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## Article

### Judicial Analysis of Complex & Cutting-Edge Science in the *Daubert* Era: Epidemiologic Risk Assessment as a Test Case for Reform Strategies

ANDREW JURIS

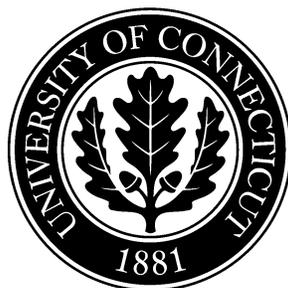
*Since Daubert, courts have faced difficulty with screening cutting-edge scientific evidence pursuant to Federal Rule of Evidence 702. By inconsistently handling particularly complex epidemiologic studies in Daubert reviews, judges analyzing this science exposed weaknesses of the Daubert system. Weaknesses of the Daubert regime include judicial skills with scientific methods, use of improper bright-line tests, outlier enhancement of experts, and the incompatibility of some judicial procedure with science. Each identified issue presents a reason why a judge may inaccurately evaluate scientific principles.*

*To address these identified weaknesses, this Article proposes modifications to the current system. One way to bring more science back into the courthouse, or to the judge's chambers, is to permit the appointment of a science consultant under a modified Federal Rule of Evidence 706. For an even smaller subset of more complex cases, advanced science procedures will be needed. A science panel approach, using a modified arbitration panel format, or a centralized court of scientific jurisdiction would have advantages over the current system.*

*By critically examining the breakdown of Daubert in the face of epidemiologic risk evidence, evaluating the nature of the weaknesses in the system, and creating reforms structured to respond to those concerns, we can modify the current Daubert system to allow judges to more consistently, accurately and efficiently handle the most complex, cutting-edge science presented in litigation.*

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# Judicial Analysis of Complex & Cutting-Edge Science in the *Daubert* Era: Epidemiologic Risk Assessment as a Test Case for Reform Strategies

ANDREW JURIS\*

## I. INTRODUCTION

In our American legal system, lawyers address controversies by reducing them to their essential elements, presenting them in a courtroom, and resolving them through the application of standard legal principles. Certainly this ideal works well enough for wide varieties of cases—criminal charges, a typical car crash, or contract disputes—subject to decision making within the general parameters of the courtroom with the application of general principles of law. Highly complex cases with disputed questions of scientific fact, however, cast doubt on the general principle.

Many commentators see science and the law as inherently incompatible, particularly with the most cutting-edge or complex science. Some highlight the distinction between the two methods of decision making: science finds truth through experiments and testing while law relies on rhetorical argument.<sup>1</sup> Another commentator states that the fundamental distinction is the handling of uncertainty: science recognizes uncertainty and acknowledges it, law results in clear decisions out of uncertain principles.<sup>2</sup> A third commentator states that the problem lies in the way judges review particularly complex science (e.g., toxicity evidence): scientists rely on all data available while judges rely on single sources to their detriment.<sup>3</sup>

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\* Assistant Professor of Law, Florida Coastal School of Law, 2009–present; Visiting Assistant Professor of Law, Wake Forest University, 2008–2009. J.D., University of California, Berkeley, School of Law (Boalt Hall); B.A., Stanford University. The author wishes to thank Michael D. Green, Sidney Shapiro, Ronald Wright, Dick Schneider, Kami Simmons, Scott Shepard, and Joseph Sanders for their comments on earlier versions of this work. Thanks also to Katie, Clara, and Milo, without whom this paper would not have been possible.

<sup>1</sup> Jan Beyea & Daniel Berger, *Scientific Misconceptions Among Daubert Gatekeepers: The Need for Reform of Expert Review Procedures*, LAW & CONTEMP. PROBS., Spring/Summer 2001, at 327, 333.

<sup>2</sup> Sander Greenland, *The Need for Critical Appraisal of Expert Witnesses in Epidemiology and Statistics*, 39 WAKE FOREST L. REV. 291, 293–94 (2004) [hereinafter Greenland, *Critical Appraisal*]. Some courts explicitly recognize this inherent limitation in the judicial versus scientific methods as well. See, e.g., *United States v. Mass. Water Res. Auth.*, 97 F. Supp. 2d 155, 157 (D. Mass. 2000).

<sup>3</sup> David E. Bernstein, *Expert Witnesses, Adversarial Bias, and the (Partial) Failure of the Daubert Revolution*, 93 IOWA L. REV. 451, 475–76 (2008).

If science and the law are fundamentally incompatible, as these scientists suggest, then what framework is appropriate for judicial review of difficult scientific principles?

Pursuant to the *Daubert* decision and Federal Rule of Evidence 702,<sup>4</sup> judges screen scientific expert testimony prior to presentation at trial.<sup>5</sup> The screening process exists to ensure evidentiary reliability and relevance so that only appropriate science is admitted at trial. In *Daubert*, the United States Supreme Court plainly stated, and therefore assumed, that judges would be able to make detailed determinations on all complex and cutting-edge scientific principles.<sup>6</sup> The Court had no data or studies to prove this assumption true, yet made it with the confidence that the proposition was unquestionable.

Since *Daubert* in 1993, contradictory case law in the area of epidemiologic risk assessment—a specialized area including highly complex and cutting-edge science—has cast doubt on the *Daubert* assumption of unquestioned judicial skill in expert testimony review. Case law in the area has been highly contradictory, and savagely critiqued by scientific reviewers.<sup>7</sup> Some courts have directly reversed course, requiring certain evidentiary underpinnings initially and then changing course in more recent cases.<sup>8</sup> Meanwhile, fundamental assumptions contained within the scientific data have been unrecognized or ignored. All of these factors from the epidemiologic risk controversy enhance uncertainty for litigants in future cases.

By examining and analyzing the cases, commentary, and theories surrounding the epidemiologic risk controversy, this Article first examines the weaknesses of the judicial handling of difficult scientific evidence under *Daubert*. By enumerating these weaknesses, one can begin to suggest reforms to address the problems in judicial evaluation of complex science. Systematic reforms allow judges the necessary tools to make appropriate *Daubert* determinations on the most cutting-edge or complex scientific controversies, such as the evidence from cases involving epidemiologic risk assessment. With these new procedural reforms in

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<sup>4</sup> Federal Rule of Evidence 702 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.

<sup>5</sup> *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993).

<sup>6</sup> *Id.* at 592–93.

<sup>7</sup> See *infra* Parts II.B.–D.

<sup>8</sup> See *id.*

place, courts can avoid the common problems with the evaluation of complex science under *Daubert*, and overcome the supposed incompatibility of the scientific and legal methodologies.

By reviewing the epidemiologic risk assessment case law and commentary, evaluating the weaknesses of judicial evaluation of complex science in the courtroom, and suggesting reform, this Article contends that judicial officers can more accurately, efficiently, and consistently handle controversies involving difficult scientific evidence.

## II. EPIDEMIOLOGIC RISK ASSESSMENT IN TOXIC TORT/PHARMACEUTICAL CASES

Epidemiology is a highly complex area of scientific inquiry, discussed in a large number of detailed toxic tort case decisions. Judges evaluating epidemiologic evidence for admissibility must use the *Daubert* test from Federal Rule of Evidence 702 for determining relevance and reliability.

To determine the difficulties with the judicial handling of epidemiologic risk, this section first briefly examines the general principles of the *Daubert* system and then examines how those principles have been applied in the epidemiologic risk case law. After reviewing the inconsistent case law on this topic, this section analyzes additional grounds that explain why epidemiologic risk case law provides a good example of difficult science in the courts.

### A. *Daubert Background*

Judicial recognition of Federal Rule of Evidence 702 as the mechanism for admission of expert testimony occurred in *Daubert*, almost twenty years after the initial adoption of Rule 702.<sup>9</sup> In doing so, the *ancien régime* of *Frye*<sup>10</sup> had been overthrown, replaced by judicial gatekeeping with a new two-pronged approach for judicial evaluation of science.

*Frye* required that proponents of scientific techniques prove that the techniques had gained general acceptance within the appropriate scientific community prior to admission in court.<sup>11</sup> During the last decade of the *Frye* regime, courts adopted a patchwork of rules whereby the *Frye* analysis would be applied for some testimony, while a Rule 702 approach would be applied to other cases, with the distinction being between those cases based on well-established theories and those employing new or novel science.<sup>12</sup>

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<sup>9</sup> *Daubert*, 509 U.S. at 585, 589, 597.

<sup>10</sup> *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

<sup>11</sup> *Id.* at 1014.

<sup>12</sup> *See, e.g., United States v. Bynum*, 3 F.3d 769, 773 (4th Cir. 1993) (discussing the argument presented at the trial court level as to whether the science was “new” and therefore a mandated

In contrast to the pre-1993 confusion with *Frye* and Rule 702 coexisting for different types of evidence, the universal *Daubert* standard promised an era of simplicity and efficient analysis of scientific expert testimony. To replace the general acceptance standard under *Frye*, the *Daubert* Court stated that Federal Rule of Evidence 702 required a two-pronged approach: judges would evaluate the reliability of the proposed testimony and then determine if it was relevant to the case.<sup>13</sup> Reliability is the measure of the scientific worthiness of the evidence, measured by multiple factors, including methodology, publication and peer review, known rate of error, and standards and controls, as well as the general acceptance.<sup>14</sup> Relevance measures the “fit” of the testimony to the controversy of the case.<sup>15</sup>

To make admissibility determinations on scientific evidence under Rule 702, judges should apply the *Daubert*/702 standard to the proffered testimony and decide if admissibility has been established. Dismissive of the difficulty of applying the test to some scientific principles, the *Daubert* Court stated plainly: “We are confident that federal judges possess the capacity to undertake this review.”<sup>16</sup>

In the case of highly complex or cutting-edge science, judges recognized immediately the burden placed upon them to make difficult decisions.<sup>17</sup> In the case of epidemiologic risk case law, judicial opinions both recognize this difficulty and display the problem with the approach.

#### B. *Epidemiology After Daubert: Daubert II and the Doubling-of-the-Risk Approach*

On remand in *Daubert II*, the Ninth Circuit faced review of the epidemiologic evidence under the new standards for judicial review of scientific evidence.<sup>18</sup> The panel commented on its review capability, stating that “judges ruling on the admissibility of expert scientific testimony face a far more complex and daunting task in a post-*Daubert* world than before.”<sup>19</sup> Acknowledging that the judges may not be qualified

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application of *Frye*); *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1132–34 (5th Cir. 1991) (debating whether only *Frye* applies only to novel techniques, or whether there should be a Rule 702 reliability analysis as well, and noting split in circuits on *Frye* applicability); *United States v. Hadley*, 918 F.2d 848, 853 (9th Cir. 1990) (rejecting party’s claims that *Frye*’s novel evidence theory should have applied rather than standard Rule 702 analysis); *United States v. Metzger*, 778 F.2d 1195, 1203–04 (6th Cir. 1985) (applying general acceptance test of *Frye*, but noting a circuit split on the issue).

<sup>13</sup> *Daubert*, 509 U.S. at 592–93.

<sup>14</sup> *Id.* at 593–94.

<sup>15</sup> *Id.* at 591 (internal quotation marks omitted).

<sup>16</sup> *Id.* at 593.

<sup>17</sup> See discussion *infra* Part II.B. and text accompanying notes 19–21.

<sup>18</sup> *Daubert v. Merrell Dow Pharm., Inc. (Daubert II)*, 43 F.3d 1311, 1315 (9th Cir. 1995).

<sup>19</sup> *Id.*

to do so, the panel described the process as “uncomfortable” and “daunting.”<sup>20</sup> All of this difficulty resulted in the panel deciding to “take a deep breath and proceed with this heady task.”<sup>21</sup>

The *Daubert* case on remand was heady indeed, although perhaps not in the same way the Ninth Circuit intended. While the judicial evaluation of complex science would be difficult, uncomfortable, or daunting in many cases involving science, the *Daubert II* panel faced a highly complex toxic tort case involving detailed epidemiologic studies with a battle of experts.<sup>22</sup>

In evaluating the epidemiologic evidence in the case, the court recognized that the relative risk ratio would be a critical issue in evaluation of the “fit” of the science to the controversy over Bendectin exposure.<sup>23</sup> Relative risk is the ratio of the incidence rate of disease in the exposed group as compared to an unexposed control group.<sup>24</sup> In the *Daubert* case the plaintiffs’ experts stated that Bendectin exposure *in utero* resulted in a statistically significant relative risk of birth defects that was less than two.<sup>25</sup> Plaintiffs presented this evidence to prove the causation element of their tort claim.

In deciding whether the plaintiffs had met their burden, the court first determined that a relative risk “exceed[ing] 2” equals the “more likely than not” standard of preponderance of the evidence, since above two the chance of illness from the exposure exceeds the background chance of disease from all other causes.<sup>26</sup> The court also stated that any relative risk of less than two tended to disprove causation.<sup>27</sup> Because the plaintiffs’ experts concluded that the relative risk from Bendectin exposure was less than two, the court concluded the plaintiffs could only show that the exposure “could possibly have caused” the injuries.<sup>28</sup> As a result, the court granted summary judgment to the defense.<sup>29</sup>

*Daubert II* provided a high-profile and detailed precedent for other courts to follow in their own analyses of epidemiologic evidence. Many

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<sup>20</sup> *Id.* at 1315–16.

<sup>21</sup> *Id.* at 1316.

<sup>22</sup> *Id.* at 1313–14, 1319.

<sup>23</sup> *Id.* at 1320–21 (internal quotation marks omitted).

<sup>24</sup> Michael D. Green et al., *Reference Guide on Epidemiology*, in FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 333, 348 (2d ed. 2000).

<sup>25</sup> *Daubert II*, 43 F.3d at 1320–21. The highest relative risk values for Bendectin and limb reduction birth defects stated in *Daubert II* were 1.6–1.7. Carl F. Cranor et al., *Judicial Boundary Drawing and the Need for Content-Sensitive Science in Toxic Torts After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 16 VA. ENVTL. L.J. 1, 37–38 (1996).

<sup>26</sup> *Daubert II*, 43 F.3d at 1321 (quoting *DeLuca v. Merrell Dow Pharm., Inc.*, 911 F.2d 941, 958 (3d Cir. 1990) (internal quotation marks omitted)).

<sup>27</sup> *Daubert II*, 43 F.3d at 1321.

<sup>28</sup> *Id.* at 1322 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 727 F. Supp. 570, 576 (S.D. Ca. 1989), *aff’d*, 951 F.2d 1128 (9th Cir. 1991), *vacated*, 506 U.S. 579 (1993)).

<sup>29</sup> *Id.*

courts would adopt reasoning similar to *Daubert II* in handling their gatekeeping review of epidemiologic evidence.

In one influential example, the U.S. District Court in Oregon addressed epidemiologic risk studies in the context of silicone breast implant litigation in *Hall v. Baxter Healthcare Corp.*<sup>30</sup> In *Hall*, the court reviewed extensive epidemiologic studies that had concluded the relative risk for silicone gel breast implants and connective tissue disease was no higher than 1.24.<sup>31</sup> The court then cited *Daubert II* regarding relative risk and the 2.0 standard: “[f]or an epidemiological study to show causation under a preponderance standard, the relative risk of [the condition at issue] arising from the epidemiological data . . . will, at a minimum, have to exceed ‘2’.”<sup>32</sup> Since the epidemiologic studies in question demonstrated a relative risk no higher than 1.24, the court concluded that the studies would not support a conclusion that the plaintiff’s diseases were “more likely than not” caused by the silicone implants.<sup>33</sup> The court even chastised the expert who attempted to testify regarding causation, stating that “[t]his is exactly the type of ‘junk science’ that the Supreme Court in *Daubert I* commanded courts to exclude.”<sup>34</sup> As a result, the plaintiff’s injury claim for the silicone implants would not proceed, as “*Daubert I* and *Daubert II* and their progeny command this disposition.”<sup>35</sup>

Similar analysis occurred outside the Ninth Circuit.<sup>36</sup> In *Allison v. McGhan Medical Corp.*, the Eleventh Circuit relied on both *Daubert II* and *Hall* in addressing epidemiologic evidence in a silicone breast implant case.<sup>37</sup> The court noted that the epidemiologic data regarding silicone breast implants and connective tissue diseases showed a relative risk of no greater than 1.24, and then affirmed the trial court’s finding that the studies were inadequate to prove causation.<sup>38</sup> As a result of this determination, and through analysis and rejection of other data on causation, the Eleventh Circuit affirmed summary judgment as granted by the district court.<sup>39</sup> Similar district court decisions requiring epidemiologic studies to reach a

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<sup>30</sup> *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1392, 1404 (D. Or. 1996).

<sup>31</sup> *Id.* at 1404–05 & n.37.

<sup>32</sup> *Id.* at 1403 (quoting *Daubert II*, 43 F.3d at 1321 (internal quotation marks omitted)).

<sup>33</sup> *Id.* at 1405 (internal quotation marks omitted).

<sup>34</sup> *Id.* at 1405 n.39.

<sup>35</sup> *Id.* at 1415. For a detailed analysis of the *Hall* case, see Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges Are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 352–56 (1999).

<sup>36</sup> For a detailed list of cases examining this issue, see RESTATEMENT (THIRD) OF TORTS § 28 cmt. c(4), note (Proposed Final Draft 2005).

<sup>37</sup> *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999).

<sup>38</sup> *Id.* at 1315 n.16, 1316.

<sup>39</sup> *Id.* at 1321–22.

doubling-of-the-risk standard before being admitted occurred in diverse jurisdictions evaluating many different toxicity claims.<sup>40</sup>

Doubling-of-the-risk methodology for review of epidemiologic evidence developed shortly after *Daubert*, and provided defendants a powerful argument for summary judgment in cases lacking relative risks over 2.0.

### C. Scientific Commentary on the Doubling-of-the-Risk Controversy

While the doubling-of-the-risk standard was not universally applied,<sup>41</sup> epidemiologists quickly reacted to *Daubert II* and its progeny. These commentators rejected the courts' analyses of the epidemiologic evidence, pointing out potential errors in these case opinions.

Much of the criticism involved the doubling-of-the-risk standard failing to represent what the courts thought it represented. The perception of a bright-line rule in the doubling-of-the-risk standard relied heavily on assumptions regarding other factors used by epidemiologists, assumptions about the use of population level statistics with specific plaintiffs, and policy choices unrelated to science. Each criticism must be addressed separately.

