Doubting **Daubert**

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Introduction

"Doubt is our product," announced a tobacco industry executive in explaining the necessity of maintaining scientific uncertainty about the harms of tobacco.² One can easily say the same about other industries whose products and processes harm human health. Indeed, it is well nigh impossible to find a consensus about the harmfulness of any modern product or byproduct, so thorough has been the industry campaign to preserve and nurture scientific uncertainty. In Daubert v. Merrell Dow Pharmaceuticals, Inc.,3 the Supreme Court gave the skeptics a new forum for their efforts when it charged federal trial courts with a duty to guard against admission of unreliable expert scientific evidence in cases before them. If courts had slogans, "doubt is our product" wouldn't be a bad one for many of the courts responding to Daubert.

But *Daubert* itself is dubious. Why doubt *Daubert*? There are many reasons:

- 1. *Unintended consequences*: The decision has had precisely the opposite effect from the one the Court said it intended.
- 2. Embrace of junk science: The case has inspired a large number and variety of unscientific rulings, including rulings dismissing the reliability of animal studies and rulings requiring plaintiffs to show particular numerical results from epidemiological studies.
- 3. *Inspired by unfounded fears*: Cases applying *Daubert* cite potential for undue juror credulousness in justifying courts' "gatekeeping" role, yet empirical evidence does not support the courts' fears.

- 4. A "lemons" problem. Courts' branding of highly credentialed scientists as "unqualified" after Daubert may create a situation in which bad experts drive good ones out of the market for expert testimony.
- 5. *Built-in bias*: The "junk science" movement that has fed *Daubert* and its progeny was a pet project of the scientifically challenged tobacco industry.
- 6. Overreaching: Daubert has gone beyond a ruling about admissibility of expert evidence to being a quiet but effective way of adjusting the substantive rules of tort.
- 7. False modesty: Courts applying Daubert have refused to seek guidance in the scientific judgments of expert administrative agencies, explaining that the courts are not fashioners of public policy.
- 8. Legalizing science: Courts have used prior legal rulings on admissibility to decide scientific questions about the reliability of expert evidence.
- 9. *Mixed signals*: Even while they use prior rulings on admissibility to decide current issues regarding expert evidence, courts insist that they are preserving the right to a jury trial, and conventional rules on issue preclusion, by deciding each case on its own terms.

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I discuss each of these unfortunate developments in turn.

Unintended Consequences

The Court granted certiorari in Daubert to address the question whether the evidentiary rule of Frye v. United States⁴ — which held that expert scientific evidence was inadmissible unless based on methodologies generally accepted in the relevant field - had survived the enactment of the Federal Rules of Evidence.⁵ Frye was widely regarded as an undue impediment to the admission of novel but well-grounded expert scientific

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evidence in the courts,6 and a victory for the plaintiffs in Daubert - who had lost below on account of application of the *Frye* rule⁷ – was widely expected to liberalize (and modernize) the rules on admitting expert scientific evidence in courts.8

The plaintiffs won in Daubert, the Frye rule was undone, and Justice Blackmun's opinion for the

Court talked of loosening the straitjacket forced on by Frye and opening the courts to a wider range of expert scientific evidence, as contemplated by the Federal Rules of Evidence.9 But Justice Blackmun didn't stop there. He went on – apparently trying to be helpful to the trial courts charged with a "gatekeeping" function in regard to expert scientific evidence - to offer several "general observations" about how to decide whether to admit expert scientific evidence. 11 Such evidence, said Justice Blackmun, must not only be scientifically reliable, but also relevant to the case at hand; it must "fit" the facts as alleged by the party seeking to introduce the evidence.¹² To be reliable, Justice Blackmun stated that it would be helpful if, for example, the evidence in question was testable, had been peer-reviewed, had been published in a scientific journal, had a low error rate, and (though, with the rejection of the Frye test, this final factor would not be dispositive) was generally accepted in the relevant field.¹³

In his partial dissent in Daubert, Chief Justice Rehnquist (joined by Justice Stevens) agreed with the Court's rejection of the Frye standard, but he criticized the majority for going on to offer its "general observations" on admitting expert scientific evidence. He worried that the majority's comments – however well-intentioned – might come back to haunt the Court because they were offered in a case in which the issues and problems they might raise were not concretely presented. 14 And indeed, that is precisely what has happened. The "general observations" of Daubert have, in practical importance, completely overwhelmed the Court's formal holding regarding Frye, and the Court's casually offered guidelines on admitting expert scientific evidence have served as the vehicle for transforming Daubert from an evidence-

