

## Proving Toxic Harm: Getting Past Slice And Dice Tactics

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### INTRODUCTION PART I: BAD LAW MAKES FOR BAD RESULTS

In complex litigation, such as personal injury or wrongful death actions based upon exposure to toxic and hazardous materials or pharmaceutical injuries, the critical issue is often one of causation: whether the substance in question caused the injury.<sup>1</sup> All too often, courts buy into defendants' arguments that the evidence must be sliced and diced into smaller and smaller subsets until it is virtually impossible to prove that the exposure caused the injury.<sup>2</sup> Plaintiffs' experts are ridiculed and attacked for reaching conclusions different from the corporate defendants.<sup>3</sup> Anything not paid for by and supportive of industry is deemed "junk science."<sup>4</sup>

Texas offers us an extreme example of the obstacles put in the path of a plaintiff seeking to prove causation against a major corporation.<sup>5</sup> Vioxx was a non-steroidal anti-inflammatory pain medication.<sup>6</sup> Merck & Co. had put it on the market in May of 1999, but just a few years later, on September 30, 2004, Merck withdrew Vioxx from the market because clinical trials had shown the drug increased the risk of heart attack and other cardiovascular problems.<sup>7</sup> Thousands of lawsuits were filed.<sup>8</sup> After a number of bell-weather trials in the multidistrict litigation (MDL) and a number of state court verdicts, Merck agreed to a \$4.85 billion settlement of the federal multidistrict litigation.<sup>9</sup>

While the federal court in the MDL had permitted plaintiffs' experts to testify that short-term low dose use of the drug could cause heart attacks, based, among other things, upon their interpretation of the raw data from Merck's clinical trials, the Texas Supreme Court took a radically different view in *Merck & Co. v. Garza*.<sup>10</sup> Even though Merck had conceded that clinical trials were the

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1. See *infra* Part I.

2. See generally PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM (1991).

3. *Id.*

4. Peter W. Huber described junk science as "meaningless data, fearful speculation and fantastic conjecture . . . elaborate, systematized, jargon-filled, serious-sounding deceptions." HUBER, *supra* note 2.

5. See *Merck & Co., Inc. v. Garza*, 277 S.W.3d 430 (Tex. App. 4th 2008).

6. *Merck & Co., Inc. v. Garza*, 347 S.W.3d 256, 260 (Tex. 2011).

7. *Merck & Co., Inc.*, 277 S.W.3d at 435.

8. *Merck & Co., Inc.*, 347 S.W.3d at 261–62.

9. *Id.*

10. *Id.* at 265.

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best evidence for determining the relationship between a drug and a health outcome, the plaintiffs' experts were not permitted to base their opinions on this data.<sup>11</sup> Instead, Texas demanded at least two statistically significant epidemiology studies that show a doubling of the risk at a similar dose for a similar duration.<sup>12</sup> This can almost never be done because each subgroup would be too small to generate statistically significant results.<sup>13</sup> If a plaintiff can somehow find two such studies, the court will then conduct a "secondary reliability inquiry" questioning the soundness of each study's findings and underlying integrity.<sup>14</sup> With this impossible burden, the door slammed shut on the plaintiffs.<sup>15</sup>

As will be discussed more fully below, Texas does not stand alone in its impedance of science in the courtroom. Other courts similarly demand levels of certainty and methodologies simply not found in the real world of science and epidemiology.<sup>16</sup> The result is a protection of corporate wealth and a shifting of the burden of injury and disease away from the responsible party and onto the victim. This Article examines much of the case law regarding expert epidemiological testimony, the hurdles plaintiffs must overcome, and how arguments can be framed to enhance the likelihood that an expert's opinion will be admitted at trial. Part I of this Article addresses the Supreme Court triumvirate<sup>17</sup> that set the standard for the admissibility of expert scientific and technical opinions. The judge has been anointed gatekeeper to assess the reliability and thus admissibility of each expert's opinions. Part II looks at those cases that have interpreted the admissibility standards so narrowly that a plaintiff's epidemiology expert is rarely permitted to testify. The court achieves this by dissecting each piece of data that the expert relies upon to see if it withstands scrutiny and independently supports the opinion being offered, even when that was never the expert's intention. Part III of this Article examines those judicial decisions that seek to understand and permit scientific testimony following methodologies actually used by scientists in the real world. These courts recognize the holistic approach so often used by real scientists outside the courtroom. Part IV highlights a framework for presenting a plaintiff's epidemiology expert so as to improve the likelihood that the opinions will withstand scrutiny and be deemed admissible at trial.

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11. *Merck*, 277 S.W.3d at 435.

12. *Id.* at 263–264.