Doubling-of-the-risk methodology does have the potential to address the probability of injury, but only under extremely limited circumstances without additional complicating factors. In the example of birth defects and medication, as seen in *Daubert II*, the risk assessment works so long as all women respond identically to the medicine, and the toxic agent has no

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<sup>40</sup> Regarding breast implants, see, e.g., *Pozefsky v. Baxter Healthcare Corp.*, No. 92CV0314LEKRW, 2001 WL 967608, at \*3 (N.D.N.Y. Aug. 16, 2001) (citing *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1226 (D. Colo. 1998)); *Grant v. Bristol-Myers Squibb*, 97 F. Supp. 2d 986, 992 (D. Ariz. 2000) (citing *Allison*, 184 F.3d 1300); *Daubert II*, 43 F.3d 1311, 1320 (9th Cir. 1995); *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1226 (citing *Daubert II*, 43 F.3d at 1321; *Hall*, 947 F. Supp. at 1398).

Regarding pharmaceutical cases, see, e.g., *Kelley v. Sec'y of Health & Human Servs.*, 68 Fed. Cl. 84, 92 (2005) (quoting *Kelley v. Sec'y of Health & Human Servs.*, No. 02-223V, 2005 WL 1125671, at \*5 (Fed. Cl. Mar. 17, 2005), *rev'd on other grounds*, 68 Fed. Cl. 84 (2005)) (explaining that epidemiology must show relative risk greater than two to provide evidence of causation); *Burton v. Wyeth-Ayerst Labs.*, 513 F. Supp. 2d 719, 730 (N.D. Tex. 2007) (citing *Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706, 717-18 (Tex. 1997)); *In re W.R. Grace & Co.*, 355 B.R. 462, 483 (Bankr. D. Del. 2006) (citing *Daubert II*, 43 F.3d at 1320).

Regarding other substances, see, e.g., *Cotroneo v. Shaw Env'tl. & Infrastructure, Inc.*, No. H-05-1250, 2007 WL 3145791, at \*3 (S.D. Tex. Oct. 25, 2007) (citing *Havner*, 953 S.W.2d at 717) (discussing radioactive material); *Sanderson v. Int'l Flavors & Fragrances, Inc.*, 950 F. Supp. 981, 1004 (C.D. Cal. 1996) (citing *Daubert II*, 43 F.3d at 1320-22) (discussing perfume and cologne).

This is not merely a federal court phenomenon. See, e.g., *Havner*, 953 S.W.2d at 717 (citing *Daubert II*, 43 F.3d at 1321) (finding the doubling-of-the-risk requirement persuasive). *Havner* does hedge on the point, however, noting that this will not be considered a litmus test. *Id.* at 718.

<sup>41</sup> See discussion *infra* Part II.D.

effect on other causes of the disease.<sup>42</sup> The methodology fails to recognize the differentiation between individuals with higher or lower overall exposure.<sup>43</sup> It fails to recognize the difficulties caused by a particular individual's sensitivity to the toxic agent.<sup>44</sup> Another factor that complicates the extrapolation of relative risk ratio to causation involves the complication of scientific assessment because of late-occurring disease, following the initial outbreak or study.<sup>45</sup> Finally, and by no means exhaustively, epidemiologists noted that confusion among definitions of which cases of disease were to be included in mathematical modeling also affected risk calculations.<sup>46</sup>

As a result of these complicating factors escaping the judicial opinions, use of doubling-of-the-risk methodology provides a false sense of pure objective analysis lacking subjective input resulting from additional factor assessment.<sup>47</sup>

Another major criticism leveled against the doubling-of-the-risk assessment is that while it may be helpful in the determination of population-level risks, it fails as a useful tool in evaluating the risks to any particular plaintiff. Relative risk is the incidence ratio of an exposed population to the disease in an unexposed but otherwise similar population.<sup>48</sup> Professor of Epidemiology Sander Greenland notes plainly that “[a]ll epidemiologic measures (such as rate ratios and rate fractions) reflect only the net impact of exposure on a *population*.”<sup>49</sup> Measures like relative risk therefore simply do not address the causation of disease in any specific person: “Population-wide risk estimates simply do not address, and thus cannot be translated to, the probability of causation in any one individual.”<sup>50</sup>

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<sup>42</sup> Beyea & Berger, *supra* note 1, at 353.

<sup>43</sup> Cranor et al., *supra* note 25, at 39–40.

<sup>44</sup> *Id.*; see also Sander Greenland, *Relation of Probability of Causation to Relative Risk and Doubling Dose: A Methodologic Error that Has Become a Social Problem*, 89 AM. J. PUB. HEALTH 1166, 1168 (1999) [hereinafter Greenland, *Methodologic Error*].

<sup>45</sup> Russel Lynn S. Carruth & Bernard D. Goldstein, *Relative Risk Greater than Two in Proof of Causation in Toxic Tort Litigation*, 41 JURIMETRICS J. 195, 207 (2001).

<sup>46</sup> Greenland, *Methodologic Error*, *supra* note 44, at 1168 (noting that interchangeable use of terms such as etiologic fraction, attributable risk, and probability of causation often results in underestimations of the probability of causation).

<sup>47</sup> Beyea & Berger, *supra* note 1, at 356.

<sup>48</sup> Green et al., *supra* note 24, at 348.

<sup>49</sup> Greenland, *Methodologic Error*, *supra* note 44, at 1168 (emphasis added).

<sup>50</sup> Finley, *supra* note 35, at 352–58; see also Greenland, *Methodologic Error*, *supra* note 44, at 1168 (discussing variations within a population); Joseph V. Rodricks & Susan H. Rieth, *Toxicological Risk Assessment in the Courtroom: Are Available Methodologies Suitable for Evaluating Toxic Tort and Product Liability Claims?*, 27 REG. TOXICOLOGY & PHARMACOLOGY 21, 24–25 (1998) (“A population risk can be said to apply to individuals in that population, but only if it is assumed that all individuals are identical in respect of those characteristics . . . that have been assumed in the estimation of risks.”).

Because relative risk fails to apply to individual-level disease, the use of the relative risk number as the *sine qua non* of toxic tort causation appears misguided as a scientific principle.<sup>51</sup>

Finally, scientific commentary criticizes the doubling-of-the-risk case law as representing underlying policy choices rather than a pure science-based limitation. Epidemiologist Dr. Jan Beyea and his co-author criticize the doubling-of-the-risk standard as essentially raising the standard in science-related cases from a preponderance standard to a standard above beyond a reasonable doubt, partially due to unrealistic expectations by judges.<sup>52</sup> Other critics suggest that the debate over epidemiologic evidence hides a deeper debate over policy choices including who should bear the risk of harm from toxic exposure, wealth-shifting through tort, and the judge and jury balance of power.<sup>53</sup> At least one group even hypothesizes that the standard may exist to benefit the intransigence of industry and to close the courthouse door to plaintiffs.<sup>54</sup> Others mention that while the standard may deter plaintiffs due to the high burden, the doubling-of-the-risk standard also has the effect of removing desirable deterrence in the form of tort incentives for industry to develop safer products and perform detailed research on products.<sup>55</sup> All of these effects can disproportionately

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<sup>51</sup> Finley, *supra* note 35, at 348. Voluminous analysis discusses the doubling-of-the-risk standard, and general and specific causation. See Michael D. Green, *The Future of Proportional Responsibility*, in *EXPLORING TORT LAW* 352, 366–70 (M. Stuart Madden ed., 2005) (reviewing the debate of courts and commentators on the 2.0 standard); Carruth & Goldstein, *supra* note 45, at 200–02 (reviewing disparate judicial handling of the 2.0 standard).

Some see the 2.0 standard as not protective enough of the requirements of causation. While discounting the use of relative risk itself as the sole method of determining causation, Freedman and Stark argue that proof of causation in a specific case, even starting with a relative risk of four, was “unconvincing.” David A. Freedman & Phillip B. Stark, *The Swine Flu Vaccine and Guillain-Barré Syndrome: A Case Study in Relative Risk and Specific Causation*, 64 *LAW & CONTEMP. PROBS.* 49, 61 (2001) (citing *Manko v. United States*, 636 F. Supp. 1419, 1437 (W.D. Mo. 1986), *aff’d in part*, 830 F.2d 831 (8th Cir. 1987) (noting a relative risk of 3.89–3.92)); see also Bert Black & David Lilienfeld, *Epidemiologic Proof in Toxic Tort Litigation*, 52 *FORDHAM L. REV.* 732, 769 (1984) (arguing evidence is insufficient to establish causal link without “data that reasonably indicate a relative risk greater than 2”); Andrew W. Jurs, Daubert, *Probabilities and Possibilities, and the Ohio Solution: A Sensible Approach to Relevance Under Rule 702 in Civil and Criminal Applications*, 41 *AKRON L. REV.* 609, 637 (2008) (considering effect on jury and noting less than 2.0 may be inviting speculation).

<sup>52</sup> Beyea & Berger, *supra* note 1, at 358–59. Beyea and Berger are not the sole authors to recognize this phenomenon. See, e.g., Cranor et al., *supra* note 25, at 61.

<sup>53</sup> Cranor et al., *supra* note 25, at 61; see also Peter White, *A Relative Risk 2.0: The Ninth Circuit Revisits Daubert’s Epidemiological Standard in In re Hanford Nuclear Reservation Litigation*, 13 *S.E. ENVTL. L.J.* 33, 65–66 (2004) (“Judges usurp the jury’s function when they effectively dismiss claims based on what typically are considered factual issues [such as the 2.0 standard in *Daubert II*].”).

<sup>54</sup> David Egilman et al., *Proving Causation: The Use and Abuse of Medical and Scientific Evidence Inside the Courtroom—An Epidemiologist’s Critique of the Judicial Interpretation of the Daubert Ruling*, 58 *FOOD & DRUG L.J.* 223, 231 (2003).

<sup>55</sup> Finley, *supra* note 35, at 363–73; see also Thomas O. McGarity, *Proposal for Linking Culpability and Causation to Ensure Corporate Accountability for Toxic Risks*, 26 *WM. & MARY ENVTL. L. & POL’Y REV.* 1, 38 (2001).

impact racial minorities or women, who have traditionally received less research focus.<sup>56</sup>

All of these policy choices underlying the epidemiologic risk assessment debate involve important societal implications, but have less to do with the analysis of science methodologies and content, which were the intended focus of *Daubert* gatekeeping.

Scientific reaction to *Daubert II* and other similar case analyses of epidemiologic risk assessment in toxic tort litigation addressed in detail the underlying assumptions of the 2.0 standard used by the courts, the limitations of relative risk in causation, and the other potentially conflicting issues getting caught in the debate over scientific admissibility.

#### D. Other Courts Reject the 2.0 Standard, Before, and After *Daubert II*

While the Ninth and Eleventh Circuit Courts of Appeal adopted the doubling-of-the-risk standard after *Daubert*,<sup>57</sup> other U.S. courts of appeals did not mandate a bright-line approach. Several opinions before 2000 rejected the *Daubert II* approach, and by 2002 the Ninth Circuit had an opportunity to re-evaluate its adherence to the doubling-of-the-risk standard.

In the same year as the Ninth Circuit's decision in *Daubert II*, the Second Circuit addressed epidemiologic risk analysis in *In re Joint Eastern & Southern District Asbestos Litigation*.<sup>58</sup> In this case, the district court excluded certain epidemiologic studies as failing to establish a strong enough connection between the asbestos exposure and colon cancer.<sup>59</sup> While the district court noted that proof of causation could be established by studies showing a doubling-of-the-risk, or by studies with less than double the risk in addition to other evidence, the judge rejected studies under 2.0.<sup>60</sup> On appeal, the Second Circuit rejected the district court's bright-line approach to the studies on the issue of risk ratio, stating the court was "reluctant to adopt such an approach."<sup>61</sup> Rather, the appellate court would hold the district court to the standard of its own pronouncements, allowing less than double the risk epidemiologic data along with other materials to suffice to prove causation.<sup>62</sup> As a result, the court reversed the district court's directed verdict on the issue of causation,

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<sup>56</sup> Finley, *supra* note 35, at 373–74.

<sup>57</sup> See *supra* notes 26, 37 and accompanying text.

<sup>58</sup> 52 F.3d 1124 (2d Cir. 1995).

<sup>59</sup> *In re Joint E. & S. Dist. Asbestos Litig.*, 827 F. Supp. 1014, 1043 (S.D.N.Y. 1993), *aff'd in part and rev'd in part*, 52 F.3d 1127 (2d Cir. 1995).

<sup>60</sup> *Id.*

<sup>61</sup> *In re Joint E. & S.*, 52 F.3d at 1134.

<sup>62</sup> See *id.* (stating a preference for the district court to instruct the jury on the science and then let the jury weigh the studies).

but in doing so also rejected the formalism of the recently issued *Daubert II*.<sup>63</sup>

The Court of Appeals for the District of Columbia would first address epidemiologic risk while specifically addressing the doubling-of-the-risk methodology of *Daubert II*, in the decision in *Ambrosini v. Labarraque*.<sup>64</sup> The court specifically noted that the Ninth Circuit's formulation for relative risk assessment requires an opinion that risk had more than doubled.<sup>65</sup> However, the court rebuffed the *Daubert II* standard by stating that the epidemiologist's testimony regarding birth defects and pharmaceuticals "does not warrant exclusion simply because it fails to establish the causal link to a specified degree of probability."<sup>66</sup> While the court conceded that the testimony itself may be insufficient to carry the burden of proof on causation, the evidence remained admissible because it might assist the jury in finding whether the chemical caused the injuries.<sup>67</sup> As a result, the court reiterated that the epidemiologist's opinions on birth defects and pharmaceutical drugs were admissible under Federal Rule of Evidence 702.<sup>68</sup> The *Ambrosini* decision openly questioned the *Daubert II* approach, and created a split in the U.S. courts of appeals' approaches to epidemiologic risk analysis.

In 1999, just as *Daubert II*'s doubling-of-the-risk analysis gained support with the Eleventh Circuit's decision in *Allison*, the non-doubling approach would garner additional support after *Ambrosini* (and *In re Joint Eastern & Southern*). The Third Circuit analyzed complex epidemiologic data regarding nuclear radiation exposure in *In re TMI Litigation*.<sup>69</sup> In this case, scientific analysis evaluated the increased risk of cancer after the radiation exposure, and determined that an exposure of ten rems would equal the "doubling dose" for an exposed individual.<sup>70</sup> At the district court level, Judge Rambo determined that the plaintiffs would have to show radiation exposure of ten rems to each plaintiff in order to succeed in establishing causation.<sup>71</sup> As with the *Ambrosini* case, the court of appeals rejected the bright-line approach of the doubling dose requirements, and

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<sup>63</sup> *Id.* at 1139. *In re Joint E. & S.* does not mention *Daubert II* in the April 6, 1995, opinion, although *Daubert II* had been issued several months prior on January 4, 1995. *Id.*; *Daubert II*, 43 F.3d 1311, 1315 (9th Cir. 1995).

<sup>64</sup> 101 F.3d 129, 135 (D.C. Cir. 1996).

<sup>65</sup> *Id.* at 135 n.8.

<sup>66</sup> *Id.* at 135.

<sup>67</sup> *Id.* at 136.

<sup>68</sup> *Id.* at 135–36.

<sup>69</sup> 193 F.3d 613, 629 (3d Cir. 1999), *amended by* 199 F.3d 158 (3d Cir. 2000).

<sup>70</sup> *See In re TMI Litig.*, 927 F. Supp. 834, 845, 864–66 (M.D. Pa. 1996), *aff'd*, 89 F.3d 1106 (3d Cir. 1996), *and aff'd in part and rev'd in part*, 193 F.3d 613 (3d Cir. 1999), *and amended by* 199 F.3d 158 (3d Cir. 2000) (stating that a dose below ten rems is insufficient to infer more likely than not the existence of a causal link).

<sup>71</sup> *In re TMI Litig.*, 927 F. Supp. at 866–67.

overturned the summary judgment granted against some plaintiffs.<sup>72</sup> The *In re TMI Litigation* case established a break with prior Third Circuit precedent, particularly *In re Paoli Railroad Yard PCB Litigation*, which previously interpreted *Daubert*, along with the preponderance burden of proof, as requiring all expert opinions to rise to the level of probabilities.<sup>73</sup>

The Third Circuit was not the sole U.S. appellate court reconsidering prior analysis on this issue. In the decision issued in *In re Hanford Nuclear Reservation Litigation*, the Ninth Circuit directly addressed its analysis of relative risk from *Daubert II* and rejected the formalism of its prior approach.<sup>74</sup> In the decision, the court assessed the *Daubert II* reasoning, but adopted the language of the Third Circuit from *In re TMI Litigation*: “We agree with the Third Circuit that the validity of a claim should not depend on whether a plaintiff was exposed to a fraction of a rem lower than the ‘doubling dose.’”<sup>75</sup> As a result, the court found error in the district court’s determination that the epidemiologic evidence would have to show a relative risk exceeding 2.0 to be admitted.<sup>76</sup> Following *In re Hanford*, courts in the Ninth Circuit had a clear mandate to rethink the doubling-of-the-risk requirement of *Daubert II*.<sup>77</sup>

Additional case law outside the Third and Ninth Circuits demonstrates similar trends. In 2006, the U.S. District Court for the District of Colorado addressed epidemiologic evidence in the case of *Cook v. Rockwell International Corp.*<sup>78</sup> The U.S. District Court in Colorado had in 1998 adopted the *Daubert II* doubling-of-the-risk requirement on epidemiologic

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<sup>72</sup> *In re TMI Litig.*, 193 F.3d at 727. The summary judgment order affected plaintiffs who had not proceeded to trial, as the “Trial Plaintiffs” had proceeded on a theory of the case that all had received at least that dose of exposure. *Id.*

<sup>73</sup> *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 751–52 (3d Cir. 1994). *In re Paoli* does not appear to require a “doubling-of-the-risk” standard *per se*, and the case occurred before *Daubert II* so it does not address the *Daubert II* formulation. *See id.* (requiring expert opinions to rise to a reasonable degree of certainty). However, as most courts agree that doubling-of-the-risk equals the preponderance of the evidence standard, *In re Paoli* is consistent with the *Daubert II* decision. *Daubert II*, 43 F.3d 1311, 1321 (9th Cir. 1995) (stating that to show preponderance, risk ratio must exceed 2.0); *see also* Green et al., *supra* note 24, at 384 (“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.”).