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evidence-narrowing one.15

Even so, a generous portion of the fault for transforming the "general observations" of Daubert into quite rigid and restrictive rules on admitting expert scientific evidence must be attributed to Chief Justice Rehnquist himself. In its first major case applying Daubert,

Rehnquist, now writing for the Court, upheld the exclusion of epidemiological and animal studies in a case in which the plaintiff alleged that his lung cancer had been caused by exposure to polychlorinated biphenyls (PCBs).¹⁶ Here again, the decision was, technically, about one important though discrete legal question (regarding the standard of review of district court judgments on admissibility of expert scientific evidence), 17 yet much of the decision's influence has come from what were in the nature of "general observations" on admissibility. Specifically, after deciding that district court judgments on the admissibility of expert scientific evidence were to be reviewed under the forgiving "abuse of discretion" standard, Chief Justice Rehnquist went on to describe why he thought the district court's ruling excluding the plaintiff's epidemiological and animal studies was not an abuse of discretion.

On the epidemiological studies, Rehnquist examined them one by one, and for each he found a flaw that, he concluded, rendered the study so unreliable as to justify the district court's exclusion of it as evidence. One study did not find a statistically significant relationship between PCBs and disease;¹⁸ one study involved a population that had been exposed to other chemicals in addition to

PCBs;¹⁹ yet another failed to find a statistically significant relationship between lung cancer and exposure to PCBs.²⁰ In each case, a single flaw or shortcoming was enough to doom the study, and after looking at each study in isolation from the other, the Court wound up excluding the entire group of studies purporting to show a link between PCBs and cancer.

On the animal studies, Chief Justice Rehnquist seemed to find it awkward in the extreme that the animals in the studies were infant rodents, while plaintiff was an adult human.²¹ Thus the animal studies failed to satisfy the requirement that expert evidence fit the facts of a case.²² Rehnquist also thought it relevant – and unfavorable to the admissibility of the animal studies – that the rodents in the studies had been given high doses of PCBs through a route different from the one by which the plaintiff himself was exposed.²³

In dissent, Justice Stevens chided the majority for making the mistake of *Daubert*: he would have rested with decision on the general question presented (concerning the standard of review for trial courts' decisions on admissibility) and omitted discussion of the specific factors relevant to the admissibility determination in this case.²⁴ He thought the Court's observations on the epidemiological and animal evidence were imprudent, and intimated they might stifle admission of well-grounded but imperfect scientific evidence in the lower courts.²⁵ In *Joiner*, therefore, Chief Justice Rehnquist appears to have forgotten the lessons of judicial restraint that he tried to impart in his dissent in *Daubert*.

Embrace of Junk Science

In another unfortunate twist, the majority opinion in *Joiner* also – in the very act of modeling an analysis of whether to admit particular expert scientific evidence – acted contrary to the well-established practices of the scientific community in exploring the implications of epidemiological evidence and animal studies. The Court's isolation of each separate epidemiological study, and its affirmation of the exclusion of each study based on minor flaws or shortcomings, goes completely against the grain of the "weight of the evidence" approach favored by actual scientists. In their daily work, scientists involved in the kinds of studies rejected in *Joiner* look at the studies as a group, trying to assess their collective meaning, rather than fixing on one study at a time.²⁶

Any epidemiologist or toxicologist will tell you that any epidemiological or animal study will have flaws and/or will signal a conclusion with imperfect clarity. But epidemiologists and toxicologists do not therefore reject all of the studies produced by their disciplines. In singling out each study for separate examination, and in rejecting each one for being flawed in some respect, the Court in *Joiner* indulged in what Professor Thomas McGarity has called the "corpuscular" approach to scientific evidence – and thereby parted company with the scientific disciplines it was purporting to follow.²⁷