13. See Bernadette Dijkman, et. al., *How to Work with a Subgroup Analysis*, NAT'L CTR. FOR BIOTECHNOLOGY INFORMATION (2009), available at <http://www.topclassactions.com/lawsuit-settlements/lawsuit-news/4621-merck-agrees-to-23m-viox-class-action-lawsuit-settlement/> (on file with the *McGeorge Law Review*) ("The chance of falsely obtaining significant subgroup effects and interactions (i.e., type I errors) increases quite dramatically when many subgroup analyses are performed.").

14. *Id.* at 266.

15. See generally *id.* at 433.

16. *Id.*

17. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993); *General Electric Co. v. Joiner*, 522 U.S. 136 (1997); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999).

INTRODUCTION PART II: EXPERT EPIDEMIOLOGY TESTIMONY IS GENERALLY  
NECESSARY TO PROVE CAUSATION IN A TOXIC TORT CASE

Most courts look at causation as a two-part question. First is the issue of “general causation”—whether the substance *can* cause the injury.<sup>18</sup> The second issue is of “specific causation”—whether the substance caused *this* injury.<sup>19</sup> Resolution of these issues depends almost entirely upon expert opinion testimony.<sup>20</sup> The admissibility of the expert opinion, governed by Federal Evidence Rule 702,<sup>21</sup> is thus critical to the case.

Two decades ago, the US Supreme Court decided *Daubert v. Merrell Dow Pharmaceuticals*,<sup>22</sup> requiring trial court judges to act as gatekeepers to assess the reliability and relevance of expert scientific opinions. This meant that the expert’s methodology had to be scientifically valid and the opinions had to “fit” the evidence in the case.<sup>23</sup>

It has been my observation that, since *Daubert*, numerous courts have aggressively exercised their gatekeeper roles to reject expert causation testimony, particularly in toxic tort cases, due to a refusal to recognize methodologies that are widely accepted in the scientific community, misconceptions about the science, or by taking an atomistic approach that examines individually and independently each piece of scientific evidence that the expert relies upon.<sup>24</sup> Thomas O. McGarity calls this the “Corpuscular Approach to Expert Testimony.”<sup>25</sup> Courts taking this “corpuscular” view have all too often rejected animal studies, *in vitro* and *in vivo* studies, case studies, meta-analyses, and weight-of-the-evidence analysis.<sup>26</sup> When looking at epidemiologic studies, they have misunderstood or misapplied relative risk, statistical significance, or dose-response to reject expert testimony based upon generally accepted methodologies. Quite simply, the “corpuscular” approach slices and dices an expert’s opinion, and the material relied upon, into ever-smaller subparts to see if they can each withstand scrutiny.

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18. *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp.2d 434, 525 (W.D. Penn. 2003).

19. *See id.*

20. *See id.*

21. 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.

22. 509 U.S. 579 (1993).

23. *Id.* at 591.

24. *See* 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, 18 (2001).

25. *See id.*

26. *Id.*

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Usually this “corpuscular” view of a plaintiff’s causation expert has been due to the defendants’ urging, asking the court to parse the individual studies and data an expert relies upon, while at the same time ignoring the well-recognized weight-of-the-evidence methodology that permits scientific opinions based upon conclusions drawn from the totality of the evidence, with no individual study or piece of data having to be sufficient on its own to prove causation.<sup>27</sup> The slicing and dicing “veg-o-matic” has made it into the courtroom at the expense of truth and a nuanced understanding of science.

Fortunately, a few courts throughout the years have recognized that this “corpuscular” view, slicing and dicing an expert’s opinion, is not a proper application of Rule 702 or *Daubert*. For example, *United States v. W.R. Grace*<sup>28</sup> noted that Evidence Rule 702 requires a “holistic approach” to an expert’s opinion evidence.

Generally, an inquiry under Rule 702 examines the expert’s testimony as a whole. The 702 inquiry typically does not examine the reliability or relevance of particular data sets that underlie the expert testimony . . . .<sup>29</sup>

Other courts have recognized that their responsibility is not to become super-scientists, but rather simply to confirm that the expert “employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”<sup>30</sup> The inquiry into the expert’s methodology and the reliability of the epidemiologic opinions to be offered is not an excuse to determine what the judge personally believes, but rather is supposed to focus on what expert epidemiologists would find reliable. “In determining whether the facts or data are admissible, the proper inquiry is not what the court deems reliable, but what experts in the relevant discipline deem it to be.”<sup>31</sup>

Recently, in *Milward v. Acuity Specialty Product Group, Inc.*,<sup>32</sup> the First Circuit Court of Appeals recognized the liberal intent of Federal Evidence Rule 702 and permitted expert testimony based upon a weight-of-the-evidence analysis.<sup>33</sup> This approach “focuses upon the totality of scientific information and asks in a holistic way whether a cause-effect conclusion seems warranted.”<sup>34</sup> This weight-of-the-evidence methodology is used by the Environmental Protection Agency (EPA), National Toxicology Program (NTP), Agency for Toxic Substances and Disease Registry (ATSDR), Occupational Safety and Health

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27. *McGarity*, *supra* note 25, at 19.