At least one district court decision in the Third Circuit, which cites both *In re Paoli* and *In re TMI Litigation*, affirmed that the doubling-of-the-risk standard would not be a “password to a finding of causation,” rejecting the “mere conclusion-oriented selection process.” *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 605 n.27, 606–07 (D.N.J. 2002), *aff’d* 68 Fed. App’x 356 (3d Cir. 2003) (quoting *Landrigan v. Celotex Corp.*, 605 A.2d 1079, 1087 (N.J. 1992)).

<sup>74</sup> *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1136–37 (9th Cir. 2002). The companion case to *In re Hanford* is *In re Berg Litigation*, decided on the same day and based on the same analysis as *In re Hanford*. *In re Berg Litig.*, 293 F.3d 1127 (9th Cir. 2002).

<sup>75</sup> *In re Hanford*, 292 F.3d at 1137.

<sup>76</sup> *Id.*

<sup>77</sup> For an example of a case decided in the same year but before *In re Hanford*, see *Ferguson v. Riverside Sch. Dist. No. 416*, No. CS-00-0097-FVS, 2002 WL 34355958 (E.D. Wash. Feb. 6, 2002).

<sup>78</sup> 580 F. Supp. 2d 1071, 1088–89 (D. Colo. 2006).

evidence in the decision *In re Breast Implant Litigation*.<sup>79</sup> In addressing the connection between radiation from the Rocky Flats nuclear weapons plant and cancer incidence, the *Cook* court determined that the *Daubert II* requirement for admissibility of epidemiologic evidence “confuses the threshold question of whether an expert’s evidence is admissible with the separate question of whether it is sufficient to prove a particular point.”<sup>80</sup> In so finding, the district court rejected its prior use of the *Daubert II* standard by adoption of the non-2.0 standard.

This is not solely a federal phenomenon. In *In re Lockheed Litigation Cases*,<sup>81</sup> a California Court of Appeals addressed epidemiologic studies in a case involving chemical exposure in the workplace and disease incidence.<sup>82</sup> Of note, the California court would use the standard of causation for California that is identical to the standard used for the *Daubert II* ruling.<sup>83</sup> Even under the same standard of causation, the court in *Lockheed* rejected the imposition of the doubling-of-the-risk standard, noting: “[A] court cannot exclude an epidemiological study from consideration solely because the study shows a relative risk of less than 2.0.”<sup>84</sup>

Appellate courts rejected a bright-line doubling-of-the-risk approach around the same time as *Daubert II*, in *In re Joint Eastern & Southern Asbestos Litigation* and *Ambrosini*.<sup>85</sup> During the next seven years, the Third Circuit’s rejection of the *In re Paoli* analysis in *In re TMI Litigation* and the Ninth Circuit’s re-evaluation of epidemiologic standard in *In re Hanford* provided evidence of a profound switch in analysis.<sup>86</sup>

The profound disagreement between the courts addressing epidemiologic risk evidence in the immediate aftermath of *Daubert*, and the later re-evaluation of the issues by some of those courts, indicate that

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<sup>79</sup> *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1226 (D. Colo. 1998) (citing *Daubert II*, 43 F.3d 1311, 1321 (9th Cir. 1995); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1398 (D. Or. 1996)).

<sup>80</sup> *Cook*, 580 F. Supp. 2d at 1083 n.8, 1084 (citing *Daubert II*, 43 F.3d at 1315). The *Cook* court also cited papers by epidemiologists Sander Greenland and David Egilman et al., both of which address concerns on court use/misuse of epidemiology and statistics. *Id.* at 1102–03; see also Greenland, *Critical Appraisal*, *supra* note 2, at 297–301; Egilman et al., *supra* note 54, at 236–41.

<sup>81</sup> 23 Cal. Rptr. 3d 762 (Cal. Ct. App. 2005).

<sup>82</sup> *Lockheed Litig.*, 23 Cal. Rptr. 3d at 765. The diseases alleged included brain, liver, and kidney damage. Appellants’ Opening Brief at 2, *Lockheed Litig.*, 23 Cal. Rptr. 3d 762 (Cal. Ct. App. 2005) (No. B166347), 2003 WL 23281037.

<sup>83</sup> *Lockheed Litig.*, 23 Cal. Rptr. 3d at 777 (citing *Daubert II*, 43 F.3d at 1320).

<sup>84</sup> *Id.* at 778.

<sup>85</sup> *Ambrosini v. Labarraque*, 101 F.3d 129, 135–36 (D.C. Cir. 1996); *In re Joint E. & S. Dist. Asbestos Litig.*, 52 F.3d 1124, 1134 (2d Cir. 1995).

<sup>86</sup> *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1137 (9th Cir. 2002); *In re TMI Litig.*, 193 F.3d 613, 727 (3d Cir. 1999), *amended by* 199 F.3d 158 (3d Cir. 2000); see also *Cook v. Rockwell Int’l Corp.*, 580 F. Supp. 2d 1071, 1083 n.8, 1084 (D. Colo. 2006) (adopting a reasonable certainty standard of causation).

judges have been either confused or inconsistent on complex epidemiologic evidence. As a result, the doubling-of-the-risk controversy provides an outstanding example of judicial handling of complex science.

E. *Why Is This a Good “Test Case” for Science in the Courtroom?*

Independent of the inconsistent handling of epidemiologic risk assessment by appellate circuits and district courts, several attributes of the relative risk controversy add to its usefulness as an example of complex or cutting-edge science in the courtroom. These features include epidemiologic research as a field of scientific analysis involving significant complexity, epidemiology as a relatively young scientific discipline lacking consensus within the field on its use in torts, and epidemiologic proof as the sole method of proving causation for certain cases.

1. *Epidemiology as a Scientific Field Containing Areas of Significant Complexity*

Epidemiology is a field of scientific research that contains areas of highly complex and specialized analysis. As a result, some judicial interpretation of epidemiology using the *Daubert* analysis comes out of a desire to seek clarity from confusion. But in doing so, the courts miss subtleties about the science that cast doubt on the proposition that judicial interpretations represent what the courts intend.

Clearly the responsibility of a district court screening the most detailed and complex research in epidemiology is a difficult task. The *In re Joint Eastern & Southern* court noted that sufficiency of proof in epidemiologic evidence cases “poses unique difficulties for trial courts.”<sup>87</sup> The United States Supreme Court in *Daubert* had previously declared that judges would “possess the capacity to undertake” this difficult task, although the Ninth Circuit disagreed as well, calling the review of epidemiology in *Daubert II* “uncomfortable” and “daunting.”<sup>88</sup>

The opinions of Judge Jones in *Hall* and Judge Sparr in *In re Breast Implant Litigation* demonstrate courts reviewing complex epidemiologic studies but focusing mostly on relative risk ratios.<sup>89</sup> Each judge evaluated a series of epidemiologic studies, but then focused most of their attention on the relative risk number of 1.24 from a published study on breast

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<sup>87</sup> *In re Joint E. & S.*, 52 F.3d at 1133.

<sup>88</sup> *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593 (1993); *Daubert II*, 43 F.3d 1311, 1315–16 (9th Cir. 1995); see *supra* notes 13–15 and accompanying text (summarizing *Daubert* decisions).

<sup>89</sup> *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1221, 1225–29 (D. Colo. 1998); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1391, 1403–05 (D. Or. 1996).

implant illnesses.<sup>90</sup> In these cases, judges missed or rejected analysis of complicating factors in the field which lessen the overall importance of relative risk ratios in declaring cause for an individual plaintiff.<sup>91</sup>

Epidemiology is the science of evaluating whether a particular exposure caused a particular disease.<sup>92</sup> Relative risk is one indicator epidemiologists may use in their evaluation of causation, but alone it serves only to show an association rather than cause.<sup>93</sup> To go from association to a causal connection, an epidemiologist analyzes multiple other factors in testing the validity of association.<sup>94</sup> Only after a detailed analysis of all factors may the expert form a final conclusion about whether the causative effect has been proven.<sup>95</sup>

As a highly complex science, judges untrained in science, and the lawyers in their courtrooms, will be less skillful in the field than practitioners. Granting judicial oversight authority on science must come with the recognition that judges may be ill-suited to the task.<sup>96</sup> Epidemiology provides one dramatic example of the difficulties judges have with complex science in the courtroom, and through this example the need for reform becomes clearer.<sup>97</sup>

## 2. *No Consensus Among Epidemiologists on Tort Applications of Their Research*

The field of epidemiology is a relative newcomer to the scientific research community, when compared to more established and recognized fields like medicine or engineering. As a result, the epidemiology

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<sup>90</sup> Hall, 947 F. Supp. at 1404–05 (citing Charles H. Hennekens et al., *Self-Reported Breast Implants and Connective-Tissue Diseases in Female Health Professionals*, 275 JAMA 616, 616 (1996) (showing a 1.24 relative risk of breast implants to connective tissue diseases)); In re *Breast Implant Litig.*, 11 F. Supp. 2d at 1227 (reviewing the same study).

<sup>91</sup> Finley, *supra* note 35, at 352–62.

<sup>92</sup> Green et al., *supra* note 24, at 374; see generally KENNETH J. ROTHMAN ET AL., MODERN EPIDEMIOLOGY (3d ed. 2008).

<sup>93</sup> See Green et al., *supra* note 24, at 348, 376 (“Relative risk measures the strength of the association.”); see also Greenland, *Methodologic Error*, *supra* note 44, at 1166 (“[P]robability of causation cannot be computed solely from the relative risk.”); Melissa Moore Thompson, Comment, *Causal Inference in Epidemiology: Implications for Toxic Tort Litigation*, 71 N.C. L. REV. 247, 256, 263–64 (1992) (noting that causation cannot be determined solely from mathematics).

<sup>94</sup> Green et al., *supra* note 24, at 375–76; Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. ROYAL SOC’Y MED. 295, 295–99 (1965) (setting forth nine factors to evaluate in determining causation). For commentary on the influence of the Bradford Hill factors in determining cause, see Egilman et al., *supra* note 54, at 241 (“Hill’s considerations are well accepted and have been widely used by epistemologists.”); Thompson, *supra* note 93, at 266–67 (stating that the Bradford Hill criteria are widely used by epidemiologists to determine causation).

<sup>95</sup> See Finley, *supra* note 35, at 359–63 (reviewing the different factors epidemiologists use in forming a judgment on causation); Thompson, *supra* note 93, at 267.

<sup>96</sup> See discussion *infra* Part III.A.

<sup>97</sup> See discussion *infra* Part IV.

presented in the courtroom lacks a critical component of other scientific fields which judges can rely upon: consensus within the field on the application of the research to tort or other legal use. As a result, judges find themselves instituting standards on scientific endeavors, like in the doubling-of-the-risk controversy.

In a field of established scientific research like medicine, courts face several advantages in making *Daubert* determinations. First, the parameters of the field of medicine are more commonly understood by laypersons, partially as a consequence of the age of the discipline but also from individual experiences with a physician.<sup>98</sup>

Second, professional associations in medicine have developed some generally accepted standards for the presentation of expert testimony in the courtroom.<sup>99</sup> For example, physicians testifying in a tort case will understand that a key component will be whether the care was within or outside the “standard of care.”<sup>100</sup> While physicians may differ on the conclusion, the framework for the analysis is well understood and relatively clear. Finally, the medical profession has worked together with the legal profession in forming joint committees to draft interprofessional codes of formalized standards for expert witnesses, like the American Medical Association (“AMA”)–American Bar Association (“ABA”)

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<sup>98</sup> Larry A. Green et al., *The Ecology of Medical Care Revisited*, 344 NEW ENG. J. MED. 2021, 2023 (2001) (stating that in a typical month, over twenty percent of adults in the United States visit a physician); Eric W. Nawar et al., U.S. Dep’t Health & Human Servs., *National Hospital Ambulatory Medical Care Survey*, in ADVANCE DATA FROM VITAL AND HEALTH STATISTICS, NO. 386, at 1, 2 (2007) (noting 115.3 million emergency room visits in the United States in 2005, for a population of 296 million); *see also*, *Minnesota v. Brom*, 463 N.W.2d 758, 767–68 (Minn. 1990) (Wahl, J., dissenting) (reviewing studies showing one of three Americans has sought or has had a family member seek help from a psychiatrist or psychologist).

<sup>99</sup> HEALTH AND ETHICS POLICIES OF THE AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES §§ 265.992 (Expert Witness Testimony), 265.994 (Expert Witness Testimony—Clinical Issues), 265.995 (Guidelines for Expert Witness), 265.997 (AMA-ABA Statement on Interprofessional Relations for Physicians and Attorneys), available at <http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf>. While aspirational, these guidelines serve as a reminder of a proposed minimal standard for expert witness conduct and ethics, and represent the involvement of the profession in standardizing legal application of the science. *See* Aaron S. Kesselheim & David M. Studdert, *Role of Professional Organizations in Regulating Physician Expert Witness Testimony*, 298 JAMA 2907, 2909 (2007) (“The increase in extrajudicial regulation of physicians in their capacity as expert witnesses . . . is unmistakable.”).

<sup>100</sup> *See, e.g.*, James A. Henderson, Jr. & John A. Siliciano, *Universal Health Care and the Continued Reliance on Custom in Determining Medical Malpractice*, 79 CORNELL L. REV. 1382, 1384 (1994) (“The central legal task in . . . a medical malpractice suit, is to determine the standard of care . . . [using] the customary practices of the medical profession as the benchmark of acceptable behavior.”); Theodore Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 WIS. L. REV. 1193, 1212–13 (1992) (noting that custom-based standard of care defines physician duty). Certain commentators see a trend of courts shifting away from custom-based standards of care. *See, e.g.*, Phillip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 164 (2000).

Statement on Interprofessional Relations for Physicians and Attorneys.<sup>101</sup> Through more generalized consensus, a field of science like medicine can create for itself certain standards for legal use of the science, thus relieving the court of the burden of implementing those standards on an unfamiliar field.

Epidemiology lacks the structures that assist judges in these more established fields. First, most citizens or judges have little experience dealing with epidemiologic analysis, and the concepts in expert epidemiologic testimony are difficult.<sup>102</sup> Second, the field of epidemiology lacks inherent standards for tort legal use. Epidemiology developed largely in the area of regulatory law, regarding questions of population-level risks from exposures to toxic agents.<sup>103</sup> Noted epidemiologist Dr. Joseph Rodricks and his coauthor observe that within the regulatory application of epidemiology, “many methodological concepts are clear and reasonably well accepted. This is not at all the case regarding the issues that arise in tort and product liability cases.”<sup>104</sup> The result is that debates over epidemiologic methodology occur within the courtroom with the judge as the referee, rather than outside the heated context of an individual case.<sup>105</sup> Finally, there is little interprofessional involvement of the communities of the type exemplified by the AMA and ABA.<sup>106</sup> All of these factors combine to leave judges as the arbiters of the legal application of complex science, but only within a single case and without systematic guidance.

The fact that the field of epidemiology is relatively new to science, has focused more on the regulatory application of the discipline, and lacks interprofessional codes for tort legal use, results in judges making fundamental rules about application of the science within the courtroom to a much greater extent than in more established fields. As with the fundamental complexity of the field, this scenario results in an important test case on the limits of judicial decision making in the *Daubert* regime.

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<sup>101</sup> HEALTH AND ETHICS POLICIES OF THE AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES, *supra* note 99, § 265.997. Joint interprofessional committees are common on the state and local level as well. See Andrew W. Jurs, *The Rationale for Expert Immunity or Liability Exposure and Case Law Since Briscoe: Reasserting Immunity Protection for Friendly Expert Witnesses*, 38 U. MEM. L. REV. 49, 90–91 n.232 (2008) (listing state and local interprofessional organizations and codes).

<sup>102</sup> Neil Vidmar & Shari Seidman Diamond, *Juries and Expert Evidence*, 66 BROOK. L. REV. 1121, 1146–48 (2001) (reviewing studies evaluating jury confusion regarding epidemiologic evidence); see also *In re Welding Fume Prods. Liab. Litig.*, No. 1-03-CV-17000, 2005 WL 1868046, at \*34 n.78 (N.D. Ohio Aug. 8, 2005) (recognizing that epidemiology evidence challenges jurors with complex issues of methodology). For additional discussion on this issue, see *infra* Part III.A.

<sup>103</sup> Rodricks & Rieth, *supra* note 50, at 23, 31.

<sup>104</sup> *Id.* at 31.

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

### 3. *Epidemiology Alone as Evidence of Causation in Toxic Tort Cases*

In addition to the fundamental complexity of the field and the lack of standards for tort legal use, a third factor also contributes to the example of epidemiology as a good test case for the application of the *Daubert* standard to science: the use of epidemiologic analysis as the sole method for proof of the causation element in complex tort cases.

In establishing a claim for toxic exposure, a critical connection for the jury to make will involve the connection between exposure to a chemical and a particular disease of the plaintiff. Randomized experimental studies with a control group are the ideal type of study to measure the relationship between exposure and disease.<sup>107</sup> The Food and Drug Administration requires these randomized controlled studies in making determinations of whether a new drug is “safe and effective” under federal law.<sup>108</sup> Controlled studies are not ethical for harmful agents, however.<sup>109</sup>

Without the controlled randomized studies, and in the absence of advanced knowledge on the molecular and biologic pathology of the disease course, epidemiologic studies by a trained researcher must provide the evidence of a causal link.<sup>110</sup> The studies will evaluate the health outcomes in a population and compare the substances to similar chemicals.<sup>111</sup> Then, a trained epidemiologist may develop an informed, but necessarily subjective, conclusion on causation.<sup>112</sup>

As a result of the inability to perform other studies, and the lack of more definitive biological or pathological evidence of causation, the epidemiologist’s analysis and informed opinion will provide the court with the main, or sole, evidence on the issue of causation.<sup>113</sup> With the causal connection resting in epidemiologic proof alone, the courts must assess these studies in isolation. Consequently, the studies are indispensable to plaintiffs in toxic tort litigation.<sup>114</sup> More succinctly, the initial *Federal Judicial Center Reference Manual on Scientific Evidence* (“Reference Manual”) noted: “In the absence of an understanding of the biological and

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<sup>107</sup> Green et al., *supra* note 24, at 338.