The divergence between the law created by *Daubert* and actual scientific practice is also evident in lower court rulings following Daubert and Joiner. Stepping onto the trail marked by Joiner, many lower courts have become highly suspicious of animal studies and the scientific practices associated with them.²⁸ Never mind that animal studies help form the backbone of the agency regulatory system that covers some of the very industries - in particular, the pharmaceutical industry - that argue, in tort cases, that animal studies are so unreliable as to be inadmissible.²⁹ Never mind that animal studies are widely accepted in the scientific community as relevant indicators of effects on humans³⁰ – a fact that, in the old, supposedly too-strict Frye days, would have been sufficient to allow such studies into court. Despite these obvious tensions, courts have happily excluded evidence from animal studies, post-Daubert. At the same time, they have questioned the scientific practices that have been used to translate the results of animal studies into predictions about effects on human health. The most important example here is the courts' treatment of the linear, no-threshold dose-response model, which posits that adverse reactions will appear in direct proportion to exposure to the substance in question and that adverse reactions will occur at any exposure level above zero. Oftentimes, courts have been remarkably dismissive of this model, labeling it "merely an hypothesis" 31 or a "guess."32 The courts seem blissfully unaware of the large volume of scientific evidence validating this doseresponse model for use in scientific studies; indeed, one court has even asserted - erroneously - that "to the extent the model has been subjected to peer review and publication, it has been rejected by the overwhelming majority of the scientific community."33

In another unscientific spin-off from Daubert and Joiner, many cases have rejected epidemiological studies that show a "relative risk" of less than 2.0, that is, studies indicating that the risk in the population exposed to the substance of concern is less than twice the risk in the unexposed population. 34 Courts in these cases have reasoned that without studies showing relative risk of greater than 2.0, plaintiffs bearing the "more probable than not" burden of proof in civil cases cannot possibly prove their cases; the courts reason that only if the relevant exposures have more than doubled the plaintiffs' risk of harm can the plaintiffs prove that it is more likely than not that the exposures caused their harm.³⁵ But, again, scientists do not behave in this way. They realize, for example, that a relative risk of less than 2.0, found in a single epidemiological study, might be augmented by findings of larger relative risks in other epidemiological studies, or by sustained findings of

exposure-disease links in animal studies.³⁶ They also recognize that many epidemiological studies are done in workplace settings, where the "healthy worker effect" might lead the studies to underestimate the risk that would be found in the general population.³⁷ The short

of the matter is that scientists would not, as courts have, rule out reliance on an epidemiological study simply because the study failed to find a relative risk of greater than 2.0.³⁸

Inspired by Unfounded Fears

Why have courts become so stingy about admitting expert scientific evidence? Here is more awkwardness. Without citation or explanation, courts have often justified their enlarged "gatekeeping" function by pointing to the likelihood that juries will be overly swayed by expert evidence finding a link between a substance or product and increased risk of disease.³⁹ Jurors will, the theory goes, give in too easily to the temptations of "junk science," and thus judges must bar the door to unreliable science in order to save the civil legal system from the irrational fears of the jury.

But there is no credible empirical evidence that jurors will in fact be so swayed.⁴⁰ Indeed, the evidence that does exist on the mindset and perceptions of jurors

points, if anything, in the opposite direction. Jurors, on average, come into the jury room predisposed against the plaintiffs in personal injury cases.⁴¹ They come inclined to believe, for example, that the plaintiff's injuries are her own fault.⁴² They come inclined to side with the corporate entities that often are the defendants in cases involving *Daubert*.⁴³ In their effort to shield juries from expert scientific evidence they believe will cause them undue alarm, courts have ignored empirical evidence indicating that their own fears are unwarranted.

A 'Lemons' Problem

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At the same time courts have been anxious, after *Daubert*, to scrutinize expert scientific evidence so that they do not admit "junk science" into the courtroom, they have also begun to frame their opinions on admissibility in such a way as to create disincentives for truly neutral and well-credentialed experts to become involved in

litigation. In a striking development, courts have ruled that the experts who offer evidence the courts deem unreliable under *Daubert* are themselves not qualified to testify.⁴⁴ Thus we have the spectacle of courts declaring that reputable, well-credentialed

scientists are "not qualified" to offer the expert opinions they are presenting.⁴⁵ In framing their decisions in terms of the qualifications of the expert rather than the reliability of the expert's testimony, courts risk branding top-notch scientists as something like charlatans, pretending to have knowledge they in fact lack. It is easy enough to predict that these kinds of decisions will have the effect of discouraging expert testimony from the very scientists who offer their opinions in the most impartial manner; scientists whose primary business is science, not litigation, will be more likely to be discouraged from offering expert testimony if by doing so they risk damage to their reputation as scientists. Scientists whose primary business is litigation risk no such loss. Where outside observers of the litigation process cannot distinguish between experts deemed unqualified because they are truly charlatans, and experts deemed unqualified because of a technical mismatch between their testimony and the facts of the case (as framed by the court), a "lemons" problem likely will be the result: bad experts will drive out the good,⁴⁶ and we will be left in a situation precisely opposite the one envisioned by the Court in *Daubert*.