28. 504 F.3d 745 (9th Cir. 2007).

29. *Id.* at 762.

30. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

31. *Rubanick v. Witco Chemical Corp.*, 593 A.2d 733, 746 (N.J. 1991).

32. 639 F.3d 11 (1st Cir. 2011).

33. *See generally id.*

34. *McGarity*, *supra* note 25, at 23.

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Administration (OSHA), International Agency for Research on Cancer (IARC) and World Health Organization (WHO), among other entities.<sup>35</sup> It is a standard and reliable process for determining causation. If judges refuse to accept this methodology and instead use the “corpusecular approach to expert testimony,” the science done in the laboratory and relied upon by federal, state, and international regulatory and standard-setting bodies will be excluded by the courts. This is precisely the kind of dichotomy *Daubert* was intended to prevent.<sup>36</sup> If the methodology is sufficiently reliable to be used in the laboratory or by a regulatory body, then it is sufficiently reliable for the courtroom. It is then up to the jury to decide if the expert’s conclusions are sufficiently persuasive.

PART I: THE ADVENT OF THE *DAUBERT* ERA HAS MADE THE ADMISSION OF  
EXPERT EPIDEMIOLOGY OPINIONS FAR MORE DIFFICULT

For decades in the past, the admissibility of expert testimony was governed by the *Frye* standard.<sup>37</sup> Under that test, the question was whether the expert’s opinion had received general acceptance by at least a substantial minority of the scientific community.<sup>38</sup> Unless a theory was generally accepted, it would not be permitted into evidence.<sup>39</sup> This standard still remains in effect in some state courts, such as Illinois.<sup>40</sup>

Then, there was a sea-change in the early 1990’s due to a US Supreme Court case, *Daubert v. Merrell Dow Pharmaceuticals*,<sup>41</sup> where the high court looked at whether the general acceptance test should be applied to assess the admissibility of scientific testimony under the Federal Rules of Evidence.<sup>42</sup> In *Daubert*, the plaintiffs claimed the pregnancy drug Bendectin had caused their children’s birth defects.<sup>43</sup> The plaintiffs’ experts sought to offer opinions on causation based upon:

- Laboratory studies showing Bendectin was a teratogen (causes damage to a fetus);
- Animal studies showing Bendectin can cause birth defects;

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35. See Thomas O. McGarity & Sidney A. Shapiro, *Regulatory Science in Rulemaking and Tort: Unifying the Weight of the Evidence Approach*, 3 WAKE FOREST J.L. & POL’Y 65, 67, 91 (2013).

36. See generally *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

37. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923).

38. *Id.*

39. *Id.*

40. See *People v. McKown*, 875 N.E.2d 1029, 1031, 1036 (Ill. 2007) (stating that the *Frye* test applies in Illinois).

41. 509 U.S. 579 (1993).

42. See generally *id.*

43. *Id.* at 582.

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- Pharmacological studies showing the chemical structure of Bendectin was similar to substances known to cause birth defects; and
- Meta-analyses of prior epidemiological studies.<sup>44</sup>

The trial court threw out the expert testimony and granted summary judgment to the defendant.<sup>45</sup> The court had found that the experts' re-analyses of epidemiology studies were not published or peer-reviewed, and that laboratory research, animal studies, and pharmacological comparisons were not sufficient to prove Bendectin caused birth defects.<sup>46</sup> The trial court concluded that the experts' opinions were not generally accepted in the scientific community and therefore not admissible.<sup>47</sup> The Court of Appeals affirmed.<sup>48</sup>

The Supreme Court accepted the case to examine whether the *Frye* general acceptance standard was the appropriate test for the admissibility of expert opinions under the Federal Rules of Evidence.<sup>49</sup> Because the Federal Rules were intended to liberalize the admissibility of evidence, the Court concluded that the old *Frye* Standard was no longer appropriate.<sup>50</sup> In fact, the Court emphasized "the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to opinion testimony."<sup>51</sup>

The Court found that under FRE 702 the judge is to act as a gatekeeper to make certain scientific testimony is both reliable and relevant.<sup>52</sup> The Court reasoned that reliability is tied to the scientific validity of the methodology applied by the expert to reach the opinions to be offered.<sup>53</sup> Relevance is tied to whether the opinions "fit" the facts of the case.<sup>54</sup>

The Supreme Court suggested a number of factors, none of which were definitive or exclusive, that courts should consider when testing the reliability of an expert's methodology:

- whether the theory or technique can be and has been tested;
- whether the theory has been subject to peer review and publication;
- the known or potential rate of error; and

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44. *Id.* at 583.

