center, pondering the significance of substances detected in a Martian meteorite, reasons that “we have these lines of evidence. None of them by itself is definitive, but taken together, the simplest explanation is early Martian bacterial life.”

Id. (footnote removed).

281. Id.

1. Evidentiary and Procedural Safeguards Protect Defendants from Spurious Epidemiological-Study Reanalyses

The Federal Rules of Civil Procedure and Evidence set forth procedures compelling transparency regarding the opinions of testifying expert witnesses.\(^{283}\) For example, all expert testimony must be based on “sufficient facts or data.”\(^{284}\) Furthermore, parties are required to disclose the names of individuals who may be called at trial to give expert testimony.\(^{285}\) Individuals that provide expert testimony must prepare and file written expert reports\(^{286}\) containing, among other things, “a complete statement of all opinions the witness will express and the basis and reasons for them” as well as “the facts or data considered by the witness in forming” these opinions.\(^{287}\) The expert report provides the basis for direct examination.\(^{288}\)

This extensive pretrial disclosure scheme is intended to prevent courtroom surprises and give the opposing party adequate opportunity to evaluate the expert’s methodology and conclusions.\(^{289}\) Disclosure permits the opposing party to prepare rebuttal reports, depose the expert, and prepare for cross-examination at trial.\(^{290}\) In other words, it prevents a party from “l[ying] in wait” and unfairly introducing expert testimony at the last minute.\(^{291}\)

Failure to meet these requirements has consequences. Information not disclosed, unless deemed harmless, can be excluded at trial.\(^{292}\) Furthermore,
“[s]ketchy and vague” reports are generally excluded.293 An expert report must be “sufficiently complete, detailed and in compliance with the Rules so that surprise is eliminated, unnecessary depositions are avoided, and costs are reduced.”294 Therefore, if an expert files a report containing a truly opaque reanalysis, the testimony should not be admitted, given that it might be nothing more than “the ipse dixit of the expert.”295

After expert reports have been filed, parties may file motions in limine to exclude deficient expert testimony, potentially triggering summary judgment if this testimony formed the prima facie case.296 Courts decide motions that set forth specific deficiencies in expert reports based on papers filed or, in certain instances, on Daubert hearings held pursuant to Federal Rule of Evidence 104(a).297

Trial courts have broad discretion to decide “whether or when special briefing or other proceedings are needed to investigate reliability.”298 If a ruling on expert evidence might have a substantial impact on the case, a Daubert hearing is advisable.299 While Daubert hearings provide the potential benefit of ensuring that parties have the opportunity to thoroughly investigate the underpinnings of expert testimony,300 they should be carefully circumscribed to avoid creating an “unnecessary preview of the trial.”301

Finally, a court can appoint its own expert or technical advisor. The Federal Rules of Evidence allow court appointment of a testifying expert.302 Alternatively, a court can appoint a technical consultant to assist it in a purely advisory role.303 One salient example of this option occurred in the silicone breast implant litigation when a judge presiding over some of the cases employed technical advisors to analyze the reliability of the experts’ opinions.304

299. Schwarzer & Cecil, supra note 296, at 53.
300. MANUAL FOR COMPLEX LITIGATION, supra note 297, § 23.353.
301. Schwarzer & Cecil, supra note 296, at 54. Furthermore, courts should be careful not to inadvertently decide factual issues and thus “encroach[ on] the province of the jury . . . .” See MANUAL FOR COMPLEX LITIGATION, supra note 297, § 23.353.
302. See FED. R. EVID. 706; Schwarzer & Cecil, supra note 296, at 59.
303. See Schwarzer & Cecil, supra note 296, at 59; see also In re Peterson, 253 U.S. 300, 312 (1920) (“Courts have (at least in the absence of legislation to the contrary) inherent power to provide themselves with appropriate instruments required for the performance of their duties.”).
304. See Schwarzer & Cecil, supra note 296, at 60–61.