The post-*Daubert* disincentives to responsible expert testimony exacerbate other developments that also threaten to limit the supply of good scientific research, in the courts and elsewhere. Experts in litigation have been subjected to intrusive questioning even in cases in which they did not testify.⁴⁷ Scientists who have published research showing risks from products and substances made by powerful industries have found themselves hounded and vilified by those industries and/or their surrogates.⁴⁸ In one especially extreme (but not unique) example, the tobacco industry launched a massive attack on a Japanese scientist whose research showed a link between secondhand smoke and lung cancer.⁴⁹

Built-in Bias

The foregoing observations lead to another of *Daubert's* many tensions. The "junk science" movement which has come to full flower in the aftermath of Daubert was fueled and funded by none other than the tobacco industry. In the early 1990s, the tobacco industry began to worry that secondhand smoke would be classified as a carcinogen, which would in turn support, among other things, the growing calls for restrictions on smoking in public places. Tobacco industry documents from the early 1990s reveal that the industry decided to spin off organizations whose affiliation with the tobacco industry would not be clear - groups that would attack the scientific basis of research finding risks from many different modern hazards, including but by no means limited to secondhand smoke.⁵⁰ By remaining organizationally distant from the groups decrying the use of "junk science" in risk assessments, and by encouraging doubts about the risks of substances like alar, asbestos, dioxin, and others, in addition to secondhand smoke, the tobacco industry could undermine the scientific case against secondhand smoke without being directly tied to that effort.⁵¹ It might well be, of course, that the kinds of scientific analysis targeted by tobacco industry surrogates are indeed scientifically problematic; but, as Daubert's progeny teach us, the fact that an empirical position has originated within the context of a legal controversy is some evidence against its reliability.52

Overreaching

Daubert and cases following it have adjusted the substantive rules of tort by creating extra obstacles to plaintiffs trying to prove their claims. Particularly in toxic tort cases, post-Daubert rulings excluding whole categories of evidence - such as animal studies, epidemiological studies failing to show a relative risk of greater than 2.0, and so forth – have, in essence, raised the substantive bar for toxic tort cases.⁵³ And they have done so despite the fact that most Daubert issues in federal court arise in diversity cases, in which state courts supposedly set the substantive rules of the road. If styled, more accurately, as substantive changes to the law of torts, federal court rulings raising the substantive bar for toxic tort cases would obviously violate the Erie principle. But because they are, in form, evidentiary rulings, not substantive law, federal courts may issue them without fear of running afoul of Erie. Thus has Daubert worked at least some shift in power away from state courts and toward federal courts in matters of substantive tort law. The federal courts, however, do not see it that way; indeed, the Seventh Circuit recently labeled a variant of the Erie argument I have mentioned here "frivolous."54

False Modesty

One can also discern, in post-Daubert cases, the subtle revival of a rather quaint judicial attitude toward the purposes of tort law. Faced with the question whether risk assessments used by regulatory agencies to estimate the risks posed by hazardous substances and activities are relevant to the issue of causation in tort cases, some courts have responded by asserting that administrative regulation and tort law serve purposes too dissimilar to warrant consideration of regulatory decisions in tort cases. Here is a typical example of the kind of reasoning these courts deploy:

A regulatory standard, rather than being a measure of causation, is a public-health exposure level that an agencies determines pursuant to statutory standards set by Congress.... [Regulation] suggests or make prophylactic rules governing human exposure ... from the preventive perspective that agencies adopt in order to reduce public exposure to harmful substances.⁵⁵

Completely overlooked are the possibility that courts in tort cases also could take a "preventive" perspective, and the reality that whatever perspective courts take in this regard, their choice reflects not just "causation" as a strictly factual matter but also policy considerations about how to allocate the burden of scientific uncertainty as between plaintiffs and defendants.⁵⁶ As Professor Richard Pierce has put it, the legal question in toxic tort cases is not simply "Did substance A cause injury X?," but rather: "Is there evidence that substance A causes injury X that is sufficient to justify taking some action with respect to substance A and those firms who are responsible for substance A?"57 To pretend, as some courts have, that "causation" in the legal world is solely a matter of fact, rather than a matter of fact intermingled with questions of policy, is to embrace a naïve and outmoded view of the role of common-law courts in shaping public policy.