45. *Id.*

46. *Id.* at 583–84.

47. *Id.* at 584.

48. *Id.*

49. *Id.* at 585.

50. *Id.* at 588.

51. *Id.* at 588 (internal quotations omitted).

52. *Id.* at 592–93.

53. *Id.* at 590.

54. *Id.* at 591.

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- the degree the theory has been generally accepted in the relevant scientific community.<sup>55</sup>

Significantly, the Court noted that the inquiry is flexible and the focus “must be solely on principles and methodology, not on the conclusions that they generate.”<sup>56</sup> Moreover, citing Rule 703,<sup>57</sup> the court recognized expert opinions are to be admitted where the facts or data are “of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject.”<sup>58</sup>

This liberalized approach to the admission of expert testimony unfortunately did not last long. Following *Daubert*, the Supreme Court revisited the question of the admissibility of expert opinions in *General Electric Company v. Joiner*.<sup>59</sup> There, the Court concluded that a trial court’s decision in its role as gatekeeper was to be reviewed on appeal by the abuse of discretion standard; that is, the trial court’s decision could be reversed only where it was “manifestly erroneous.”<sup>60</sup> Significantly, while the focus in *Daubert* had been solely on the expert’s methodology, in *Joiner* the Court noted that often “conclusions and methodology are not entirely distinct from one another.”<sup>61</sup> Thus, the Court held that while experts may extrapolate from existing data and research to reach an opinion, a court need not accept an expert’s opinion that is connected to the underlying data solely by the “*ipse dixit*” of the expert where “there is simply too great an analytical gap between the data and the opinion proffered.”<sup>62</sup> The door to an examination of an expert’s conclusions, not just methodology, was now open.

The decision in *Joiner* is significant because the Court found that it was not an abuse of discretion for the trial court to have examined the sufficiency of the epidemiologic studies the plaintiff’s experts had relied upon to conclude that PCBs could and in fact did cause the plaintiff’s lung cancer.<sup>63</sup> Likewise, the Court found no abuse of discretion where the trial court had found that the experts’ extrapolation from various studies and animal research to reach their conclusion on causation was impermissible.<sup>64</sup>

Justice Breyer, concurring, expressed concern that the gatekeeper function under Rule 702 asks judges to make “subtle and sophisticated determinations” even though these judges are “not scientists and do not have the scientific

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55. *Id.* at 593–94.

56. *Id.* at 595.

57. FED. R. EVID. 703.

58. *Daubert*, 509 U.S. at 595.

59. 522 U.S. 136 (1997).

60. *Id.* at 141–42.

61. *Id.* at 146.

62. *Id.*

63. *Id.* at 146–47.

64. *Id.* at 144–45.

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training that can facilitate the making of such decisions.”<sup>65</sup> Justice Breyer then suggested that in such cases judges use FRE 706<sup>66</sup> to “appoint an expert to serve on behalf of the court” to independently advise the judge about scientific methodology.<sup>67</sup>

In his dissent in *Joiner*, Justice Stevens noted that the plaintiff’s experts had used a weight-of-the-evidence methodology, relying on all of the studies taken together, along with other available data, to reach their conclusions.<sup>68</sup> “The District Court, however, examined the studies one by one and concluded that none was sufficient to show a link between PCB’s and lung cancer . . . . The focus of the opinion was on the separate studies and the conclusions of the experts, not on the experts’ methodology.”<sup>69</sup> Like the Court of Appeals, Justice Stevens found that the weight-of-the-evidence methodology was scientifically acceptable and valid. “It is not intrinsically ‘unscientific’ for experienced professionals to arrive at a conclusion by weighing all available scientific evidence—this is not the sort of ‘junk science’ with which *Daubert* was concerned.”<sup>70</sup>

Finally, Justice Stevens found solace in the fact that the majority had not held that it would have been an abuse of discretion for the trial court to have admitted the expert testimony.<sup>71</sup> “[N]othing in either *Daubert* or the Federal Rules of

65. *Id.* at 147–48.

66. FED. R. EVID. 706. Court-Appointed Expert Witnesses

- (a) Appointment Process. On a party’s motion or on its own, the court may order the parties to show cause why expert witnesses should not be appointed and may ask the parties to submit nominations. The court may appoint any expert that the parties agree on and any of its own choosing. But the court may only appoint someone who consents to act.
- (b) Expert’s Role. The court must inform the expert of the expert’s duties. The court may do so in writing and have a copy filed with the clerk or may do so orally at a conference in which the parties have an opportunity to participate. The expert:
  - (1) must advise the parties of any findings the expert makes;
  - (2) may be deposed by any party;
  - (3) may be called to testify by the court or any party; and
  - (4) may be cross-examined by any party, including the party that called the expert.
- (c) Compensation. The expert is entitled to a reasonable compensation, as set by the court. The compensation is payable as follows:
  - (1) in a criminal case or in a civil case involving just compensation under the Fifth Amendment, from any funds that are provided by law; and
  - (2) in any other civil case, by the parties in the proportion and at the time that the court directs—and the compensation is then charged like other costs.
- (d) Disclosing the Appointment to the Jury. The court may authorize disclosure to the jury that the court appointed the expert.
- (e) Parties’ Choice of Their Own Experts. This rule does not limit a party in calling its own experts.