Another approach to protecting parties from spurious reanalyses is judicial education. Instead of fussing over the Daubert and Frye doctrinal tests themselves, some scholars have proposed educating the judiciary about science.305 An acclaimed example of this approach is the Federal Judicial Center’s Reference Manual on Scientific Evidence.306 An addendum to the manual specifically focused on the subject of reanalysis seems appropriate.307

Judicial education is not as monumental an endeavor as it might, at first, sound. It is true that courts have expressed anxiety over the “heady task” of “resolv[ing] disputes among respected, well-credentialed scientists about matters squarely within [the scientists’ realm of] expertise.”308 However, judicial education does not require turning judges into scientists; rather, it entails the much simpler task of providing judges with the materials and training they need to become “critical consumers of the science that comes before them.”309 Judges do not need to know how to design a scientific study, but they should know what issues experts should be addressing when scientific testimony is proffered in legal proceedings.310

C. Milward v. Acuity Specialty Products Group, Inc.

Milward v. Acuity Specialty Products Group, Inc.311 concerned a toxic tort—purported workplace exposure to the defendants’ benzene-containing products allegedly caused Mr. Milward’s rare form of leukemia.312 Dr. Martyn

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307. Specific factors for courts to consider when determining whether or not to admit an epidemiological study reanalysis are outside the scope of this Note. For a good start, see Raymond Neutra et al., Toward Guidelines for the Ethical Reanalysis and Reinterpretation of Another’s Research, 17 Epidemiology 335 (2006).

308. Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1316 (9th Cir. 1995). Judge Kozinski stated:

Our responsibility, then, unless we badly misread [Daubert], is to resolve disputes among respected, well-credentialed scientists about matters squarely within their expertise, in areas where there is no scientific consensus as to what is and what is not “good science,” and occasionally to reject such expert testimony because it was not “derived by the scientific method.” Mindful of our position in the hierarchy of the federal judiciary, we take a deep breath and proceed with this heady task.

Id.

309. Sophia Gatowski et al., supra note 305, at 455.

310. Id.

311. 639 F.3d 11 (1st Cir. 2011).

312. See id. at 13.
Smith, a toxicology professor at the University of California, Berkeley, served as the plaintiff’s expert for general causation.313

Leukemia is a general term for a cancer of the blood cells.314 The disease can be subdivided on the basis of two classifications.315 The first separates the acute and chronic forms of leukemia, while the second distinguishes between the types of stem cells affected.316 Combining these classifications creates four broad categories of leukemia, including acute myeloid leukemia.317 Mr. Milward’s leukemia, acute promyelocytic leukemia (APL), is a subtype of acute myeloid leukemia (AML) known to be caused in part by a chromosomal translocation.318

Although much scientific evidence (including case reports, in vitro studies, and epidemiological studies) links benzene exposure and leukemia,319 there is no consensus regarding the causes of the chromosomal genetic translocation that induces APL.320 Therefore, Dr. Smith used a weight-of-the-evidence methodology to tie benzene exposure to APL using five lines of evidence.321 Specifically, to form his general causation opinion, he relied on evidence that

• benzene can cause AML as a class;
• all AML subtypes (including APL) appear to have a common etiology;
• benzene can cause chromosomal damage similar to the damage characteristic of APL;
• benzene inhibits an enzyme in a way that is otherwise known to cause APL; and
• APL has been reported in benzene-exposed workers by epidemiological studies.322

Dr. Smith derived the last piece of evidence by reanalyzing three existing epidemiological studies.323

The district court refused to admit Dr. Smith’s testimony, calling it a series of “hypothoses.”324 The court held that, because each line of evidence was
itself insufficient to infer causation, the testimony was in sum unreliable.\textsuperscript{325} It rested its rejection of the epidemiological-study reanalyses on the absence of statistical significance\textsuperscript{326} and did not address the fact that the fifth line of evidence contained unpublished, litigation-generated reanalyses.