Legalizing Science

In *Joiner*, the Supreme Court held that the abuse-of-discretion standard of review governs appellate review of district courts' evidentiary rulings under *Daubert*. The Court distinguished *Daubert* findings from the kinds of factual issues that, on a motion for summary judgment, are to be decided in favor of the non-moving party (in *Daubert* cases, this is usually the plaintiff).⁵⁸ Thus the Court thinks *Daubert* issues aren't standard factual issues. But they must not be conventional legal issues, either, since in that case the standard for evaluating district courts' judgments about them would be *de novo* review.⁵⁹

Frequently, however, courts have treated prior rulings on the admissibility of specific evidence as legally binding precedent. Thus, for example, in Allen v. Pennsylvania Engineering Corp., the Fifth Circuit cited a prior legal decision for the proposition that epidemiological evidence on some kinds of cancer was not probative with respect to the causation of brain cancer, and it also cited a prior case for the idea that animal studies were not reliable indicators of risks to humans.⁶⁰ In the latter instance, the court cited a prior decision as precedent even though the prior case was about a different allegedly harmful drug and involved different tests in animals. Here is not only another example of a court adopting unscientific principles in the name of Daubert; no scientific principle countenances rejecting animal studies across the board, without reference to specific details

from the specific context in question. Here is also an example of a court turning the supposedly discretionary issues raised by *Daubert* into issues answerable through general legal rules about particular kinds of evidence.⁶¹

It is easy enough to understand the temptation to give precedential legal effect to prior rulings on the admissibility of expert evidence. One of the potential embarrassments of Joiner's abuse of discretion standard is the possibility of apparently inconsistent evidentiary judgments among courts. Since one consequence of this lenient standard of review is that district judges may come to different conclusions on the same evidence, it may be that different judges could find, for example, that expert evidence concluding that PCBs cause lung cancer is both reliable and unreliable. It doesn't take much of a step from there to announce that courts have concluded that PCBs both cause and do not cause cancer. When the issue is one of general causation – whether PCBs could cause cancer, in general, to someone – this apparent inconsistency in the legal treatment of the same phenomenon could cause discomfort.⁶² How could it be, one might ask, that PCBs could cause cancer in some courts or jurisdictions but not in others? One obvious answer is that individual judges have different perspectives on the reliability of evidence of the carcinogenic potential of PCBs. Another answer is that some plaintiffs might have better lawyers, or more seasoned or credible experts, than others. Neither answer will be comforting to people who cling to the belief that American justice is meted out in a neutral way, without regard to the personal predilections of judges or the wealth and resources of individual litigants. One can imagine, therefore, the (perhaps unconscious) desire of judges to tidy up this mess by applying stare decisis principles to evidentiary rulings. Yet it is hard to square this application of stare decisis with Joiner's implicit insistence that Daubert issues are not purely legal issues.

Mixed Signals

Even while they give precedential effect to prior evidentiary rulings under *Daubert*, courts also claim to be preserving parties' rights to jury trials and claim not to be expanding the concept of issue preclusion. For example, in *In re TMI Litigation*, the Third Circuit refused to apply its ruling on expert testimony to plaintiffs in a different class from the plaintiffs offering the expert testimony in question. The court thought that doing so

would endanger the other plaintiffs' right to a jury trial and would improperly enlarge the doctrines of collateral estoppel and issue preclusion. Yet if courts use prior evidentiary rulings as binding precedents in future cases, the only difference between that and the position rejected in *In re TMI Litigation* is that it will take more time to reach what is in any event a preordained conclusion on admissibility. This is a very silly way to run a railroad.