67. *Joiner*, 522 U.S. 136 at 150.

68. *Id.* at 151.

69. *Id.* at 152–53 (citations omitted).

70. *Id.* at 153.

71. *Id.* at 155.

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Evidence requires a district judge to reject an expert's conclusions and keep them from the jury when they fit the facts of the case and are based on reliable scientific methodology."<sup>72</sup>

This case highlights the problem with an abuse of discretion standard for review of decisions on the admissibility of expert testimony.<sup>73</sup> The trial court rejected the expert testimony in *Joiner* under the abuse of discretion standard.<sup>74</sup> But as Justice Stevens recognized, the Supreme Court did not say that if the lower court had reached the opposite conclusion it would have been an abuse of discretion.<sup>75</sup> Once the expert testimony was held inadmissible, the plaintiff could not meet her burden of proof and summary judgment for defendant was inevitable.<sup>76</sup> Yet under normal circumstances, the summary judgment would have been reviewed *de novo* and examined for any factual or legal error. Instead, the critical evidence was rejected under a standard looking only for gross error.<sup>77</sup>

Finally, in *Kumho Tire Company, Ltd. v. Carmichael*,<sup>78</sup> the Supreme Court held that the *Daubert* gatekeeper function applies to all expert opinions, including technical and other specialized knowledge, not just scientific opinions.<sup>79</sup> Furthermore, the trial court has broad discretion not only in its determination on the admissibility of the expert opinions, but also as to the procedures to follow in fulfilling its "gatekeeper role."<sup>80</sup> While the objective of the gatekeeper requirement "is to make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field,"<sup>81</sup> that simple standard is frequently ignored, as evidenced by *Merck & Co., Inc. v. Garza*,<sup>82</sup> where the Texas Supreme Court drew a bright line (requiring two statistically significant studies showing at least a doubling of the risk),<sup>83</sup> even though that is not how experts in the field practice.

While the Supreme Court's original intention in *Daubert* was to liberalize the admission of scientific opinion testimony and permit novel but scientifically sound theories to be put before a jury, that all too often has not been the practical result. For example, on remand in *Daubert*, the Court of Appeals applied the new standard and still threw out the plaintiffs' expert testimony.<sup>84</sup>

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72. *Id.*

73. *See id.* at 155.

74. *Id.* at 141.

75. *Id.*

76. *Id.* at 143–46.

77. *Id.*

78. 526 U.S. 137 (1999).

79. *Id.* at 141.

80. *Id.*

81. *Id.* at 152.

82. 347 S.W.3d 256 (Tex. 2011).

83. *Id.* at 265.

84. *See generally* *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir. 1995).

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Under *Daubert* and its progeny, if the court determines that an expert is qualified, the judge then looks at the methodology, studies, and data relied upon by the expert to decide if these support the expert's opinions. Under the old *Frye* standard, interpretation of studies and data was the function of the expert; and the court was not supposed to determine whether the expert properly relied upon data and studies that experts in the field generally rely upon.<sup>85</sup> Thus, under *Frye*, it was generally deemed wrong for a judge to independently review each study or piece of data the expert relied upon and decide if it supports the expert's opinion.<sup>86</sup> The question was whether the opinions were generally accepted by at least a substantial minority of experts in the field.<sup>87</sup> Peer review and publication was thus pivotal to show general acceptance in the relevant scientific community.<sup>88</sup>

Now, after *Daubert* and *Joiner* in particular, the judge often substitutes his own assessment of scientific studies for that of the expert. This is the judge as super-scientist. Justice Rehnquist, in his concurrence in *Daubert*, recognized that Rule 702 gave the judge a gatekeeping responsibility, but he did not believe that the Rule "imposes on them either the obligation or authority to become amateur scientists in order to perform that role."<sup>89</sup> Unfortunately, in spite of the Chief Justice's warning, too many judges look at each piece of the scientific puzzle separately to see if it is reliable, instead of looking at the totality of the evidence to see if, as a whole, it supports the expert's opinion. Judges engage in this "corpuscular" or "slice and dice" process, reinterpreting the scientific studies and articles the experts rely upon, even though they lack the expertise and what they do is not consistent with good science or good law.