On appeal, the First Circuit took issue with the district court’s rejection of the weight-of-the-evidence methodology and the treatment of each line of Dr. Smith’s evidence “atomistically,”\textsuperscript{327} explaining that “[t]he fact that the role of judgment in the weight of the evidence approach is more readily apparent than it is in other methodologies does not mean that the approach is any less scientific.”\textsuperscript{328} How much weight to give to Dr. Smith’s evidence, however aggregated, was therefore a determination squarely within the province of the jury.\textsuperscript{329}

Defendants raised the issue of the epidemiological-study reanalyses on appeal. They encouraged the First Circuit to affirm the district court’s finding that “Dr. Smith’s attempt to rely on new epidemiological ‘evidence’ generated from his own ‘reinterpretation’ of earlier study data was riddled with serious errors that rendered his methodology scientifically unreliable.”\textsuperscript{330} However, the First Circuit rejected this contention, holding that “[e]pidemiological studies are not per se required as a condition of admissibility regardless of context.”\textsuperscript{331}

In reversing the exclusion of Dr. Smith’s general causation opinion, the First Circuit implicitly accepted the propriety of using epidemiological-study reanalyses for “indirect support” in a causation opinion.\textsuperscript{332}

One scholar already has noted that \textit{Milward} can be read as exemplary for its endorsement of the weight-of-the-evidence methodology and for its recognition that a scientist’s judgments inherent in this process are consistent with the scientific method.\textsuperscript{333} However, he urges caution that \textit{Milward} should not be overstated because \textit{Daubert} still applies, and, therefore, courts “in the First Circuit still wield the discretion of gatekeepers.”\textsuperscript{334}

\textit{Milward}’s recognition that there can be a role for epidemiological-study reanalyses in a causation opinion is also exemplary. \textit{Milward} can be interpreted as urging judicial restraint on the knee-jerk exclusion of scientific testimony under \textit{Daubert} based on the inclusion of epidemiological-study reanalyses.

\textsuperscript{325} \textit{Id.} at 144–49.
\textsuperscript{326} \textit{Id.} at 148–49.
\textsuperscript{327} \textit{Milward v. Acuity Specialty Prods. Grp.}, 639 F.3d 11, 23 (1st Cir. 2011).
\textsuperscript{328} \textit{Id.} at 18.
\textsuperscript{329} \textit{See id.} at 14.
\textsuperscript{330} Brief for Defendants-Appellees, \textit{supra} note 323, at 35.
\textsuperscript{331} \textit{Milward}, 639 F.3d at 24 (emphasis added).
\textsuperscript{332} \textit{Cf. id.} at 24 n.17 (stating that “Dr. Smith did not claim that the [epidemiological-study reanalyses] provided direct support. Rather, his characterization of his methodology makes clear that he was using them as indirect support”).
\textsuperscript{333} Gold, \textit{supra} note 17, at 1577–81.
\textsuperscript{334} \textit{Id.} at 1581 (noting that “[e]ven in the First Circuit, a plaintiff who overplays a \textit{Milward} hand will likely lose a \textit{Daubert} challenge: procuring an expert willing to incant ‘weight of the evidence’ will not provide an automatic ticket to a jury”).
Given the amount and types of evidence Dr. Smith marshaled for his general causation opinion, Milward illustrates the problematic scenario of allowing the judicial “shark” to exclude scientific testimony after sniffing one drop of evidentiary “blood”—any use of epidemiological-study reanalysis—even when diffused among a vast “sea” of other cogent scientific evidence.

CONCLUSION

Without a categorical crutch on which to rely, this proposed relaxation of the strong presumption to exclude epidemiological-study reanalyses does not make a federal court’s job any easier. But in the interest of justice for Truly Deserving Victims, the question of whether to take this step deserves, at a minimum, a fresh look. Because of the difficulties of introducing scientific evidence into legal proceedings and addressing harms from potentially toxic substances through the tort system, the deck is often stacked against toxic tort victims. The optimal solution would reduce the number of Truly Deserving Victims without creating additional Truly Blameless Manufacturers.

Relaxing categorical rules, like courts’ near-total rejection of epidemiological-study reanalyses to date, is a step in this direction. Categorical rules for screening scientific testimony do not promote justice and are the products of judicial laziness. Indeed, Daubert itself explicitly eschewed categorical rules. Instead, “[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”

The fact that Daubert handed trial courts the reins as evidentiary “gatekeeper[s]” was “not intended to serve as a replacement for the adversary system.” It strains credulity to suggest that unexamined judicial reliance on an ill-conceived categorical rule—such as the almost-categorical rejection of epidemiological-study reanalyses—achieves anything else.

337. Id. at 596.

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