<sup>108</sup> 21 U.S.C. § 355 (2009); 21 C.F.R. § 312.21 (2009).

<sup>109</sup> Green et al., *supra* note 24, at 339.

<sup>110</sup> Beyea & Berger, *supra* note 1, at 355–56.

<sup>111</sup> Mark Geistfeld, *Scientific Uncertainty and Causation in Tort Law*, 54 VAND. L. REV. 1011, 1012 (2001).

<sup>112</sup> Beyea & Berger, *supra* note 1, at 356–57; Green, *supra* note 51, at 375.

<sup>113</sup> Martin L. Norton, *The Physician Expert Witness and the U.S. Supreme Court—An Epidemiologic Approach*, 21 MED. & L. 435, 440–41 (2002).

<sup>114</sup> Michel F. Baumeister & Dorothea M. Capone, *Admissibility Standards as Politics—The Imperial Gate Closers Arrive!!!*, 33 SETON HALL L. REV. 1025, 1032 (2003); *see also In re Joint E. & S. Dist. Asbestos Litig.*, 827 F. Supp. 1014, 1026–28 (S.D.N.Y. 1993) (describing the usefulness of epidemiological evidence).

pathological mechanisms by which disease develops, epidemiological evidence is *the most valid* type of scientific evidence of toxic causation.”<sup>115</sup>

Following the Reference Manual affirming the importance of epidemiologic studies in the absence of other methods of causation, courts would adopt similar language. In *In re Breast Implant Litigation*, Judge Sparr wrote: “Epidemiology is the best evidence of causation in the mass torts context.”<sup>116</sup> In a drug tort case, *Hollander v. Sandoz Pharmaceuticals Corp.*, Judge Thompson cited both the Reference Manual and Judge Sparr for the proposition that the epidemiologic evidence would be “*the most valid* type of scientific evidence of toxic causation.”<sup>117</sup>

Because of its crucial role in toxic torts, and because of its isolation in establishing causation in the absence of other definitive studies, courts evaluating epidemiology in toxic tort cases handle complex, but similar, fact questions at the cutting-edge of science. The test cases provide a sample of judges dealing with similar cases, similar issues, and even identical scientists, showing how the judiciary *as a whole* handles the most difficult *Daubert* challenges.

#### 4. Result

With a combination of these factors—the complexity, the lack of standards within the profession for tort-legal use, and the use of epidemiology alone to prove causation—courts reach the outer limits of their capacity to make difficult gatekeeping determinations under *Daubert*. Inconsistent handling of the evidence appears as one result.<sup>118</sup> However, the combination of these factors makes the judicial handling of epidemiologic risk analysis a “test case” for the *Daubert* regime, and exposes difficulties that can be anticipated for future Rule 702 reviews.

### III. EPIDEMIOLOGIC RISK CASES SHOW WEAKNESSES IN JUDICIAL HANDLING OF SCIENCE

Since *Daubert*, the epidemiologic risk assessment controversy cases demonstrate judges’ treatment of complex cutting-edge epidemiologic science, thereby providing a discrete group of opinions on which the judicial ability to handle complex science can be assessed. Evaluating the

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<sup>115</sup> Linda A. Bailey et al., *Reference Guide on Epidemiology*, in FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 121, 126 (1st ed. 1994) (emphasis added).

<sup>116</sup> *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998) (citing Bailey et al., *supra* note 115, at 126).

<sup>117</sup> *Hollander v. Sandoz Pharm. Corp.*, 95 F. Supp. 2d 1230, 1235 n.14 (W.D. Okla. 2000), *aff’d in part*, 289 F.3d 1193 (10th Cir. 2002) (quoting *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1224; Bailey et al., *supra* note 115, at 126) (emphasis added) (internal quotation marks omitted).

<sup>118</sup> See discussion *supra* Parts II.B.–D.

judicial opinions in these cases demonstrates some of the weaknesses of the *Daubert* regime.

Some of the difficulties seen in the epidemiologic risk controversy include basic judicial knowledge of scientific processes, the judicial handling of statistical/mathematical evidence, use of bright-line tests that may not be scientifically sound, outlier enhancement of experts, and the constraints of legal procedure on science. By evaluating each of these difficulties, we can recognize inherent weaknesses in the judicial handling of complex science in the epidemiologic risk controversy that may also affect other cutting-edge scientific controversies subject to *Daubert* review.

#### A. *Judicial Knowledge of and Background with Scientific Principles*

Epidemiologic risk case law shows judges evaluating extremely complex science, in a field lacking consensus among researchers, when the admissibility decision will either permit the plaintiff to proceed, or end the case. *Daubert* anticipated that judges would be placed in this role.<sup>119</sup> In the epidemiologic risk controversy, judges are openly skeptical of their abilities to analyze the epidemiologic evidence, but then must in detail analyze the expert opinions on the science.<sup>120</sup> Do judges have the skills to make these decisions? Justice Stephen Breyer remains skeptical: “[M]ost judges lack the scientific training that might facilitate the evaluation of scientific claims or the evaluation of expert witnesses who make such claims.”<sup>121</sup>

In evaluating the judicial capacity to analyze complex science, two essential questions should be addressed: the scientific background of the judiciary, and judicial familiarity with the essential components of the scientific method. By reviewing the research on these issues, some doubt in the *Daubert* assumption that judges “possess the capacity to undertake this review” must be acknowledged.<sup>122</sup>

Two studies performed by social science researchers directly measured the scientific background of judges.<sup>123</sup> In a 2001 study, Sophia Gatowski and her colleagues surveyed 400 state court judges to determine their scientific backgrounds, their views on *Daubert*, and their knowledge of

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<sup>119</sup> *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592–93 (1993).

<sup>120</sup> *E.g., Daubert II*, 43 F.3d 1311, 1316 (9th Cir. 1995).

<sup>121</sup> Stephen Breyer, *Introduction* to FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE I, 4 (2d ed., 2000).

<sup>122</sup> *Daubert*, 509 U.S. at 593.

<sup>123</sup> See Sophia I. Gatowski et al., *Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-Daubert World*, 25 LAW & HUM. BEHAV. 433, 435 (2001); Valerie P. Hans, *Judges, Juries, and Scientific Evidence*, 16 J.L. & POL’Y 19, 19–21 (2007).

scientific principles.<sup>124</sup> The results show that judges lack preparation for their *Daubert* role.

When asked to discuss their educational training, 85% of judges had some social science coursework in their past, while 77% had coursework in the physical sciences, and 67% in biological sciences.<sup>125</sup> Finally, while some judges did get training in specific scientific areas, a vast majority (96%) of those judges found the training lacking on the *general* scientific methods and principles.<sup>126</sup> In conclusion, judges split 52% to 48% on the issue of whether they had enough science in their background to prepare them for the complex issues handled under *Daubert*.<sup>127</sup> As a result, the Gatowski study shows that judges themselves question their experience to make the tough calls necessary under *Daubert*.

Dr. Valerie Hans's study involving judicial background sheds additional light on this issue.<sup>128</sup> Dr. Hans surveyed judges in order to compare their reactions to juror responses in her study *Judges, Juries, and Scientific Evidence*.<sup>129</sup> By surveying sixty-five judges, all of whom attended a "Science for Judges" conference, Hans provided additional insight into judicial scientific background.<sup>130</sup>

In the Hans study, judges reported 10.29 classes from high school and college in math and science, compared to the jurors' average of 9.72.<sup>131</sup> When compared to jurors with college degrees—who showed an average of 14.04 classes—as opposed to the overall jury pool, judges showed a significant deficit in math and science training.<sup>132</sup> Of the sixty-five judges surveyed, only five (7.7%) reported having some job experience with math or science.<sup>133</sup>

Through the Gatowski and Hans studies, empirical research demonstrates that the judiciary is poorly prepared to handle the difficult scientific issues presented in courtrooms. Average jurors are not statistically worse off than judges, and judges are deficient as compared to a group of college-educated jurors.<sup>134</sup> The judges themselves recognize

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<sup>124</sup> Gatowski et al., *supra* note 123, at 435.

<sup>125</sup> *Id.* at 442. For a comparison of this data to the data from Dr. Hans's study, see *infra* notes 131–32 and accompanying text.

<sup>126</sup> Gatowski et al., *supra* note 123, at 442.

<sup>127</sup> *Id.*

<sup>128</sup> Hans, *supra* note 123, at 19–20.

<sup>129</sup> *Id.* at 29.

<sup>130</sup> *Id.* at 28.

<sup>131</sup> *Id.* at 30. Dr. Hans saw this difference as not statistically different. *Id.*

<sup>132</sup> *Id.* This appears to be a more appropriate sample with which to compare judges, who have college and law degrees.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.*

this deficiency, splitting on the issue of whether they have the background to make decisions on *Daubert* issues.<sup>135</sup>

Background need not condemn judges to inadequate performance, however, so it is also important to review judicial scores on their current ability to handle science. In the Gatowski study, judges responded to questions on basic scientific study principles, regarding falsifiability, error rate, peer review, and general acceptance.<sup>136</sup> Judges answered that these factors, enumerated in the *Daubert* opinion for the review of scientific reliability,<sup>137</sup> were useful in evaluating science under *Daubert*.<sup>138</sup> In defining some of these admittedly important principles, the judges scored poorly. On the issue of error rate, the study indicated that only four percent of the sample judges could correctly demonstrate “true understanding” of the concept.<sup>139</sup> On the issue of falsifiability, the study indicated that only six percent of judges could demonstrate a “true understanding” of the principle.<sup>140</sup> While scores for peer review and general acceptance were higher,<sup>141</sup> Gatowski’s study shows a judiciary struggling with basic scientific concepts.

Hans also studied judicial performance on application of scientific principles, by testing judicial and juror responses to a questionnaire regarding DNA evidence after a videotaped mock trial on the issue.<sup>142</sup> Out of eleven questions regarding the DNA evidence, judges fared better than the total jury pool on three questions.<sup>143</sup> When compared to the college-educated juror group, the judges scored lower than the jurors on three of the eleven questions, and exceeded the college-educated jurors on one question.<sup>144</sup> Again considering that judges all will be college-educated,<sup>145</sup> this performance is underwhelming.

In the epidemiologic risk controversy, basic definitional errors about the application of relative risk resulted in judges evaluating epidemiologic evidence outside its usual application.<sup>146</sup> It is important to note that we need not assume that judges have little experience with epidemiology from

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<sup>135</sup> Gatowski et al., *supra* note 123, at 442.

<sup>136</sup> *Id.* at 444–48.

<sup>137</sup> *Daubert*, 509 U.S. 579, 593–94 (1993).

<sup>138</sup> Gatowski et al., *supra* note 123, at 444–47 (noting favorable responses of falsifiability (88%), error rate (91%), peer review (92%), and general acceptance (93%)).

<sup>139</sup> *Id.* at 447.

<sup>140</sup> *Id.* at 444.

<sup>141</sup> *See id.* at 447–48 (noting results of 71% peer review and 82% general acceptance).

<sup>142</sup> Hans, *supra* note 123, at 29.

<sup>143</sup> *Id.* at 36.

<sup>144</sup> *Id.* at 37–38.

<sup>145</sup> *See supra* note 132 and accompanying text (noting that in the Hans study, “judges showed a significant deficit in math and science training”).

<sup>146</sup> *See supra* text accompanying notes 48–50 (discussing the difficulty of using a population-wide study to assess the risks of an individual).

the case law alone; rather, the Gatowski study indicated that a large majority of judges had “no experience at all” with epidemiology.<sup>147</sup> Use of epidemiology to extrapolate causation to a specific plaintiff requires the legal use of epidemiologic definitions beyond the scope of what researchers would do in the lab.<sup>148</sup> Lack of familiarity with the complexities of the scientific field, based on background demographics or understanding of concepts, appears to play a role in these errors.

When this data is reviewed in relation to the epidemiologic risk controversy,<sup>149</sup> one must wonder if the judges are truly “up to the task” as *Daubert* assumed.<sup>150</sup> Reform efforts should address judges’ deficit in training and application of scientific principles, seeking a solution to the weaknesses exposed by the empirical research of Gatowski and Hans.<sup>151</sup>

### B. *Judicial Difficulty with the Use of Statistics*

General scientific principles are not the sole area where judges score poorly in empirical studies.<sup>152</sup> The judicial handling of complex statistical data is a distinct and critically important part of the *Daubert* system, mandating review for judicial competence.

In an important study on the issue of judicial handling of statistical information, Dr. Gary Wells studied the handling of statistics by judges as compared to mock jurors (psychology students).<sup>153</sup> By presenting the jurors and judges with varying statistical information on a potential liability issue in a mock case, and then comparing the data with results from a similar probability issue without the statistical involvement, Wells concluded that judges and the mock jurors were equally poor in analysis of

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<sup>147</sup> Gatowski et al., *supra* note 123, at 442 (noting that seventy-three percent of judges have no experience at all with epidemiology).

<sup>148</sup> See, e.g., *Daubert II*, 43 F.3d 1311, 1321–22 (9th Cir. 1995) (noting experts were unable to provide sufficient evidence to prove causation); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1403–04 (D. Or. 1996) (discussing *Daubert II* and applying its evidentiary standards to the case); see also *supra* text accompanying notes 19–23, 26–28 (discussing *Daubert II* and its holding that the standard of proof is met when a substance’s relative risk to cause an injury is above 2.0).

<sup>149</sup> See discussion *supra* Parts II.B.–E. (discussing epidemiological risk overview in relation to judges’ evaluation of such evidence).

<sup>150</sup> For discussion on whether the lack of knowledge results in poor admissibility decisions under *Daubert*, see Joseph Sanders, *The Merits of the Paternalistic Justification for Restrictions on the Admissibility of Expert Evidence*, 33 SETON HALL L. REV. 881, 926–28 (2003) (analyzing Margaret Bull Kovera & Bradley D. McAuliff, *The Effects of Peer Review and Evidence Quality on Judge Evaluations of Psychological Science: Are Judges Effective Gatekeepers?*, 85 J. APPLIED PSYCHOL. 574, 575 (2000)).

<sup>151</sup> See discussion *infra* Part IV (discussing reform efforts to help judges make informed decisions).

<sup>152</sup> See discussion *supra* Part III.A. (discussing the areas in which judges lack certain training that would assist in their evaluation of scientific claims).

<sup>153</sup> Gary L. Wells, *Naked Statistical Evidence of Liability: Is Subjective Probability Enough?*, 62 J. PERSONALITY & SOC. PSYCHOL. 739, 739 (1992).

statistical evidence.<sup>154</sup> Of interest for *Daubert* purposes, the judges showed wide variance on their determinations of liability for the mock case when the judges reviewed statistical data, as compared to when the judges reviewed equally probable non-statistical information.<sup>155</sup> Wells noted that there was “no theoretical reason in the current psychological literature to expect that these versions of the evidence, which yield functionally equivalent subjective probabilities, would produce highly discrepant verdicts.”<sup>156</sup> As a result, the judicial handling of statistical evidence may not be a strength of the *Daubert* approach.

Other studies support the Wells results. A National Research Council collection of six case studies regarding statistical assessment in a variety of case settings supports the conclusion that judges fare poorly with statistical analysis.<sup>157</sup> The editor of the National Research Council collection, in a different study, declared that “the complexity of statistical issues raised in some cases will clearly put a resolution of conflicting expert testimony beyond the ken of even the most thoughtful and well-trained jurist.”<sup>158</sup> Examination of statistical evidence in Title VII litigation led Richard Lempert to the same conclusion: “[S]tatistically untrained judges are poorly equipped to make distinctions regarding statistical precedent.”<sup>159</sup> Legal commentators note that this weakness affects the *Daubert* assumption of judicial competence to handle complex cutting-edge science involving statistics.<sup>160</sup> In sum, the “reception of statistical evidence in the courtroom has been cautious at best and uninformed at worst; the nonuse and misuse of statistics have been more common than its use.”<sup>161</sup>

Judges’ poor performance with statistical evidence casts doubt on their

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<sup>154</sup> See *id.* at 748 (noting that both judges and psychology students made similar decisions based on statistics, but that statistics were often ignored when using the preponderance of evidence standard).

<sup>155</sup> *Id.* at 739, 743 (noting that students and trial judges averaged fewer than ten percent affirmative decisions of liability based on statistical evidence alone, while the subjects averaged sixty-five percent affirmative decisions of liability using other forms of evidence).

<sup>156</sup> *Id.* at 750.

<sup>157</sup> NAT’L RESEARCH COUNCIL, *EVOLVING ROLE OF STATISTICAL ASSESSMENTS AS EVIDENCE IN THE COURTS* 72 (S.E. Fienberg ed., 1989).

<sup>158</sup> Stephen E. Fienberg, *The Increasing Sophistication of Statistical Assessments as Evidence in Discrimination Litigation*, 77 J. AM. STAT. ASS’N 784, 786–87 (1982).

<sup>159</sup> Richard Lempert, *Befuddled Judges: Statistical Evidence in Title VII Cases*, in LEGACIES OF THE 1964 CIVIL RIGHTS ACT 263, 278 (Bernard Grofman ed., 2000).

<sup>160</sup> See Cranor et al., *supra* note 25, at 6 (“[J]udges and lawyers may need to experience a quantum leap in the subtleties of scientific inquiry in order to prevent various simplified views of scientific evidence from undermining and subverting the goals of tort law.”); Gatowski et al., *supra* note 123, at 454 (“[T]he survey findings raise concerns, however, about how well judges can exercise their discretion if they lack the requisite understanding of science and its methods.”); Vidmar & Diamond, *supra* note 102, at 1170–73 (discussing recent studies that investigate whether judges are superior to juries in interpreting statistical evidence).

<sup>161</sup> DAVID W. BARNES & JOHN M. CONLEY, *STATISTICAL EVIDENCE IN LITIGATION* 3–4 (1986); see Breyer, *supra* note 121, at 4.

ability to evaluate epidemiology under *Daubert*. Initially, it is important to note again that the Gatowski study showed a substantial majority of judges had no experience with epidemiologic evidence,<sup>162</sup> and therefore its statistical underpinnings. Since epidemiologists “speak in the statistical language of risks and probabilities,”<sup>163</sup> the role of statistical literacy in *Daubert* determinations regarding epidemiology cannot be understated.