The issue for plaintiffs therefore becomes how to persuade a trial judge to look at an expert's methodology the way scientists look at problems and reach conclusions outside the courtroom, rather than defense lawyers' approach, which wants the underlying basis for opinions to be parsed *ad nauseum*. By examining how some judges have misunderstood or misapplied scientific methodology at defendants' urging, and how other judges have implicitly understood and accepted the scientific method, a framework for future arguments in *Daubert* hearings can be constructed.

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85. *Donaldson v. Cen. Ill. Pub. Serv. Co.*, 767 N.E.2d 314, 324 (Ill. 2002).

86. *Id.* at 326.

87. *Id.* at 323–24.

88. *See generally Donaldson*, 767 N.E.2d at 314.

89. *Daubert*, 509 U.S. at 600–01.

PART II: MISPLACED ATTACKS ON EPIDEMIOLOGICAL EVIDENCE IMPROPERLY  
KEEP PLAINTIFFS' EXPERTS AT BAY

As noted above, one of the greatest problems found in decisions from courts considering expert epidemiological testimony is the failure or refusal of judges to look at the science in the same manner as scientists: the court “slices and dices” the studies and other data relied upon by the expert to determine if each piece of the total puzzle independently supports the expert’s opinion. Of course, this is precisely what the defendants want and urge the court to do. By taking this approach, courts ignore general scientific principles, misinterpret and misapply generally accepted methodology, and reach distorted and incorrect results. These courts refuse to apply in the courtroom the same methodology that scientists use in the field, and American and international regulatory and standard-setting bodies apply. While the court in *Joiner* may have said this is not an abuse of discretion, it certainly is bad science and bad policy.<sup>90</sup>

In *Henrickson v. ConocoPhillips*,<sup>91</sup> the plaintiff claimed his acute myelogenous leukemia (AML) was caused by benzene found in the gasoline he was exposed to when he worked in a terminal and as a gasoline tanker driver.<sup>92</sup> There was no dispute that benzene causes AML.<sup>93</sup> However, the court focused on defendant’s argument that benzene in gasoline cannot cause AML.<sup>94</sup> The court said it could not presume that the qualitative toxic and carcinogenic effects of benzene from all sources are the same and questioned whether benzene in gasoline was somehow different from benzene alone.<sup>95</sup> The court also questioned whether the small amount of benzene in gasoline (one to two percent) was enough to cause AML.<sup>96</sup>

In conducting its gatekeeper role, the court stated that to extrapolate from benzene studies to gasoline containing benzene, the experts “must explain and demonstrate why the extrapolation is scientifically proper.”<sup>97</sup> Plaintiff’s expert epidemiologist had done just that, stating in his report that the “toxicity of gasoline to the bone marrow has mirrored the toxicity of benzene even though the literature related to gasoline has lagged that of benzene.”<sup>98</sup> He pointed to studies of “occupational exposure to gasoline containing 1-2% benzene [that] demonstrate an elevated risk of leukemia, including AML, with cumulative

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90. See generally *General Electric Co. v. Joiner*, 522 U.S. 136 (1997).

91. 605 F. Supp. 2d 1142 (E.D. Wash. 2009).

92. *Id.* at 1148.

93. See *id.* at 1156 (indicating that the only “question before the court is whether exposure to the benzene-component of gasoline is capable of causing AML”).

94. *Id.* at 1156.

95. *Id.*

96. *Id.*

97. *Id.* at 1156.

98. *Id.* at 1151.

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benzene exposures of as low as 1.5 ppm-years.”<sup>99</sup> He also showed epidemiological studies “demonstrat[ing] ‘significantly elevated risks’ of AML among those who transport gasoline and those who are engaged in terminal work . . . where gasoline is loaded and unloaded.”<sup>100</sup> And finally, he noted that the “genotoxic effects of benzene in gasoline support the biological plausibility of gasoline to induce leukemia.”<sup>101</sup>

The court concluded that the expert’s general causation testimony “must be excluded because the studies [he relied] upon singly or in combination [did] not support the causation conclusions [he made].”<sup>102</sup> The court was persuaded by the defendant’s arguments even though they were based upon contradictory and inconsistent epidemiological evidence, such as refinery studies which did not even show AML was caused by benzene (a generally recognized fact) and compared occupational exposures to exposures in the general population (ignoring the healthy worker effect).<sup>103</sup> Clearly, the judge improperly weighed contradictory evidence and chose to adopt the defendant’s arguments.