Conclusion

What is to be done about the mess that has followed in the wake of *Daubert*? There are several possibilities, ranging from the modest to the more adventurous.

One possibility would be for the Supreme Court to begin to mend the damage it has done in the same way it did the damage in the first place: by modeling for lower courts the kind of analysis they should be undertaking in rendering judgments on admissibility after *Daubert*. Only in this case, the idea would be for the Court to model good analysis – analysis that gave expression to *Daubert*'s stated goal of liberalizing decisions on admissibility, did not embrace junk science, did not mischaracterize the nature of the decision at hand, and so forth. More than any doctrinal change the Court could make, such a modeling exercise would send a significantly different signal to the lower courts that have

become emboldened, after *Daubert*, to exclude a good deal of evidence as unreliable.

Other, more radical possibilities would entail adjusting the substantive rules of tort so as to avoid the factual conundrums revealed by *Daubert*. Professors Margaret Berger and Wendy Wagner have separately proposed, for example, that if a defendant failed to do studies on the potential harms of a product the defendant placed on the market, then the defendant should be liable based on its failure to develop and disclose information on harmfulness.⁶⁴ This proposal would shift attention away from causation and toward the creation of incentives to produce information about health effects of products.

Another possibility, which I have advocated, is to recognize that the knowing imposition of risk on one human by another is a tort sounding in dignity, the closest cousins of which are the torts of assault, battery, and trespass. This approach would allow courts to avoid the numbingly complex scientific questions that *Daubert* has asked them to manage, and would refocus their attention on the motivations and dignitary consequences of human actions – subjects that are familiar and congenial to law, and that *Daubert* has relegated to the sidelines in its singular fixation on scientific expertise.

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Notes

- ¹ Professor of Law, Georgetown University Law Center. I am grateful to Gerry Spann and Rena Steinzor for helpful comments. I am also grateful to Danielle Woods for excellent research assistance.
- ² Brown & Williamson Smoking and Health Proposal, Doc. No. 332506, at http://tobaccodocuments.org/bw/332506.html.
- ³ Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).
- ⁴ 293 F. 1013 (D.C. Cir. 1923).
- ⁵ Daubert v. Merrell Dow Pharmaceuticals, Inc., Brief for Petitioner, 1992 U.S. Briefs 102.
- ⁶ For criticism of Frye, see, e.g., Paul C. Gianelli, The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later, 80 COLUM. L. REV. 1198 (1980).
- ⁷ 951 F.2d 1128, 1129-1301 (9th Cir. 1991).
- ⁸ See, e.g., David G. Savage, *Scientific Evidence: Court May Decide When Jury Can Hear It*, L.A. Times at 5 (Mar. 30, 1993).
- ⁹ 509 U.S. at 588-589.
- ¹⁰ *Id.* at 597.
- ¹¹ *Id.* at 593.
- ¹² *Id.* at 591 (quoting United States v. Downing, 753 F.2d 1224, 1242 (3rd Cir. 1985).
- ¹³ *Id.* at 593-94.
- ¹⁴ Daubert, 509 U.S. at 598-601.
- ¹⁵ See, e.g., Scientific Knowledge and Public Policy, *Daubert: The Most Influential Supreme Court Ruling You've Never Heard Of*, at 4 (June 2003) [hereinafter "SKAPP Report"].
- ¹⁶ General Electric Co. v. Joiner, 522 U.S. 136 (1997).
- ¹⁷ *Id.* at 141-142.
- ¹⁸ *Id.* at 145.
- ¹⁹ *Id.* at 146.
- ²⁰ *Id.* at 145.