Evaluation of the judicial handling of statistical information in the epidemiologic risk controversy cases demonstrates the judicial difficulty in analyzing and weighing statistical information. Statistical weakness leads to two scientifically false propositions from the epidemiology case law: probability of causation being computed solely from relative risk, and the bright-line determination of an exposure dose that results in a probability of causation exceeding fifty percent, equaling the “doubling dose” for all individuals.<sup>164</sup> Essentially, the courts have adopted a statistical test that scientists devalue as representing what the courts believe it represents.<sup>165</sup>

When the use/misuse of statistics is evaluated in the epidemiologic risk controversy, one must again wonder if judges are “up to the task,” as *Daubert* suggested. Reform efforts must also address judges’ lack of statistical background and misuse of statistical principles, seeking a solution to the weaknesses exposed by the studies done by Wells, the National Research Council, and others, as well as the epidemiologic case law.<sup>166</sup>

### C. *Bright-Line Tests May Not be Scientifically Sound*

The *Daubert* framework allows for the ultimate bright-line test: admissibility. Of course it is proper that judges should make these choices. But in the creation of bright-line rules about science, and then using those rules—scientifically sound, and otherwise—to make evidence admissibility determinations, judges risk enshrining poor science into law. The epidemiologic relative risk controversy is a textbook example of bright-line rule valuation trumping scientific principles.

A bright-line rule is, by definition, a rule of decision that resolves ambiguities at the potential expense of equity.<sup>167</sup> Bright-line rules can

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<sup>162</sup> Gatowski et al., *supra* note 123, at 442 (reporting that seventy-three percent of judges indicate no experience at all with epidemiology).

<sup>163</sup> *In re Joint E. & S. Asbestos Litig.*, 52 F.3d 1124, 1128 (2d Cir. 1995).

<sup>164</sup> Greenland, *Methodologic Error*, *supra* note 44, at 1166. For examples of the use of these doubling dose/relative risk numbers in cases for the “more likely than not” standard, see discussion *supra* Part II.B. Regarding courts rejecting this approach as unsound, see *infra* text accompanying notes 167–84. See also Carruth & Goldstein, *supra* note 45, at 209 (criticizing the use of the doubling/dose relative risk standard).

<sup>165</sup> Thompson, *supra* note 93, at 264–65.

<sup>166</sup> See discussion *infra* Part IV (discussing appropriate suggestions for successful reform).

<sup>167</sup> BLACK’S LAW DICTIONARY 205 (8th ed. 2004).

work well in the judicial system, providing ease of application, notice, and clear standards. As a result, bright-line tests appeal to courts in a diverse range of legal disputes, from First Amendment case law,<sup>168</sup> to Fourth Amendment search and seizure cases,<sup>169</sup> to antitrust litigation.<sup>170</sup> The *Black's Law Dictionary* definition recognizes that the clarity of the rule is achieved at the potential cost of equity.

In the epidemiologic risk controversy, courts enshrined bright-line tests for relative risks in order to prove causation.<sup>171</sup> In doing so, courts sacrificed scientific validity at the altar of certainty. Part of the problem is the competing cultures of the fields of law and science.<sup>172</sup> Uncertainty remains an integral part of scientific analysis.<sup>173</sup> After all research is completed, data taken, and analysis performed, scientists recognize the place for uncertainty.<sup>174</sup> Epidemiology is a field that contains a large degree of subjective analysis, involving uncertainty and the analysis thereof.<sup>175</sup>

In overemphasizing the bright-line tests, courts gloss over the uncertainty inherent in the epidemiologic analysis with a veneer of objectivity.<sup>176</sup> In doing so, the courts deviate from the practice of scientists,<sup>177</sup> who must perform their research with additional complicating subjective factors.<sup>178</sup> Finally, the bright-line rule negatively affects the

<sup>168</sup> See, e.g., *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 279–80 (1964) (creating a bright-line rule that “prohibits a public official from recovering damages for a defamatory falsehood relating to his official conduct unless he proves the statement was made with ‘actual malice’” in certain circumstances); Frederick Schauer, *Fear, Risk, and the First Amendment: Unraveling the “Chilling Effect,”* 58 B.U. L. REV. 685, 716–17 (1978) (discussing, in part, the bright-line test used to determine what speech constitutes obscenity).

<sup>169</sup> See, e.g., Leslie A. Lunny, *The (Inevitably Arbitrary) Placement of Bright Lines: Belton and Its Progeny*, 79 TUL. L. REV. 365, 375–76 (2004) (discussing, for example, the bright-line rule articulated by the United States Supreme Court with regard to the permissible scope of a search and seizure without a warrant).

<sup>170</sup> See, e.g., Mark A. Lemley & Christopher R. Leslie, *Categorical Analysis in Antitrust Jurisprudence*, 93 IOWA L. REV. 1207, 1211, 1259 (2008) (noting that antitrust law is “rife with categorical distinctions,” that bright-line rules have developed in the courts and are not necessarily related to antitrust statutes, and that bright-line rules are valuable in that they allow for business strategy planning).

<sup>171</sup> See discussion *supra* Part II.B. (discussing *Daubert II* and the development of the rule regarding relative risk).

<sup>172</sup> See Greenland, *Critical Appraisal*, *supra* note 2, at 293–94 (discussing conflict between sound scientific principles and the adjudication process).

<sup>173</sup> *Id.*

<sup>174</sup> *Id.*

<sup>175</sup> Beyea & Berger, *supra* note 1, at 356–57; Finley, *supra* note 35, at 365.

<sup>176</sup> Finley, *supra* note 35, at 365; see also Cranor et al., *supra* note 25, at 58 (noting that statistical associational probabilities are only one form of relevant evidence important to decision-making).

<sup>177</sup> See Finley, *supra* note 35, at 359–62 (discussing courts’ implicit and explicit deviation from strict adherence to scientific principles when considering epidemiological evidence).

<sup>178</sup> See *supra* notes 92–95 and accompanying text (discussing epidemiologists’ role in the adjudication process).

perception of other, less seemingly objective, scientific principles.<sup>179</sup>

Some courts clearly recognized the problem with making certainty out of scientific judgment and doubt.<sup>180</sup> The Ninth Circuit explicitly rejected the need for a bright-line approach in *In re Hanford*: “[T]he validity of a claim should not depend on whether a plaintiff was exposed to a fraction of a rem lower than the ‘doubling dose.’”<sup>181</sup> In doing so, the panel recognized a flaw in the reasoning of the Ninth Circuit’s opinion in *Daubert II*.<sup>182</sup> The rejection of the bright-line approach produced a different result in *In re Hanford*, but the *Daubert II* precedent had been relied upon for seven years to that point, and it continues to influence decisions today.<sup>183</sup>

Bright-line tests play an important role in the legal system, and clearly can have beneficial effects. The epidemiologic risk controversy shows the valuation of bright-line tests can come with unexpected or undesirable consequences, and may lack scientific validity. Reform efforts must note the tendency of the law to seek objectivity, even when it may not be present or used by the field, in the evaluation of scientific evidence under *Daubert*.<sup>184</sup>

#### D. Outlier Enhancement Concerns

Yet another consideration for evaluation of complex science under the *Daubert* standard is the issue of “outlier enhancement”; that is, when the scientific evidence presented gives the court a false or incomplete picture of the state of the overall scientific knowledge in the field. Both run-of-the-mill and highly complex scientific issues can potentially suffer from this difficulty, although the more complex the science, the less likely the judge will be to be able to spot and compensate for the potential of skewed science.<sup>185</sup>

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<sup>179</sup> See Cranor et al., *supra* note 25, at 58 (noting that courts’ use of stringent rules in deciding the admissibility of evidence “may lead to consideration of a narrower range of evidence” than scientists would normally consider).

<sup>180</sup> See discussion *supra* Part II.D. (noting courts that have rejected the *Daubert II* bright-line rule).

<sup>181</sup> *In re Hanford Nuclear Reservation Litig.*, 292 F.3d 1124, 1137 (9th Cir. 2002).

<sup>182</sup> See *id.* By holding that the validity of a claim should not depend on a bright-line rule, the panel effectively disagreed with the *Daubert II* court’s use of the “doubling dose” standard. See *id.*

<sup>183</sup> See, e.g., *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1153 (E.D. Wash. 2009) (citing *Daubert II* as controlling precedent).

<sup>184</sup> See discussion *infra* Part IV (detailing reform efforts that will, in part, consider the tendency of the law to seek objectivity by ensuring courts take science into account prior to making decisions).

<sup>185</sup> Both the judge and the jury will usually, as untrained non-experts, have difficulty evaluating the weaknesses and overall state of science in the field. Bernstein, *supra* note 3, at 486; see also Jennifer L. Mnookin, *Expert Evidence, Partisanship, and Epistemic Competence*, 73 BROOK. L. REV. 1009, 1030–31 (2008) (discussing use of expert judges and juries as solution to the problem); Joseph Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases*, 46 STAN. L. REV. 1, 37–39 (1993) (noting that even with the use of expert witnesses, juries will have difficulty ascertaining whether the expert’s opinion is, in fact, accurate).

Selection bias can occur through a litigant's selection of an expert mainly in order to represent a perspective on science that a litigant proposes for his/her case.<sup>186</sup> The bias is based in the narrow interest of the party to maximize the persuasive effect of the presentation to the jury in the promotion of the case.<sup>187</sup>

In a more general sense, the problem of outlier enhancement is a byproduct of the basic antithesis between the legal and scientific methods. Scientific inquiry is rooted in the testing of opinions through the collection of data, debate among alternatives, recognition of the limitations or areas of uncertainty in the field, and the assumptions necessary to make a conclusion.<sup>188</sup> Legal process involves the partisan presentation of materials to a necessarily generalist jury pool.<sup>189</sup> The method of decision making has a great effect on the selection of experts.

Experts in the fields of science should remain open-minded, recognize the limitations of their research, and should be open to the consideration of new theories or hypotheses.<sup>190</sup> In contrast, expert witnesses get selected for their positions in the field, loyalty for the client, and advocacy.<sup>191</sup>

Two byproducts of expert witness bias in the legal system are immediately apparent: that experts selected by a party in a legal case may represent opinions that are accepted by only a small minority of persons in their field,<sup>192</sup> and that opposing experts must be neutralized by attack whether or not their position is more or less valid than the opposing viewpoint.<sup>193</sup>

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<sup>186</sup> See Bernstein, *supra* note 3, at 456 (discussing selection bias with those providing expert testimony).

<sup>187</sup> See Mnookin, *supra* note 185, at 1011 (noting that the typical expert witness is one who might not be the most knowledgeable expert, but is often the one who is most persuasive to the jury).

<sup>188</sup> See Greenland, *Critical Appraisal*, *supra* note 2, at 293 (arguing that scientific inferences are "derived from assumptions as well as from data").

<sup>189</sup> See *id.* at 294 (noting that expert witnesses are chosen in order to argue one party's position). The more professional experience the witness may have, the less likely the jury may be able to make determinations on the issues contained within the testimony rather than the expert himself or herself. See Sanders, *supra* note 185, at 37 ("Persuasiveness is not always a useful indicator of truth.").

<sup>190</sup> See Greenland, *Critical Appraisal*, *supra* note 2, at 293-94 (discussing basic goals of scientific reporting).

<sup>191</sup> See *id.* at 294 (discussing the need for lawyers to advocate for their clients); Vidmar & Diamond, *supra* note 102, at 1133 (noting that experts are often selected based on their loyalty to a particular party). For a detailed examination of the issue of selection bias in the context of complex toxic torts, see Sanders, *supra* note 185, at 26 n.130. See also Bernstein, *supra* note 3, at 456 (discussing selection bias in the context of choosing expert witnesses).

<sup>192</sup> See Vidmar & Diamond, *supra* note 102, at 1133 (discussing the fact that some experts' opinions do not represent the majority position on particular issues); see also Bernstein, *supra* note 3, at 456-57 (discussing a jury's perspective when hearing multiple experts' testimony); Greenland, *Critical Appraisal*, *supra* note 2, at 305 (noting that scientists represent their own viewpoints as standard within the field).

<sup>193</sup> See Vidmar & Diamond, *supra* note 102, at 1133-34 (noting that the adversary system pits one expert against the other); see also Bernstein, *supra* note 3, at 456-57 (arguing that when the consensus

When the *Daubert* regime replaced the *Frye* system, the consideration of “general acceptance” of the scientific information changed from the central analysis on the admissibility of the testimony, to one of many considerations in a multi-factorial test for reliability.<sup>194</sup> After *Daubert*, judges applying the multi-factorial *Daubert* reliability test must also consider error rate, peer review, methodology, existence of standards and controls, and overall methodology, in addition to or instead of analyzing general acceptance.<sup>195</sup> Added to the problem is that judges, untrained in science themselves,<sup>196</sup> are more likely to see “science” as a logical, coherent, and largely irrefutable process seeking truth from the natural world.<sup>197</sup> Under these circumstances and with this viewpoint, scientists outside the mainstream are more likely, if not nearly universal, in the analyses of scientific disputes in the court; these “outliers” have stormed the courtroom with nonstandard or unusual science, as part of the adversarial system.

The epidemiologic risk controversy is an example of the “outlier enhancement” of scientists in the courtroom. The acceptance of epidemiologic relative risk as the *sine qua non* of causation in toxic torts is an example of the science within the courtroom clearly diverting away from the mainstream practice of science.<sup>198</sup> As one epidemiologist notes, the doubling-of-the-risk analysis of the Ninth Circuit in *Daubert II* “is not the most reasonable inference [for the court] to make.”<sup>199</sup> Rather, the court’s determinations were suspect, and it “seems clear that a substantially different conclusion would have been reached on some of these scientific issues in the regulatory context.”<sup>200</sup> There lies the problem: judges making decisions on complex science, outside of their expertise, guided by experts selected based on their loyalty to the party and advocacy for the cause.<sup>201</sup> As a result, judges make decisions memorializing questionable scientific

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lies closer to one expert’s view, a jury gets a false sense that the litigated issue is a close one); Greenland, *Critical Appraisal*, *supra* note 2, at 294 (noting that lawyers are working in an adversary system and need to protect their client’s interests); Sanders, *supra* note 185, at 47 (“[C]ross-examination becomes a ritual that does not little to clarify the strengths and weaknesses of a witness’ testimony.”).

<sup>194</sup> *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593–94 (1993); *see also supra* text accompanying notes 13–15.

<sup>195</sup> *See supra* text accompanying notes 13–15 (discussing the new *Daubert* requirements).

<sup>196</sup> *See discussion supra* Parts III.A.–B.

<sup>197</sup> *See Beyea & Berger, supra* note 1, at 330–31 (noting that judges are likely to require scientists “to make generalizations from observations or data to general laws of nature”).

<sup>198</sup> *See discussion supra* Part II.B. and *supra* notes 92–95 and accompanying text (discussing epidemiology and noting that evaluation of science in the courtroom can be difficult, uncomfortable, or daunting).

<sup>199</sup> Beyea & Berger, *supra* note 1, at 354.

<sup>200</sup> Rodricks & Rieth, *supra* note 50, at 29.

<sup>201</sup> *See supra* note 185 and accompanying text (noting that judges tend to have more difficulty identifying skewed science when the scientific complexity of an issue increases).

reasoning into decisions.

Expert witnesses play an important role in the legal system, and clearly are necessary to assist the jury/judge in evaluating scientific or technical issues. The epidemiologic risk controversy shows that reliance on experts, largely selected for their loyalty and advocacy to a party in an adversarial system, can result in non-representative science being presented within the courtroom that would not succeed in the scientific field. Reform efforts must take into account this procedural and systematic concern when seeking appropriate amendments to the system of evaluation of scientific evidence under *Daubert*.<sup>202</sup>

### E. Constraints of Legal Procedure

In addition to the concerns about judicial scientific and statistical backgrounds, bright-line rules, and outlier enhancement, concerns about the legal system structure also deserve mention for consideration in reform efforts. Two examples—the role of cross-examination in expert evaluation and discovery timelines under the Federal Rules of Civil Procedure—will provide some insight into the procedural problems affecting the quality of complex science in the courtroom.

#### 1. Cross-Examination

Cross-examination is considered the “greatest legal engine ever created for the discovery of truth.”<sup>203</sup> It is the central right of the Sixth Amendment’s Confrontation Clause,<sup>204</sup> and is so central to the determination of truth in many civil cases as to be required by due process.<sup>205</sup> Clearly cross-examination will and must remain a facet of trial practice.

This is not to say, however, that in the context of complex or cutting-edge science that cross-examination is foolproof or flawless. Cross-examination can feed upon the jury’s preconceived notions of the truth and fact. As an example, in one study performed in a simulated rape trial, an attorney introduced through cross-examination a negative fact about the

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<sup>202</sup> See discussion *infra* Part IV (discussing various ways to improve courts’ ability to process complex scientific evidence).

<sup>203</sup> *California v. Green*, 399 U.S. 149, 158 (1970) (quoting 5 J. WIGMORE, EVIDENCE § 1367 (3d ed. 1940)).

<sup>204</sup> See *Crawford v. Washington*, 541 U.S. 36, 60–61 (2004) (discussing the Sixth Amendment and how courts seek reliable evidence in part through cross-examination).

<sup>205</sup> See, e.g., *Van Harken v. City of Chicago*, 103 F.3d 1346, 1352 (7th Cir. 1997) (noting that in civil cases, “live testimony and cross-examination might be so important as to be required by due process,” although noting judicial equivocation on the issue).

expert.<sup>206</sup> Even when denied and uncorroborated, the innuendo of the cross-examination question negatively affected the credibility of the expert.<sup>207</sup> The study's authors concluded that "the use of presumptuous questions is a dirty trick that can be used to distort jurors' evaluations of a witness' credibility. As cross-examiners regularly employ such tactics, judges should be aware of the dangers and make a serious effort to control them."<sup>208</sup> Note that in this study, the researchers used a presumed fact based in common-sense regarding the outside perception of the experts' research.