On the issue of epidemiological studies, the court noted that plaintiff’s expert had relied upon studies that just showed positive associations (relative risk (RR) < 2) but not a supposedly definitive causal relationship (RR > 2).<sup>104</sup> In general, epidemiological studies are most often used to prove general causation.<sup>105</sup> “[A] relative risk greater than 1.0” means the substance “has the capacity to cause the disease.”<sup>106</sup> A relative risk above 2.0 implies a probability that the agent at issue caused the illness being studied.<sup>107</sup> It also indicates “that the agent more likely than not was responsible for a particular individual’s disease.”<sup>108</sup> This means that a relative risk that is greater than 2.0 is probative evidence of both general and specific causation.<sup>109</sup>

But the *Henrickson* court, like so many others, refused to permit reliance on studies showing a RR < 2 as just one piece of a puzzle showing general causation, even though epidemiologists routinely rely upon such studies in their scientific practice. Confusion over relative risk has become a major problem in *Daubert* reviews because of this growing refusal to consider RRs < 2 as being

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99. *Id.* at 1168.

100. *Id.*

101. *Id.*

102. *Id.* at 1175.

103. *See, e.g.,* Bernard D. Goldstein & Stuart L. Shalat, *The Causal Relation Between Benzene and Multiple Myeloma*, 95 BLOOD 1512, 1512 (Feb. 15, 2000); Peter F. Infante, *Benzene Exposure and Multiple Myeloma: A Detailed Meta-Analysis of Benzene Cohort Studies*, 1076 ANN. OF N.Y. ACAD. OF SCI. 90, 90–91 (2006).

104. *Henrickson*, 605 F. Supp. 2d at 1175.

105. *Id.* at 1158.

106. *Id.*

107. *Id.*

108. *Id.*

109. *Id.*

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reliable in conjunction with other evidence to prove general causation.<sup>110</sup> The key to the bad result in *Henrickson* was the court's refusal to look at the totality of the evidence or to examine the methodology applied by experts: conclusions based upon all the pieces of the puzzle in conjunction, not piecemeal.<sup>111</sup>

Another example of slicing and dicing can be found in *Valentine v. Conrad*.<sup>112</sup> There, the plaintiff had worked in a laboratory at a PPG Industries paint plant and was exposed to various toxic chemicals, including organic solvents such as benzene.<sup>113</sup> He developed glioblastoma multiforme and died. The widow sought workers compensation where she only had to show that something in the work environment had "contributed" to her husband's brain tumor.<sup>114</sup>

The Ohio Supreme Court, applying the *Daubert* standard, held that in analyzing the methodology and reliability of an expert's opinion, the trial court must "apprise itself of the details of the proffered evidence."<sup>115</sup> Thus, in Ohio, courts are required to examine each of the studies that an expert relies upon and decide if it supports what the expert claims.<sup>116</sup> This clearly turns the judge into a super-scientist who examines studies and data relied upon by experts, re-interprets them, and decides if they support the expert's opinions.

The court in *Valentine* concluded that none of the studies that the plaintiff's expert witnesses relied upon involved workers in the same industry, none showed a direct causal relation between a single specific chemical and brain tumors, and animal studies were not adequate to prove causation.<sup>117</sup> So, the court sliced and diced the studies and data relied upon by the experts, found that each individually did not support the experts' opinions, and excluded the testimony, leading to summary judgment for the defendant.<sup>118</sup>

But the majority decision failed to address significant evidence that played a critical part in the experts' methodology.<sup>119</sup> Mr. Valentine and a coworker died within a week of each other.<sup>120</sup> Both had glioblastoma multiforme.<sup>121</sup> Both had worked for thirty years in the same lab and were exposed to the same chemicals.<sup>122</sup>

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110. This is evident in the recent Texas Supreme Court decision rejecting reliance on any study with a relative risk <2. See generally *Merck & Co. Inc. v. Garza*, 277 S.W.3d 430 (Tex. 2008). A bright-line legal test has replaced science.

111. See generally *Henrickson*, 605 F. Supp 2d.

112. 850 N.E.2d 683 (Ohio 2006).

113. *Id.* at 685.

114. *Id.*

115. *Id.* at 687.

116. *Id.*

117. *Id.*

118. *Id.* at 688.

119. *Id.* at 689.

120. *Id.*

121. *Id.*

122. *Id.*

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There were only seventeen people with these exposures for this length of time.<sup>123</sup> The odds of the two of them dying like this were 1 in 1,442,206.<sup>124</sup>

Moreover, various studies cited by the experts showed that workers exposed to the same types of toxic chemicals found in the PPG lab developed brain tumors.<sup>125</sup> These studies included a petrochemical research facility and a petrochemical plant.<sup>126</sup> They also included a study of workers in China showing persons exposed to organic solvents had a significantly elevated risk for brain cancer.<sup>127</sup> The experts also cited studies showing that lab technicians and chemists who, like Mr. Valentine, routinely handled solvents had a higher than expected incidence of brain cancer.<sup>128</sup> Plaintiff's neurosurgeon also cited genetic research showing that animals exposed to benzene developed the same type of brain tumor as Mr. Valentine.<sup>129</sup> He concluded that the cumulative evidence in the medical literature and his twenty-five years of experience provided a substantial basis for the opinion that long-term excessive exposure to the solvents and other cancer-causing chemicals identified in Mr. Valentine's work environment can cause brain cancers such as glioblastoma multiforme.<sup>130</sup>