- ²¹ *Id.* at 144.
- ²² Id. at 144.
- ²³ *Id.* at 144.
- ²⁴ *Id.* at 150.
- ²⁵ *Id.* at 152-154.
- ²⁶ See, e.g., Jerome P. Kassirer & Joe S. Cecil, *Inconsistency in evidentiary standards for medical testimony:* disorder in the courts, 288 JAMA 1382 (Sept. 18, 2002).
- ²⁷ Thomas O. McGarity, Science in the Regulatory Process: On the Prospect of "Daubertizing" Judicial Review of Risk Assessment, 66 L. & Contemp. Probs. 155, 172-176 (2003); Thomas O. 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 Kan. L. Rev. 897, 921-923 (2004).
- ²⁸ See, e.g., Grims v. Hoffmann-LaRoche, Inc., 907 F. Supp. 33 (1995); Caraker v. Sandoz Pharmaceuticals, 188 F. Supp.3d 1026 (S.D. Ill. 2001); Allen v. Pennsylvania Engineering Corp., 102 F.3d 194 (5th Cir. 1996); Barrett v. Atlantic Richfield Co., 95 F.3d 395 (5th Cir. 1996); Hollander v. Sandoz Pharmaceuticals Corp., 289 F.3d 1193 (10th Cir. 2002).
- ²⁹ New drugs are tested in pre-clinical studies in animals, before they are tried on humans. See, e.g., Althea Gregory, *Denying Protection to Those Most in Need: The FDA's Unconstitutional Treatment of Children*, 8 ALBANY J. Sci. & Tech., 121, 125 (1997).
- ³⁰ For general discussion, see Carl F. Cranor, *The Dual Legacy of Daubert v. Merrell-Dow Pharmaceutical: Trading Junk Science for Insidious Science*, in RESCUING SCIENCE FROM POLITICS (Rena Steinzor & Wendy Wagner, eds. Cambridge University Press forthcoming 2005) (unpublished manuscript on file with the author).
- ³¹ Sutera v. The Perrier Group, 986 F. Supp. 655, 667 (D. Mass. 1997).
- ³² Whiting v. Boston Edison Co., 891 F. Supp. 12, 23 (D. Mass. 1995).
- ³³ Id. at 25.

- ³⁴ See, e.g., In re Breast Implant Litigation, 11 F. Supp.2d 1217, 1226-27 (D. Co. 1998); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1315 n. 16 (11th Cir. 1999); Pozefsky v. Baxter Healthcare Corp., 2001 U.S. Dist. LEXIS 11813 (N.D.N.Y. 2001); Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp.2d 584, 606 (D.N.J. 2002).
- ³⁵ Several courts have taken their cue in this regard from (law professor) Michael Green's "Reference Guide on Epidemiology," written for the Federal Judicial Center, which states that "the threshold for concluding that an agent was more likely than not the cause of an individual's disease is a relative risk greater than 2.0." MICHAEL D. GREEN, REFERENCE GUIDE ON EPIDEMIOLOGY 384 (2000).
- ³⁶ SKAPP Report at 9-10.
- ³⁷ See, e.g., Russellyn S. Carruth & Bernard D. Goldstein, *Relative Risk Greater Than Two in Proof of Causation in Toxic Tort Litigation*, 41 JURIMETRICS 195, 200-01 (2001).
- ³⁸ For an excellent discussion of these issues, see Cranor, *The Dual Legacy of Daubert v. Merrell-Dow Pharmaceutical, supra* note 30.
- ³⁹ See, e.g., Whiting v. Boston Edison Co., 891 F. Supp. 12, 24 (D. Mass. 1995).
- ⁴⁰ See, e.g., Neil Vidmar, *The Performance of the American Civil Jury: An Empirical Perspective*, 49 ARIZ. L. REV. 849, 863-66 (1998); Valerie P. Hans & Sanja Kutnjak Ivkovich, *Jurors and Experts*, 16 ADVOC. MAG. DEL. TRIAL LAW. 17 (1994).
- ⁴¹ Valerie P. Hans & William S. Lofquist, *Jurors' Judgments of Business Liability in Tort Cases: Implications for the Litigation Explosion Debate*, 26 L. & Soc'y Rev. 85 (1992).
- ⁴² Valerie P. Hans, The Contested Role of the Civil Jury in Business Litigation, 79 Judicature 242 (1990); Neil Vidmar, Medical Malpractice and the American Jury: Confronting the Myths About Jury Incompetence, Deep Pockets and Outrageous Damage Awards (1995).
- ⁴³ Valerie P. Hans, *The Illusions and Realities of Jurors' Treatment of Corporate Defendants*, 48 DEPAUL L. REV. 327 (1998).