In a case involving complex or cutting-edge scientific thought, improper cross-examination questions have an even greater chance to influence the jury.<sup>209</sup> When expert testimony has been approved, jurors are *necessarily* unknowledgeable about the subject matter involved.<sup>210</sup> So should the cross-examining attorney introduce a fact regarding the *subject* of the science rather than a common-sense perception about the expert, the jury is necessarily unable to make an objective determination about that fact.<sup>211</sup> When lacking the necessary signposts to evaluate material, the jurors can unintentionally oversimplify the material and rely overwhelmingly on peripheral cues.<sup>212</sup> The more difficult the material, the more likely the jury will have to rely on non-central peripheral cues, rather than an understanding of the details of the testimony.<sup>213</sup> In many complex cases, cross-examination will feed to these jury biases by focusing on tangential areas of credibility, from accepting fees for expert review to the perception of inconsistency with deposition testimony.<sup>214</sup> Cross-examination in this context becomes a ritual: less about the strengths and weaknesses of the expert opinions and more about jury bias and peripheral matters.<sup>215</sup> Research has shown that juror comprehension in complex

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<sup>206</sup> See Saul M. Kassir et al., *Dirty Tricks of Cross-Examination: The Influence of Conjectural Evidence on the Jury*, 14 LAW & HUM. BEHAV. 373, 376 (1990) (noting that the negative fact regards whether the expert's data has been "sharply criticized").

<sup>207</sup> *Id.* at 378.

<sup>208</sup> *Id.* at 382 (internal citations omitted).

<sup>209</sup> For an evaluation of various studies in complex and other fields, see Sanja Kutnjak Ivkovic & Valerie P. Hans, *Jurors' Evaluations of Expert Testimony: Judging the Messenger and the Message*, 28 LAW & SOC. INQUIRY 441, 447-49 (2003).

<sup>210</sup> FED. R. EVID. 702. See Mnookin, *supra* note 185, at 1012 (noting that expert witnesses are necessary because the jury would otherwise not be knowledgeable about the subject at hand).

<sup>211</sup> See Mnookin, *supra* note 185, at 1012-14 (discussing evaluation of competence of an expert witness).

<sup>212</sup> See Vidmar & Diamond, *supra* note 102, at 1138-39 (noting that juries often take "mental short cuts" when evaluating expert testimony).

<sup>213</sup> See *id.* at 1139 (stating that jurors often rely on peripheral clues); Mnookin, *supra* note 185, at 1013 (noting that jurors often have to rely on "proxy criteria" in assessing expert testimony).

<sup>214</sup> See Sanders, *supra* note 185, at 47-48 (discussing tendency of opposing counsel to attempt to discredit an expert witness by highlighting irrelevant facts such as expert fees).

<sup>215</sup> See *id.* (noting that cross-examination can become ritualistic).

epidemiologic cases is less than ideal.<sup>216</sup> In evaluating jurors' knowledge about epidemiologic risk after complex trials, several researchers have concluded that jurors misunderstood the epidemiologic evidence presented to them at trials.<sup>217</sup> As a result, at least one study determined that in an epidemiologic case, jurors tended to focus on the individual expert's personality and behavior rather than the substance of the testimony.<sup>218</sup> The cross-examination tactics in complex cases involving epidemiology—including focusing on tangential issues of credibility or demanding an unscientific level of accuracy in any statements—result in the process diminishing as a useful tool for the judge or jury to determine facts.<sup>219</sup>

Studies showing juror susceptibility to lawyers injecting misleading bias information, in addition to the research regarding the complexity and uncertainty posed by epidemiologic evidence, demonstrate that jurors' capacity to be misled in complex cases cannot be seriously doubted. As a result, reform including the addition of some level of objectivity, or at most signposts of credibility, might allow jurors to focus more on the substance of testimony in the most complex cases.<sup>220</sup>

## 2. *Discovery Deadlines*

One final consideration regarding the *Daubert* regime meriting mention is the discovery timeline in federal civil litigation. The civil discovery process involves formalized disclosure of relevant evidence of each party well before trial. While meeting the requirements of due process, the discovery process may negatively affect the scientific merit of the witnesses as compared to the practice of science outside the courtroom. This is particularly true with epidemiologic evidence.

Discovery timelines are set according to a formalized schedule. Under Federal Rule of Civil Procedure 16, a court will hold a pretrial conference and set a discovery schedule including expert witness disclosures.<sup>221</sup> While there is no set time at which the expert disclosure must occur except that which is set by the pretrial order, pretrial orders often involve

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<sup>216</sup> See *supra* text accompanying notes 143–44 (discussing studies evaluating juries' comprehension of complex statistical information).

<sup>217</sup> See MOLLY SELVIN & LARRY PICUS, *THE RAND CORPORATION, THE DEBATE OVER JURY PERFORMANCE* 24 (1987); Joseph Sanders, *The Jury Deliberation in a Complex Case: Havner v. Merrell Dow Pharmaceuticals*, 16 JUST. SYS. J. 45, 52 (1993) (noting that complex cases involving plaintiffs' injuries following mass-exposure to certain substances are often difficult for juries to decide). Both studies are discussed, along with complex non-epidemiologic case studies, in Vidmar & Diamond, *supra* note 102, at 1146–49.

<sup>218</sup> SELVIN & PICUS, *supra* note 217, at viii–ix.

<sup>219</sup> Sanders, *supra* note 185, at 50–51 (discussing how battling experts tend to diminish benefits of cross-examination).

<sup>220</sup> See discussion *infra* Part IV (noting reform efforts should work toward bringing “science back into the courthouse”).

<sup>221</sup> FED. R. CIV. P. 16(c)(2).

disclosure deadlines early in the case, so that the case may be in an advanced procedural posture earlier than otherwise.<sup>222</sup> Once set, the pretrial order cannot be modified except on a finding of good cause.<sup>223</sup> Through this process, the litigants will discover their opponents' expert witnesses' identities, the substance of their testimony, and some indication of the trial strategy from the expert reports.

While fair for due process, this procedure is in opposition to the general tenets of the scientific method. Scientists in general are trained to utilize new data, reinterpret studies, and take new information into account when formulating and testing hypotheses.<sup>224</sup> As a result, a researcher must be willing to review and analyze new information for the effect it may have on the overall theory.

Epidemiology is a science particularly invested in re-evaluation of new information. Because of the use of epidemiology largely in the regulatory public health sphere,<sup>225</sup> a premium exists for the early dissemination of information regarding public health risks.<sup>226</sup> The risks are then taken into account and evaluated as continued study progresses.<sup>227</sup> Through this process, the public health is protected from an exposure where the initial data indicates a threat to human health. However, the system works poorly outside the regulatory sphere, in the context of tort litigation. In the tort legal system, the need to disclose particular information at an early stage in the proceedings can prevent or limit any additional analysis, or re-analysis, of information due to the discovery deadlines, resulting in a limited amount of data regarding the issue being contested.<sup>228</sup>

Because the *Daubert* standard asks courts to hold scientists to the same standard in the courtroom as used in the laboratory,<sup>229</sup> it seems odd to think that courts mandate, through discovery procedures, a timeline that excludes a valid and appropriate method of scientific inquiry. While not appropriate in every case, some consideration of the effect that a rigid discovery timeline has on scientific evidence in the courtroom would also be an

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<sup>222</sup> Some states have specific deadlines set into rule. *See, e.g.*, COLO. R. CIV. P. 16 (providing rules regarding trial management).

<sup>223</sup> FED. R. CIV. P. 16(b)(4).

<sup>224</sup> *See, e.g.*, Greenland, *Critical Appraisal*, *supra* note 2, at 293 (noting that a scientist should review all available data and may recognize a need for additional study prior to forming a conclusion).

<sup>225</sup> *See* Rodricks & Rieth, *supra* note 50, at 31 (discussing the epidemiological studies in light of the regulatory scheme).

<sup>226</sup> Carruth & Goldstein, *supra* note 45, at 207.

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*; *see* Cranor et al., *supra* note 25, at 61 (noting that judges should consider whether admission of certain types of evidence will further the legal purposes of tort law).

<sup>229</sup> *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318 (7th Cir. 1996).

appropriate consideration for reform efforts.<sup>230</sup>

#### IV. SUGGESTIONS FOR REFORM TO ADDRESS THE IDENTIFIED WEAKNESSES

The epidemiologic risk controversy exposed *Daubert* as a system with multiple problems with judicial evaluation of cutting-edge complex science, including basic judicial knowledge of scientific principles, the judicial handling of statistical evidence, use of bright-line tests that may not be scientifically sound, outlier enhancement, and the constraints of the legal process on science.

Having reviewed and analyzed the nature of each difficulty, this section will now address potential solutions to those exposed weaknesses. In doing so, the goal is to forge a better compromise between science and the courtroom, in order to increase the efficiency, accuracy, and consistency of judicial gatekeeping decisions under *Daubert*.

##### A. *Use of Rule 706 Experts as Judicial Science Consultants*

The first area ripe for modification is the current structure of the Court Appointed Expert Rule, to allow for appointment of a science consultant to assist the judge with gatekeeping under *Daubert*. The current rules create practical restraints on the appointment of an independent expert, so modification of the current system would encourage science consultants to be appointed in appropriate cases.<sup>231</sup> As a result, the use of independent experts can shift from the exception rather than the rule to an expectation in most complex tort cases.

The current structure of the Federal Rules of Evidence results in practical limitations on the appointment of a science consultant. Under Federal Rule 706—the Court Appointed Expert Rule—the court may appoint an independent expert on motion of the court or the parties.<sup>232</sup> This expert may be selected by the judge or by nominations of the parties, and will be paid by the parties “in such proportion and at such time as the court directs, and thereafter charged in like manner as other costs.”<sup>233</sup> While the expert serves the court, a Rule 706 expert under the current rule must advise the parties of his/her opinions, can be deposed by either party, and can be called to testify at trial.<sup>234</sup>

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<sup>230</sup> See discussion *infra* Part IV (offering a general discussion of reform efforts designed to remedy problems resulting from expert witnesses’ presentations of epidemiological evidence in court).

<sup>231</sup> The independent expert appointments should be limited to those cases that do not meet the qualifications for advanced science procedures. See *infra* Parts IV.B.1.–2.

<sup>232</sup> FED. R. EVID. 706(a).

<sup>233</sup> FED. R. EVID. 706(b). See, e.g., *Leesona Corp. v. Varta Batteries, Inc.*, 522 F. Supp. 1304, 1312 n.21 (S.D.N.Y. 1981) (discussing Rule 706(b)).

<sup>234</sup> FED. R. EVID. 706(a).

Independent of the Court Appointed Expert Rule 706 powers, the court also has an inherent power to appoint experts to assist in the determination of preliminary issues of fact under Federal Rule of Evidence 104. Under Rule 104, the judge must make initial determinations of whether evidence should be admissible for consideration by the jury, as an exercise of a parallel and more general power like *Daubert* gatekeeping under Rule 702.<sup>235</sup> Courts have used this power to appoint experts to evaluate complex science, avoiding the necessity of availability for trial testimony or deposition.<sup>236</sup> In the *Hall* litigation regarding silicone gel breast implants and disease, the judge explicitly mentioned Rule 104 as an alternative to Rule 706, to “keep the advisors independent of any ongoing proceedings” and because Rule 706 requires the appointed experts “in effect, to act as additional witnesses subject to deposition and trial.”<sup>237</sup>

Judges support the power to appoint experts, while remaining sometimes reluctant to actually do so, based on survey results in empirical research.<sup>238</sup> In one important study, surveys were sent to 537 federal judges.<sup>239</sup> These judges indicated overwhelmingly (87%) that court appointed experts are likely to be helpful in certain cases.<sup>240</sup> A separate study also demonstrated that a high percentage of federal (76%) and state (70%) court judges approved of court appointed expert appointment.<sup>241</sup>

However, independent experts do not appear to be appointed very often. In the Cecil and Willging federal judicial poll, only twenty percent of judges had appointed an independent expert.<sup>242</sup> While lack of cases requiring an independent expert was one reason for failure to appoint, judges surveyed indicated that their failure to use an expert related to respect for and adherence to the adversarial system.<sup>243</sup>

As a response, and to encourage the use of court appointed independent experts, the Court Appointed Expert Rule should be rewritten to account for judicial reluctance to appoint independent scientific

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<sup>235</sup> FED. R. EVID. 104(a).

<sup>236</sup> See, e.g., *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1392 n.8 (D. Or. 1996) (utilizing Rule 104 rather than 706).

<sup>237</sup> *Id.*

<sup>238</sup> “Since passage in 1975, the rule has been little used, although authors often discuss its possible use.” MORRIS H. DEGROOT ET AL., *STATISTICS AND THE LAW* 309 (1986).

<sup>239</sup> See Joe S. Cecil & Thomas S. Willging, *Accepting Daubert’s Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995, 1004 n.33 (1994) (noting 431 responses to a survey sent to 537 judges).

<sup>240</sup> *Id.* at 1008–09.

<sup>241</sup> Louis Harris & Associates, Inc., *Judges’ Opinions on Procedural Issues: A Survey of State and Federal Trial Judges Who Spend at Least Half Their Time on General Civil Cases*, 69 B.U. L. REV. 731, 741 (1989).

<sup>242</sup> Cecil & Willging, *supra* note 239, at 1004.

<sup>243</sup> See *id.* at 1018–19 (noting that respect for the adversarial system is cited by judges as a rationale for not allowing expert testimony).

consultants. Additional language would be added to Rule 706, as Rule 706(e), allowing appointment of a court appointed science consultant, under the same payment terms of Rule 706(a) experts, for the use of the judge to evaluate and address specific scientific questions that arise from the dispute.<sup>244</sup> With this change, the court would have an expert to assist the judge in addressing complicated scientific material under *Daubert*, with the proper background to do so, but without throwing a third expert into the presentation aspects of trial.

The ability of a court to appoint a scientific consultant has several beneficial effects on complex litigation. First, the appointment of a non-deposable expert would reduce the main hindrance to judges in appointing scientific experts to assist them. Second, it would allow a knowledgeable specialist to provide much-needed insight into scientific issues arising in complex litigation, overcoming the judicial scientific-and-statistical-background weaknesses exposed by empirical studies.<sup>245</sup> Third, the litigants' experts, who may be chosen as a result of "outlier enhancement,"<sup>246</sup> may recognize that their scientific opinions will be subject to third party review by the judge's science consultant, and produce opinions with a more neutral, less partisan opinion.<sup>247</sup> Fourth, the use of independent experts will offer reluctant but skilled scientists a chance to participate in legal cases involving their field.<sup>248</sup> Finally, the use of scientific consultants will bring back to the courtroom a lost, or perhaps misplaced, part of scientific inquiry: the general state of knowledge in the field.<sup>249</sup> By evaluating the general state of knowledge in the field, the court can understand and place the opinions of the litigants' experts into perspective on the range of scientific opinion in the area.<sup>250</sup>

Certain weaknesses of this proposal merit response. Some critics

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<sup>244</sup> See Robert L. Hess II, Note, *Judges Cooperating With Scientists: A Proposal for More Effective Limits on the Federal Trial Judge's Inherent Power to Appoint Technical Advisors*, 54 VAND. L. REV. 547, 587 (2001) (suggesting a new Rule 707 to allow for separate technical advisors to serve as judicial experts).

<sup>245</sup> See discussion *supra* Parts III.A.–B. (discussing judges' difficulty in understanding evidence presented in particularly complex litigation).

<sup>246</sup> See discussion *supra* Part III.D. (discussing outlier enhancement in the context of evaluation of complex science).

<sup>247</sup> See *Confronting the New Challenges of Scientific Evidence*, 108 HARV. L. REV. 1481, 1590–91 (1995) (noting the general effect of reducing partisanship through independent consultant appointment).

<sup>248</sup> Hess, *supra* note 244, at 562–63. Regarding the benefits of the one-time expert, see Jurs, *supra* note 101, at 80–81.

<sup>249</sup> Sanders, *supra* note 185, at 67. Under *Frye*, the general acceptance test was the sole inquiry of scientific admissibility. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923). Under *Daubert*, general acceptance became one of many considerations to evaluate in the reliability consideration, but is without question not necessary for admissibility. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593–94 (1993).

<sup>250</sup> Bernstein, *supra* note 3, at 475.

allege that the potential bias of experts may be re-created with the appointment of a singular expert.<sup>251</sup> In response, the science consultant would be available in some cases, but on the most technical and complex cases a panel of experts or a science court approach may be used, as discussed in the next section.<sup>252</sup> In addition, the judge will ultimately maintain control of the situation, and should he be trained and sensitive to the issue,<sup>253</sup> be able to narrow the inquiry so that the expert makes only *scientific* determinations rather than *legal* ones. Finally, any judicial analysis of the science under *Daubert* will ultimately result in a judicial opinion, so the judge's analysis of the issue will be available for review and, if necessary, appeal. Collectively, these mechanisms should assure fairness to the parties.

Other critics might suggest that since the ability of the parties to depose the expert has been removed, asking the litigants to pay the costs of expert appointment may no longer be permissible.<sup>254</sup> Initially, one should note that Rules of Evidence are approved by an Act of Congress, so that the statutory basis would be clear. If the court then requires the litigants to pay the costs, such costs are not a "taking" as the litigants should recognize the court's need to properly and correctly evaluate complex science under *Daubert*. As such, the costs are no different than other litigation costs, like stenography or copies, and do not fit within the narrow confines of judicial "takings" law.<sup>255</sup> There appears to be no reason why these expert costs

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<sup>251</sup> This concern is mentioned in Beyea & Berger, *supra* note 1, at 364 (citing Ellen E. Deason, *Court-Appointed Expert Witnesses: Scientific Positivism Meets Bias and Deference*, 77 OR. L. REV. 59, 62 (1998)). See also Bernstein, *supra* note 3, at 477; Sanders, *supra* note 185, at 69.

<sup>252</sup> See *infra* Part IV.B.; see also Sanders, *supra* note 185, at 69. Note also that these approaches can be used in concert, as a judge could appoint a Rule 706 consultant to review appropriate scientific materials, but also await the results of a directly related Complex Science Litigation Panel or Court of Scientific Jurisdiction review before rendering a final decision. This approach is reminiscent of Judge Jones in *Hall*, who issued a ruling following use of Rule 104 experts, but decided to defer the effective date of the opinion until the Science Panel from the Multi District Breast Implant case rendered a decision. *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1394 (D. Or. 1996) (citing *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV 92-P-10000-S, 1996 WL 34401813, at \*1-2 (N.D. Ala. May 31, 1996)). The decision in *Hall* was issued in December 1996, while the Panel issued its report on December 1, 1998. Laurens Walker & John Monahan, *Scientific Authority: The Breast Implant Litigation and Beyond*, 86 VA. L. REV. 801, 810, 815 (2000); *Hall*, 947 F. Supp. at 1387; *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV 92-P-10000-S, 1998 WL 35223618, at \*1 (N.D. Ala. Dec. 16, 1998).

<sup>253</sup> See *infra* Part IV.C.2. Note that in cases that follow a scientific panel opinion, the court's analysis of the issue could be pared down to the essential elements unique to the new case before it. See *infra* Part IV.B.1.

<sup>254</sup> Under this proposal, costs would remain taxable to the parties, per Federal Rule of Evidence 706(b).

<sup>255</sup> See Roderick E. Walston, *The Constitution and Property: Due Process, Regulatory Takings, and Judicial Takings*, 2001 UTAH L. REV. 379, 431-38 (2001) (discussing takings law as applied to the judiciary and whether the court should be "subject to the same takings restraints that apply to legislative regulation").

could not be lawfully taxable to the parties.

Permitting appointment of independent scientific consultants would overcome some of the weaknesses of the current *Daubert* regime. It would allow scientific analysis back into the chambers of the courts, and provide for the wise exercise of Rule 702 *Daubert* discretion.

#### B. *The Most Complex Cases Receive Advanced Science Procedures*

The benefit of singular, independent science consultants does have limitations. For a subset of more complex cases, particularly those of first impression, an enhanced review process may be in order. In such cases, the courts should have advanced methods for evaluating cutting-edge or complex science. I propose two distinct alternative methods for advanced scientific analysis: creating case-level Complex Litigation Science Panels, or establishing a new Court of Scientific Jurisdiction.

##### 1. *Complex Litigation Science Panels*

The first alternative is to empower the courts to appoint a Complex Litigation Science Panel (“CLSP”) in certain “complex science cases” to thoroughly evaluate issues and create the best possible precedent for evaluation of issues by subsequent judges. This Article therefore proposes a new rule, Federal Rule of Civil Procedure 74, to meet these goals.<sup>256</sup>

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<sup>256</sup> Proposed FED. R. CIV. P. 74:

##### Complex Litigation Science Panel

- a. In cases designated under subsection (b), the District Court shall have the authority to appoint a Complex Litigation Science Panel, empowered to review the litigants’ expert disclosures and reports, if any, and issue a Scientific Panel Advisory Report pursuant to subsection (e).
- b. Cases Included: a Complex Litigation Science Panel shall be permissible when the court finds any of the following:
  1. Scientific or Technical Information is essential to assist the court in the determination of admissibility of evidence under FED. R. EVID. 702;
  2. The science or technical information presented in the case has a high potential to be evaluated by other courts; or
  3. A single science consultant may not provide the needed perspective on all the issues presented by the litigants.
- c. Selection of Panelists: a Complex Litigation Science Panel shall consist of three members. The Plaintiff or group of Plaintiffs shall select a single member, and the Defendants shall select a single member. In the event a panelist cannot be selected, the court shall make a selection on behalf of that party. Upon selection of each of the first two panelists, the panelists shall meet and select a third member, to serve as chair of the Panel.
- d. Duty of Panel Members: Panel members must affirm, by oath or otherwise, that they will review the scientific material impartially and, to the best of their abilities, within the normal constraints of their particular scientific discipline.
- e. Contents of Report: A Scientific Panel Advisory Report Shall include Analysis of:
  1. Areas of Consensus between the Litigants’ Expert or Experts;
  2. Areas of Disagreement between the Litigants Expert or Experts;
    - a. Those areas which the Panel Members Agree on How to

The threshold question in a case involving expert testimony is whether it is a case that will qualify for a CLSP under the rule, rather than the standard science consultant method from a modified Rule 706. The proposed Rule 74 lists three separate considerations for appointment of a CLSP: (1) a determination of essential need by the judge; (2) high potential for evaluation in the future; or (3) the determination that a single scientific consultant would not be appropriate.<sup>257</sup> While these may allow for use of the procedure in a wide variety of cases where the court finds a need, it is important to remember that use of science panels is limited since this procedure will take time and be expensive. As a practical reality, then, the procedure may be limited to those cases that meet more than one of the three requirements.

Next, the selection procedure for the science panel should be indisputably fair, in order to enhance legitimacy of its views. In other areas of dispute resolution, a tripartite panel of arbitrators may address hotly contested issues and issue a final report.<sup>258</sup> Each party to the dispute is able to appoint one arbitrator to the panel, and the two arbitrators then select the third member of the panel.<sup>259</sup> This time-tested method of dispute

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- Resolve;
  - b. Those areas which the Panel Members Disagree on How to Resolve; and
  - 3. Panelists Report on Areas of Disagreement Between Panelists;
    - a. Explanation of Competing Theories in the Area;
    - b. Scientific Basis of Each Competing Theory
    - c. Criticism of Each Theory by Adherents to the Opposing Theories.
    - f. Costs: all reasonable fees of the members of the Complex Litigation Science Panel shall be taxed to the parties as costs under FED. R. CIV. P. 54(d).

Commentators evaluating proposals for scientific review beyond a single independent expert under Federal Rule of Evidence 706 have used varied approaches to the legal basis of the panel. Walker & Monahan, *supra* note 252, at 826 (proposing a science panel formed under Federal Rule of Civil Procedure 53). Due to the significance of the change from existing rules, this author suggests a new, separate rule, distinct from the prior existing framework.

<sup>257</sup> Proposed FED. R. CIV. P. 74, *supra* note 256; see also *supra* Part IV.A. (discussing the idea of a scientific consultant).

<sup>258</sup> See Michael Straubel, *Enhancing the Performance of the Doping Court: How the Court of Arbitration for Sport Can Do Its Job Better*, 36 LOY. U. CHI L.J. 1203, 1225 (2005) (citing Int'l Olympic Comm., Court of Arbitration for Sport, Statutes of the Bodies Working for the Settlement of Sports-Related Disputes R41.1 (1984), available at <http://www.tas-cas.org/d2wfiles/document/281/5048/0/3.1%20CodeEngnov2004.pdf>) (discussing appointment process for arbitrators in disputes requiring panel of multiple arbitrators). See also North American Free Trade Agreement, U.S.-Can.-Mex., art. 1120, Dec. 17, 1992, 32 I.L.M. 605 (providing for submission of claims to arbitration under NAFTA).

<sup>259</sup> North American Free Trade Agreement, U.S.-Can.-Mex., art. 1120, Dec. 17, 1992, 32 I.L.M. 605. In the Breast Implant Multi District Litigation, Judge Pointer used a separate method of selection involving a committee created to determine whom to choose. Walker & Monahan, *supra* note 252, at 808 (reviewing order issued by Judge Pointer, from *In re Silicone Gel Breast Implant Prods. Liab. Litig.*, No. CV 92-P-10000-S, 1996 WL 34401813, at \*1-2 (N.D. Ala. May 31, 1996)).

resolution would work well for selection of the CLSP as well.

Finally, any CLSP must issue a “Scientific Panel Advisory Report” (“SPAR”) regarding the issue in dispute before the court.<sup>260</sup> In reviewing the reports of the litigants’ experts, the SPAR should detail the areas of consensus between the litigants’ experts, and areas of disagreement between those experts. For the areas of disagreement, the panel should report on which disagreements between the litigants’ experts the panelists are uniform in opinion, and on which the panelists disagree and why. As for areas of disagreement among panelists, the panel should report the two or more major bodies of theory in the area, the scientific basis, and the criticism of each. Finally, the report should provide recommendations to the judge for future analysis of similar areas or potential developments in the field.<sup>261</sup> With each of these components, the SPAR informs the judge of areas that are not subject to disagreement, those that are, and why, so that the judge can use that information in his final application of the *Daubert* rules.

The CLSP approach provides a series of benefits in complex litigation: the review of the parties’ expert reports by experts knowledgeable in the field, the fair selection process through an arbitration model, and the potential for a complex, detailed, and complete report (including minority views) on the issues in dispute. Scientists would select the third panel member, so they would presumably be able to select someone whose scientific credentials and methodology are respected in the field.<sup>262</sup> In addition, a tripartite panel overcomes the potential bias claims against an individually appointed scientific consultant, assuming that three scientists might have more diverse opinions than one lone expert.<sup>263</sup> Finally, the SPAR report would provide enough detail for the judge to make a final and informed *Daubert* decision, and provide guidelines for other judges to review when faced with similar admissibility decisions. Each of these considerations overcomes potential weaknesses in the *Daubert* system seen in the epidemiologic risk controversy.<sup>264</sup>

As with the issue of individual science consultants under Rule 706, critics may attack the science panel approach by charging it is too costly or

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<sup>260</sup> The procedure described in this paragraph comes from *Proposed FED. R. CIV. P. 74(e)*, *supra* note 256.

<sup>261</sup> The recommendations for judicial review assist the judge in the initial case with the *Daubert* findings, but are extremely helpful to future judges in analyzing similar but not identical scientific information.

<sup>262</sup> This overcomes a concern of judges that they are unable to find a suitable expert. Cecil & Willging, *supra* note 239, at 1022.

<sup>263</sup> See discussion *supra* Part IV.A. (addressing criticism that a singular court appointed expert might taint the process with his own individual bias).

<sup>264</sup> See discussion *supra* Part III (discussing flaws in the *Daubert* regime when applied to epidemiologic risk cases).

inefficient. On the issue of cost, a three-expert panel will certainly entail significant expenditure. However, this expense can be mitigated to some degree by the expertise and experience of the selected scientists. With their collective knowledge base, they should be able to easily and efficiently identify and address pertinent issues. Cost may also be mitigated by the involvement of appropriate professional societies to provide services within this panel system.<sup>265</sup> Another consideration is that the cost, while initially high, should be measured against the value of keeping the courthouse door open to valid claims which otherwise might be shut out, and the cost of “getting it right” the first time in the report issued by the panel. Had the *Daubert II* court been more discerning in its review of the epidemiology in that case, by either using a more detailed scientific basis for the opinion, or by reconsidering the scientists portrayal of the doubling of the risk standard as poor science, many other errors in similar cases relying on *Daubert II* might have been avoided.<sup>266</sup>

For the most complex and detailed cases, and for cases of first impression in scientific fields, a science panel approach based on arbitration principles would overcome some of the weaknesses of the current *Daubert* regime. It would allow for the wise exercise of Rule 702 judicial discretion, provide detailed insight for further court opinions, and use the knowledge of specialists in the field for the benefit of the judicial process.

## 2. Court of Scientific Jurisdiction

A specialized Court of Scientific Jurisdiction (“CSJ”) provides an alternative to the science panel approach. The idea of a science court handling specialized cases dates to the 1960s, and was largely debated in the 1970s and 1980s.<sup>267</sup> Proposals from this era varied from scientific

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<sup>265</sup> Some scientists champion the need for greater interaction among professional societies and lawyers within complex science. Rodricks & Rieth, *supra* note 50, at 31. On the issue of the National Academy of Sciences weighing in on a controversy before courts, see Walker & Monahan, *supra* note 252, at 812–13.

<sup>266</sup> See *supra* Parts II.B.–D. (reviewing the caselaw in the wake of *Daubert II*). Walker & Monahan, evaluating their proposal of using a Rule 53 independent panel, have noted that “the greatest benefits in terms of efficiency and justice would occur in collateral or other cases involving the same question of general causation. In this situation, the scientific authority model permits the use of doctrines of precedence to reduce redundancy and encourage courts to decide similar cases similarly.” Walker & Monahan, *supra* note 252, at 830.

<sup>267</sup> See David L. Bazelon, *Coping with Technology Through the Legal Process*, 62 CORNELL L. REV. 817, 817–18 (1977) (discussing the role of courts in evaluating and deciding complex issues of science and technology); Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 CORNELL L. REV. 469, 470–71 (1988) (considering a “regulatory apparatus” to resolve “hazardous-substance-induced injury claims” as an alternative to tort actions); Arthur Kantrowitz, *The Science Court Experiment*, 17 JURIMETRICS J. 332, 332 (1977) (reporting on the “feasibility of a series of experiments to help define the promise and problems of the Science Court approach for providing factual basis for policy-making”); Arthur

advisory panels to appellate panel structures, subject-specific to general in scope.<sup>268</sup> While the subject generated much commentary many years ago, science court proposals and analysis lessened during the shift from the *Frye* to the *Daubert* regime of evidentiary review. However, now with over fifteen years of *Daubert* review to analyze, and with the *Daubert* system revealing weaknesses in complex scientific review,<sup>269</sup> the idea of a science court should be reconsidered.

A centralized CSJ could manage a science docket consisting of an enumerated class of certified complex science cases delegated to it from the general federal courts.<sup>270</sup> Congress would have to pass enabling legislation to create the CSJ as an Article III court, and when doing so Congress should authorize permanent placement of the CSJ in the national capital.<sup>271</sup> Two questions regarding the CSJ then immediately arise: what cases will qualify to be heard within the CSJ, and what will be the structure of the court. By answering these, the benefits of a CSJ become apparent.

For a federal court to have jurisdiction at all, Congress must maintain minimal diversity requirements.<sup>272</sup> With minimal diversity jurisdiction satisfied, the substantive jurisdiction of the court would then include the same class of complex, cutting-edge, and likely-to-be-addressed-again set of cases that the CLSP would have under Proposed Federal Rule of Civil Procedure 74.<sup>273</sup> Under that rule, and for the CSJ, the science docket includes three separate considerations: a determination of essential need by the initial generalist judge, high potential for re-evaluation in the future, or the determination that a single scientific consultant under Rule 706 would

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Kantrowitz, *Proposal for an Institution for Scientific Judgment*, 156 SCI. 763, 763 (1967) (concerning the “institutionaliz[ation] [of] the scientific advisory function” of the science community and recommendations to increase the “presumptive validity of the scientific input”); William V. Luneburg & Mark A. Nordenberg, *Specially Qualified Juries and Expert Nonjury Tribunals: Alternatives for Coping with the Complexities of Modern Civil Litigation*, 67 VA. L. REV. 887, 888 (1981) (discussing use of “‘special’ juries and expert nonjury tribunals” for “complex federal civil cases”); James A. Martin, *The Proposed ‘Science Court,’* 75 MICH. L. REV. 1058, 1058 (1977) (evaluating “the desirability of establishing some kind of science court”); *Confronting the New Challenges of Scientific Evidence*, *supra* note 247, at 1603–05 (proposing the “establishment of a special court presided over by expert judges” to hear “complex and scientific cases”).

<sup>268</sup> Compare, e.g., Brennan, *supra* note 267, at 523 (discussing hazardous substance panel proposal), with Luneburg & Nordenberg, *supra* note 267, at 995–99 (proposing generalized structure for all complex disputes).

<sup>269</sup> See discussion *supra* Part III.

<sup>270</sup> The class of cases qualifying for adjudication by the Court of Scientific Jurisdiction would be the same class of certified complex cases listed in *Proposed* FED. R. CIV. P. 74(b), *supra* note 256.

<sup>271</sup> *Confronting the New Challenges of Scientific Evidence*, *supra* note 247, at 1604 (recognizing that any science court proposal requires Congressional authorization under Article III of the Constitution).

<sup>272</sup> See 28 U.S.C. § 1332(d) (2009) (setting minimal diversity jurisdiction limit for class action suits, created by the Class Action Fairness Act of 2005, Pub. L. No. 109-2, 119 Stat. 4 (2005)). The CSJ would require a similar minimal diversity for jurisdictional purposes.

<sup>273</sup> See *supra* note 256.

not be appropriate.<sup>274</sup> Under the enabling act, the CSJ would have original jurisdiction over cases meeting the substantive standard for the CSJ, and also could accept cases re-assigned to it by general federal courts when the judge makes a finding of need for reassignment.

Second, the structure of the CSJ would be fundamentally different than a typical, generalist district courthouse. Judges assigned to the CSJ would be Article III judges, but since their docket would contain mainly complex science, they must be selected for judicial worthiness with some consideration of scientific background or skill. The enabling act need not explicitly mandate a certain level of scientific or mathematical training, but as a practical matter an advanced degree should be a prerequisite. Judges could also come from a variety of disciplines, so that overall a wide variety of skills come together under the one roof of the CSJ.

In addition to scientifically skilled judges, the CSJ could, as the centralized court in the field, regularly appoint “science clerks” in addition to the legal clerks a federal court normally appoints. Science clerks would permit the judges to further evaluate and refine science testimony and issues, particularly if outside the particular discipline of the judge.<sup>275</sup> If judges can appoint clerks to assist them in making legal findings, a science clerk to assist in making science findings under *Daubert* seems appropriate as well.

Besides the staffing on the bench and in chambers, the CSJ would operate under the identical Rules of Civil Procedure and Rules of Evidence as a standard federal court. As a result, the CSJ judges would continue to make *Daubert* rulings on litigants’ expert testimony, hold trials, and draft written rulings. In these rulings, the CSJ judges could offer an advanced level of detail in scientific areas, separating the legal and scientific bases of the opinions, to provide other judges with non-CSJ cases more guidelines to use in their work. On appeal, the CSJ cases should be appealable to the U.S. Court of Appeals for the Federal Circuit.<sup>276</sup> Not unlike patent litigation, the Federal Circuit could become an appellate court familiar with the special intricacies of the CSJ, and it would become better able to

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<sup>274</sup> *Id.* See also *supra* Part IV.A. (recommending use of scientific consultant). The Independent Expert from Rule 706 would therefore remain the default method to deal with complex cases, and solely those cases meeting these advanced criteria merit the use of the science panel/science court approach. See *supra* note 231; see also *supra* text accompanying note 252; Sanders, *supra* note 185, at 81.

<sup>275</sup> The “clerk as advisor” approach has been tried famously in a notable case, when Judge Wyzanski appointed an economist, Carl Kaysen, to serve as his clerk during the time of a major antitrust case. *United States v. United Shoe Mach. Corp.*, 110 F. Supp. 295 (D. Mass. 1953). For analysis of *United Shoe* and the law clerk analogy, see Deason, *supra* note 251, at 138–40.