- ⁴⁴ See, e.g., Wintz v. Northrop Corp., 110 F.3d 508 (7th Cir. 1997); Diaz v. Johnson Matthey, Inc., 893 F. Supp. 358, 372-74 (D.N.J. 1995); Sutera v. The Perrier Group, 986 F. Supp. 655, 667 (D. Mass. 1997).
- ⁴⁵ For general discussion, see Harvey Brown, *Eight Gates for Expert Witnesses*, 36 Hous. L. Rev. 743, 757-773 (1999).
- ⁴⁶ George A. Ackerlof, *The Market for "Lemons":* Qualitative Uncertainty and the Market Mechanism, 84 QUART. J. ECON. 488 (1970).
- ⁴⁷ See Jon Wiener, *Cancer, Chemicals and History*, THE NATION (Feb.7, 2005) (chemical companies issued subpoenas to historians who were not involved in the relevant litigation who had reviewed book written by expert hired by plaintiffs in toxic tort case).
- ⁴⁸ See, e.g., Devra Lee Davis, When Smoke Ran Like Water: Tales of Environmental Deception and the Battle Against Pollution 74-77, 126-133 (2002) (describing industry efforts to discredit research of scientists Mary Amdur and Herbert Needleman); Goldie Blumenstyk, *The Story of Syngenta and Tyrone Hayes at UC Berkeley: The Price of Research*, 50 Chronicle Higher Ed., issue 10, p. A26 (Oct. 31, 2003) (describing industry efforts to discredit work of Tyrone Hayes, showing risks from pesticide Atrazine); McGarity, *Our Science Is Sound Science, supra* note 27, at 914-921.
- ⁴⁹ McGarity, *Science in the Regulatory Process*, *supra* note 27, at 172-199.
- ⁵⁰ Elisa K. Ong & Stanton A. Glantz, Constructing "Sound Science" and "Good Epidemiology": Tobacco, Lawyers, and Public Relations Firms, 91 Am. J. Pub. HEALTH 1749 (Nov. 2001).
- ⁵¹ *Id.* See also Sheldon Rampton & John Stauber, Trust Us, We're Experts! How Industry Manipulates Science and Gambles With Your Future 229-244 (Center for Media and Democracy 2001).
- ⁵² See, e.g., Daubert v. Merrell Dow Pharmaceuticals, Inc. 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand from Supreme Court's ruling in Daubert, the Ninth Circuit stated that in decisions on admissibility, "one

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very significant fact to be considered is 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").

- ⁵³ See Lucinda Finley, *Guarding the Gate to the Courthouse*, 49 DePaul L. Rev. 335 (1999).
- ⁵⁴ See Schrott v. Bristol-Myers Squibb Co., 403 F.3d 940 (7th Cir. 2005).
- ⁵⁵ Sutera v. The Perrier Group, 986 F. Supp. at 664, quoting Allen v. Pennsylvania Engineering Corp., 102 F.3d 194, 198 (5th Cir. 1996).
- ⁵⁶ See, e.g., Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORN. L. REV. 773 (1997).
- ⁵⁷ Richard J. Pierce, Jr., *Causation in Government* Regulation and Toxic Torts, 76 WASH. U. L. Q. 1307, 107 (1998).
- ⁵⁸ *Joiner*, 522 U.S. at 141-142.

- ⁵⁹ See, e.g., Pierce v. Underwood, 487 U.S. 552, 588 (1998).
- 60 102 F.3d 194, 197 & n. 3 (5th Cir. 1996).
- ⁶¹ For other cases along the same lines, see Cuevas v. EI DuPont de Nemours & Co., 956 F.3d 1306, 1309-1311 (S.D. Miss. 1997); Glastetter v. Novartis Pharmaceuticals Corp., 107 F. Supp.2d 1015, 1030 (E.D. Mo. 2000).
- ⁶² For discussion, see David L. Faigman, *Appellate Review of Scientific Evidence Under Daubert*, 48 HASTINGS L.J. 969, 976-77, 978 (1997).
- 63 193 F.3d 613, 725-726 (3rd Cir. 1999). See also
 DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911
 F.2d 941, 952 (3rd Cir. 1990).
- ⁶⁴ See Margaret A. Berger, Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts, 97 COLUM. L. REV. 2117 (1997); Wagner, Choosing Ignorance, 82 CORN. L. REV. 773, supra note 56.
- ⁶⁵ Lisa Heinzerling & Cameron Powers Hoffman, Tortious Toxics, 26 Wm. & MARY ENVIL. L. & Pol. Rev. 67 (2001).

About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation and improved public access to information.



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