<sup>276</sup> See LeRoy L. Kondo, *Untangling the Tangled Web: Federal Court Reform Through Specialization for Internet Law and Other High Technology Cases*, 2002 UCLA J.L. & TECH. 1, 92 (2002); see also Hess, *supra* note 244, at 554; Luneberg & Nordenberg, *supra* note 267, at 930–31.

handle CSJ appeals over time.<sup>277</sup>

The CSJ proposal offers significant benefits over the current structure of generalist judges handling science cases. The consideration of scientific literacy in the appointment of Article III judges for the CSJ would overcome the empirical research finding of generalist judges' significant weaknesses in handling complex science and statistics.<sup>278</sup> Judges with scientific training would not have this Achilles' heel.

Second, the CSJ proposal brings science back into the judicial process again, in a way not seen since the abrogation of *Frye*.<sup>279</sup> With judges who have been trained in scientific fields, science knowledge and the "general state of scientific knowledge" re-enters the courtroom, not through the litigants' experts, but through the judge.<sup>280</sup>

An additional benefit comes from the location of the CSJ in the national capital. Since the court would be in Washington, D.C., the CSJ could call upon national bodies of scientific research, such as the National Academies of Sciences, National Science Foundation, or the American Association for the Advancement of Science, should the need for court-appointed experts arise.<sup>281</sup> This offers the benefit of a large number of well-trained technicians, unmatched in diversity of fields, within the same city as the CSJ, and is a benefit unique to this location in the United States.

Finally, the CSJ proposal, as a court of special jurisdiction, is a specialized structure that has proven to be valuable in other areas of complex litigation such as business disputes. In the most well-known example, the Delaware Court of Chancery has been adjudicating complex business disputes since 1792.<sup>282</sup> In handling complex business litigation,

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<sup>277</sup> See Kondo, *supra* note 276, at 92 (discussing the use of specialized judges at the Federal Circuit level); Hess, *supra* note 244, at 554 (analogizing specialist judges of a science court with Federal Circuit judges). On the general question of familiarity resulting in judicial accuracy, see Sanders, *supra* note 185, at 82.

<sup>278</sup> See *supra* Parts III.A.–B.

<sup>279</sup> See *supra* note 249 (discussing how the general acceptance test of *Frye* was relegated to only one consideration in the *Daubert* system).

<sup>280</sup> *Id.* This also occurs, to a lesser extent, with the science clerks.

<sup>281</sup> The National Academies of Sciences, the National Academy of Engineering, the National Research Council, and the Institute of Medicine are headquartered in Washington, D.C., as is the American Association for the Advancement of Science. The National Science Foundation is across the Potomac in Arlington, VA. See The National Academies: Advisors to the Nation on Science, Engineering, and Medicine, <http://www.nationalacademies.org/> (last visited July 17, 2009); The American Association for the Advancement of Science, <http://www.aaas.org/> (last visited July 17, 2009); The National Science Foundation, <http://www.nsf.gov/> (last visited Aug. 4, 2009). See *supra* Part IV.A. (suggesting court-appointed experts). For a discussion of the benefit of the scholarly societies in the Washington area, see Beyea & Berger, *supra* note 1, at 364; Greenland, *Critical Appraisal*, *supra* note 2, at 308; Rodricks & Rieth, *supra* note 50, at 31.

<sup>282</sup> See William T. Quillen & Michael Hanrahan, *A Short History of the Delaware Court of Chancery—1792–1992*, in BICENTENNIAL COMMEMORATION COMMITTEE, COURT OF CHANCERY OF THE STATE OF DELAWARE 1792–1992 (1992), reprinted in 18 DEL. J. CORP. L. 819, 822 (1993).

the court has “earned a worldwide reputation for fairness, experience, and expertise in presiding over corporate disputes.”<sup>283</sup> Based on this reputation, the court attracts litigants from around the United States interested in a specialized and fair process of adjudication for their complex disputes.<sup>284</sup> Due to the success of the Delaware model, other states have authorized business or complex commercial courts with similar models.<sup>285</sup> In the context of complex commercial litigation, litigants see the benefits of a specialized docket and court with specialized knowledge.<sup>286</sup> The same should be true for complex science.

Critics of the science court of specialized jurisdiction may attack the CSJ proposal on several grounds. Initially, there is a question whether the court could proceed with jury trials, since the guarantee of a jury trial often involves a cross-sectional jury from the location of the court.<sup>287</sup> It is first helpful to note that juries need not be selected from the location of the dispute, but may constitutionally be selected from a district in which there could have been jurisdiction, after transfer of venue,<sup>288</sup> or from another unrelated district as in a case of media bias.<sup>289</sup> Unless the CSJ used a jury pool selection procedure that impedes on equal protection rights, jury fairness would be preserved by the proposed structure.<sup>290</sup> As long as the enabling statute of the science court grants it jurisdiction over any case meeting the substantive terms of jurisdiction, then the court would be an appropriate location for any complex dispute.<sup>291</sup>

A second criticism of the proposal could include the argument that any proposal with nonrandom assignment of judges is bad policy and subject to abuse.<sup>292</sup> In response, it is important to first examine the sources of a

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<sup>283</sup> Donald F. Parsons, Jr., & Joseph R. Slights III, *The History of Delaware's Business Courts: Their Rise to Preeminence*, BUS. L. TODAY, Mar./Apr. 2008, at 21.

<sup>284</sup> *Id.* at 25.

<sup>285</sup> See Lee Applebaum, *The “New” Business Courts: Responding to Modern Business and Commercial Disputes*, BUS. L. TODAY, Mar./Apr. 2008, at 13, 14–17 (discussing establishment of business courts in Florida, Maine, North Carolina, South Carolina, and others); Mnookin, *supra* note 185, at 1031 (discussing increased use of business/complex civil litigation court model).

<sup>286</sup> Specialized decisionmakers are unquestioned in the context of patent and bankruptcy litigation. See 35 U.S.C. §101 *et seq.* (2006) (patent statute); 28 U.S.C. §151 *et seq.* (2006) (bankruptcy court designation).

<sup>287</sup> 28 U.S.C. § 1861 (2006).

<sup>288</sup> *Id.* § 1404(a).

<sup>289</sup> *Id.* § 1404(b).

<sup>290</sup> Luneburg & Nordenberg, *supra* note 267, at 923–25.

<sup>291</sup> Jurisdiction for the CSJ would be based on a particular jurisdictional statute, for example, 28 U.S.C. § 1332 (1996), creating jurisdiction to that court for all cases which could be brought in federal court elsewhere but, due to their subject matter, belong at the CSJ. For another example, see the bankruptcy jurisdictional statute, 28 U.S.C. § 1334 (1996). See *supra* text accompanying note 271 (noting Congress would need to create CSJ as an Article III court).

<sup>292</sup> See, e.g., David J. Damiani, Comment, *Proposals for Reform in the Evaluation of Expert Testimony in Pharmaceutical Mass Tort Cases*, 13 ALB. L.J. SCI. & TECH. 517, 542–45 (2003) (discussing neutrality and undue influence concerns in specialized science courts).

potential randomness requirement. While Congress has seen bills requiring random assignment of judges, those proposals have not been passed into law.<sup>293</sup> Under the current United States Code, 28 U.S.C. § 137, the chief judge of the district court is responsible for the observance of assignment rules adopted by the district judges.<sup>294</sup> This statute does not mandate random assignment,<sup>295</sup> and so far the case law regarding a constitutional right to random assignment has been “generally hostile to the approach and undertake[n] little thoughtful analysis.”<sup>296</sup> Randomness is often a result of local rules within the circuit, but often the rules are deemed “‘housekeeping’ measures” or are not enforced.<sup>297</sup> Since there is no “right” to random assignment, the courts have not enforced random assignment as an obligation on the judicial selection of cases.<sup>298</sup> As a result, the assignment of a controversy to the CSJ would not infringe upon a protected right of a litigant.

Even if not a “right,” courts often mention that the selection of the judge or courtroom should not be arbitrary, based on improper grounds, or create an appearance of impropriety.<sup>299</sup> None of these concerns are raised by the CSJ. Because the court is created to handle a certain class of cases, and structured to better handle them, a reassignment is not arbitrary or without cause. Nor is a reassignment based on improper grounds; rather, it reflects the judgment of Congress, in enacting the CSJ enabling act, that well-trained specialists with technical backgrounds can better handle disputes involving complex or cutting-edge scientific evidence. Finally, as to the appearance of impropriety, the CSJ enhances rather than diminishes the fairness to the parties, allowing for fair, impartial adjudication of the dispute, within the framework of a court better able to handle the dispute.<sup>300</sup> That structure is more appropriate and addresses the weaknesses exposed within the current system.

For the subset of the most complex, detailed, and first-impression cases in scientific fields, a court of special jurisdiction for science would provide an institutionalized alternative to the science panel approach.<sup>301</sup> The court would allow dispute resolution in a specialized setting, proven to

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<sup>293</sup> See Blind Justice Act of 1999, S. 1484, 106th Cong. (1999) (referred to the Committee on the Judiciary) (proposing random assignment of judges except in related cases and technical cases).

<sup>294</sup> 28 U.S.C. § 137 (2006).

<sup>295</sup> See J. Robert Brown, Jr. & Allison Herren Lee, *Neutral Assignment of Judges at the Court of Appeals*, 78 TEX. L. REV. 1037, 1090 (2000) (discussing the absence of statutory authority prescribing neutral assignment of federal judges).

<sup>296</sup> *Id.* at 1099.

<sup>297</sup> *Id.* at 1096 (citations omitted).

<sup>298</sup> *Id.* at 1096–99 (citing *In re Yagman*, 796 F.2d 1165 (9th Cir. 1986)).

<sup>299</sup> *Id.* at 1098, 1101–02 (citations omitted).

<sup>300</sup> See *supra* text accompanying notes 282–84 (discussing the Delaware Court of Chancery’s reputation for fairness in adjudicating complex business disputes).

<sup>301</sup> See *supra* Part IV.B.1. (describing Complex Litigation Science Panels).

be effective in the complex business litigation context. It also has the added benefit of proximity to the major organizations of scientific advancement in the U.S. By sending the most complex science cases to the CSJ, the court system could overcome weaknesses of the current *Daubert* regime, allowing for the wise exercise of Rule 702 discretion within the *Daubert* framework.

### C. Discrete Points of Modification

Independent of the structural reform for scientific evidence questions, discussed in Parts IV.A.–B., several smaller modifications could also enhance the judicial accuracy and efficiency in handling complex or cutting-edge science.

#### 1. Allow Modifications to Expert Opinion to Account for New Science, as “Good Cause” Under Rule 16

In *Daubert* evaluations, the Supreme Court commands that scientists bring the same rigor of their discipline to the courtroom as from the laboratory.<sup>302</sup> Under the current formulation of Federal Rule of Civil Procedure 16, this may not be possible.

The basic scientific method, and epidemiologic science in particular, mandates the continued evaluation of new data in formulation and testing of conclusions.<sup>303</sup> Under Federal Rule of Civil Procedure 16, however, the case management order mandates a single disclosure of data and opinions from experts.<sup>304</sup> Any new information after that date cannot be used as a basis for an opinion of an expert, unless the court grants an amendment to the case management order for “good cause.”<sup>305</sup>

In order to ensure that scientists may continue to assimilate data, or at least take into account new data or studies postdating the initial disclosure, a Rule 16 determination of “good cause” should include language allowing modifications of experts’ opinions based on the scientific method. Whether by committee note, or by including a specific caveat within the language of Rule 16(b)(4), litigants should be granted leave to amend the scheduling order for good cause to allow for additional scientific opinion based on new data postdating the initial disclosures.

The proposal to allow modification of a scheduling order for scientific good cause has several benefits. First, it returns the rigor of the laboratory to the courtroom, as *Daubert* commands.<sup>306</sup> In addition, it allows for the court to correct, before it is enshrined in precedent, a scientific

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<sup>302</sup> *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

<sup>303</sup> *See supra* Part III.E.2. (noting how the discovery process may impede this goal).

<sup>304</sup> *See supra* text accompanying notes 221–23.

<sup>305</sup> FED. R. CIV. P. 16(b)(4); *see supra* text accompanying note 223.

<sup>306</sup> *See supra* notes 229, 302, and accompanying text.

misconception that has *already* been shown to be without scientific basis. In doing so, it prevents what has been deemed “judicial junk” by prominent commentators in the field of epidemiology.<sup>307</sup> “Judicial junk” has a tendency to mislead future courts,<sup>308</sup> so correcting known errors early in the process is worth the time and expense necessary to modify the disclosed expert opinions. Otherwise, the ability to re-examine the scientific content will be lost as appellate decisions focus on the legal rules under the appropriate standard of review.<sup>309</sup>

Critics of this proposal may state that it is impractical in application, allowing late endorsement of experts by lazy litigants who erroneously endorsed the expert at the first disclosure. Some litigants may see this as an opportunity to try to “game” the system, play hide the ball, or whatever metaphor applies to disingenuous litigation tactics. Judges should be aware of this as a possibility, using the “good cause” rule on science only for those cases when the new data or studies truly postdate the initial disclosures. We trust judges to make these determinations in normal Rule 16(b)(4) motions to modify a scheduling order, and we should trust that judges will be able to make determinations on the issue of scientific changes as well.

## 2. Focus of Judicial Training

Another method to increase the judicial accuracy, efficiency, and consistency of scientific evidence under *Daubert* is to increase the opportunity for judicial training in the general theories, methodologies, and practice of scientific research.

Empirical research demonstrates that judges lack fundamental knowledge in basic science concepts and statistics.<sup>310</sup> In addition, when asked about the number of classes in science or math in their educational background, judges scored below a subset of the jury pool consisting of college graduates.<sup>311</sup> As a result, judges as a class of professionals lack some of the essential skills needed to handle the *Daubert* analysis. One approach to dealing with this issue is to bring science into chambers, by either appointment of independent experts or use of science panels or a science court.<sup>312</sup>

However, for some scientific principles the reform need not advance that far. Judges can be, and are, trained at conferences, workshops, or

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<sup>307</sup> Beyea & Berger, *supra* note 1, at 348–49.

<sup>308</sup> *Id.* at 348, 353.

<sup>309</sup> *Daubert* decisions are subject to an abuse of discretion standard. *G.E. v. Joiner*, 522 U.S. 136, 141 (1997).

<sup>310</sup> See discussion *supra* Parts III.A.–B. (discussing judicial weakness in these areas).

<sup>311</sup> See *supra* text accompanying note 132.

<sup>312</sup> See discussion *supra* Parts IV.A.–B. (detailing proposed science panel or science court).

other events held by scientists.<sup>313</sup> While there may be a potential for conflicts of interest in the sponsorship of these training sessions,<sup>314</sup> workshops and conferences appear to be utilized by judges in their training in science or statistics.<sup>315</sup>

An important consideration, even in light of this use of CLE and workshops in specific areas of science, is that empirical evidence shows judges overwhelmingly (ninety-six percent) have not received training in *general* scientific principles.<sup>316</sup> As a result, the training in the specific areas may well be too complex, or too subject specific, to be of use in the wide variety of cases before a court of general jurisdiction.

In response, the respected bodies of scientists should tailor some of their continuing education goals to filling the unmet need in general methodologies and procedures of scientific research. As a result, judges can be trained to be critical of proposed expert testimony, better able to know the assumptions contained within research, and less dependent on the opposing expert to point out weaknesses in an opinion by a litigant's expert.<sup>317</sup>

## V. CONCLUSION

The *Daubert* system for judicial screening of expert evidence for relevance and reliability assumed judges would be able to analyze, critically evaluate, and make value judgments about the relative worth of highly complex, cutting-edge science.

Following *Daubert*, courts faced difficulty with these determinations under Federal Rule of Evidence 702. In a series of cases following *Daubert*, courts faced the challenge of complex epidemiologic risk evidence. While inconsistently handling the epidemiologic risk evidence under *Daubert*, the judicial handling of this complex field of science exposed other weaknesses of the *Daubert* system.

Weaknesses of the *Daubert* regime include judicial knowledge and background with fundamental scientific principles, judicial ability to handle complex statistical information, overuse of bright-line tests that

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<sup>313</sup> Beyea & Berger, *supra* note 1, at 370; see DAVID L. FAIGMAN, LEGAL ALCHEMY 200 (1999) (explaining the training programs of the Federal Judicial Center, National Judicial College, and Private Adjudication Center, to teach judges science and statistics).

<sup>314</sup> Greenland, *Critical Appraisal*, *supra* note 2, at 309. This is not a reason to fail to have training sessions, but rather emphasizes the need for content-neutral, non-conflicted sponsorship by organizations such as the Federal Judicial Center or National Judicial College. See FAIGMAN, *supra* note 313, at 200.

<sup>315</sup> See Gatowski et al., *supra* note 123, at 442 (finding that sixty-three percent of judges surveyed reported having attended a CLE class about specific scientific evidence).

<sup>316</sup> *Id.*

<sup>317</sup> *Id.* at 455; Greenland, *Critical Appraisal*, *supra* note 2, at 309; Beyea & Berger, *supra* note 1, at 370.

may lack scientific validity, the use of litigation experts who may not represent the general state of knowledge in the field, and the incompatibility of the judicial procedure with measured evaluation of complex scientific principles. Each identified issue presents a reason why a judge may inconsistently or inaccurately evaluate the most difficult scientific principles.

Identifying weaknesses with the *Daubert* review, however, allows us to work to fix the problems by modifying the current system. One way to bring more science back into the courthouse, or to judges' chambers, is to permit the appointment of a science consultant under a modified Federal Rule of Evidence 706. For an even smaller subset of cases, more radical reform is appropriate. In those cases, use of a science panel constituted under a modified arbitration panel format would create a formalized process for review. In the alternative, a Court of Scientific Jurisdiction offers significant advantages to the process, and has met with great success in the complex business litigation context. Finally, other smaller reforms, such as refocusing continuing education efforts and the expansion of "good cause" to include the development of knowledge in the field, plug holes in the *Daubert* system exposed by the epidemiologic risk controversy.

By critically examining the breakdown of *Daubert* in the face of epidemiologic risk evidence, evaluating the nature of the weaknesses in the system, and initiating changes structured to respond to those reforms, we can modify the current *Daubert* system to allow judges to more consistently, accurately, and efficiently handle the most complex cutting-edge science presented in the courtroom.