As the dissent concluded, "These witnesses were not 'hired guns.' They did not use unscientific principles and methodology. These opinions are not 'junk science.'"<sup>131</sup> But the court threw out the testimony by looking at each piece of evidence that the experts relied upon separately and finding that it alone was not sufficient to support the opinion on causation.<sup>132</sup> The court refused to accept that scientists look at the totality of the evidence, not just individual bits in isolation.<sup>133</sup>

A litany of other cases has rejected epidemiologic testimony for various reasons. For example, the court in *Castellow v. Chevron USA, Inc.*<sup>134</sup> refused to accept opinion testimony based on case reports on the grounds they were "unscientific and speculative."<sup>135</sup> Similarly, the court in *LeBlanc v. Chevron USA, Inc.*<sup>136</sup> held that "individual case reports, while interesting, do not constitute reliable scientific evidence" to support an opinion on general causation.<sup>137</sup> That same court

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123. *Id.*

124. *Id.* at 689.

125. *Id.* at 691.

126. *Id.*

127. *Id.*

128. *Id.* at 691.

129. *Id.*

130. *Id.*

131. *Id.* at 693.

132. *Id.* at 687–88

133. *Id.*

134. 97 F. Supp. 2d 780 (S.D. Tex. 2000).

135. *Id.* at 787.

136. 513 F. Supp. 2d 641 (E.D. La. 2007).

137. *Id.* at 663–64.

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later refused to permit opinion testimony based on a meta-analysis because the underlying studies did not independently show a statistically significant risk.<sup>138</sup>

Many courts have endorsed the view that an expert's reliance on epidemiological studies must be delved into in detail, with the court reviewing and judging each and every study the expert relied upon. Thus, in *Kilpatrick v. Breg, Inc.*,<sup>139</sup> the court held that it was proper for the lower court to analyze each study in detail to determine its independent reliability.<sup>140</sup> The court also found that the use of case reports was not a scientific methodology.<sup>141</sup>

*Magistrani v. One Hour Martinizing Dry Cleaning*<sup>142</sup> considered the admissibility of expert testimony based upon the weight-of-the-evidence methodology, where the expert evaluated multiple types of studies and data, such as epidemiology studies, *in vitro* and animal studies, toxicology studies, and biological plausibility. Then, taking all of the information as a whole, the expert reached his opinion.<sup>143</sup> The court found that the expert's opinion was not admissible because there was no reliable scientific method dictating how to weigh all of this evidence.<sup>144</sup> Rather, the court accepted the defense expert's opinion that each underlying study and piece of evidence must be separately analyzed and its reliability independently assessed.<sup>145</sup> In other words, an expert cannot look at the totality of the evidence and determine that the whole is greater than the sum of its parts.<sup>146</sup>

Similarly, in *Knight v. Kirby Inland Marine, Inc.*,<sup>147</sup> the court rejected a weight-of-the-evidence analysis by looking at the fifty-plus studies relied upon by the expert and concluding that none standing alone gave an adequate basis for the causation opinion.<sup>148</sup> The court simply ignored or misunderstood the weight-of-the-evidence methodology.<sup>149</sup>

PART III: JUDICIAL RECOGNITION OF THE METHODOLOGY USED BY REAL WORLD SCIENTISTS WILL LEAD TO THE ADMISSIBILITY OF PLAINTIFFS' EXPERT OPINIONS

Other courts have chosen not to become amateur scientists or to adopt defense arguments lock, stock, and barrel, instead simply doing what FRE 702

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138. 2009 U.S. Dist. LEXIS 106339, at \*13 (E.D. La. 2009).

139. 613 F.3d 1329 (11th Cir. 2010).

140. *Id.* at 1341.

141. *Id.* at 1339.

142. 180 F. Supp. 2d 584 (D. N.J. 2002).

143. *Id.* at 599–600.

144. *Id.* at 601–02.

145. *Id.*

146. *Id.*

147. 482 F.3d 347 (5th Cir. 2007).

148. *Id.* at 355.

149. *See generally id.*

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and *Daubert* require: confirm that the expert is applying the same rigor in the courtroom as would be applied in the laboratory and before federal, state, and international regulatory and standard-setting bodies.

The critical determination is whether comparable experts accept the soundness of the methodology, including the reasonableness of relying on this type of underlying data and information. Great difficulties can arise when judges, assuming the role of scientist, attempt to assess the validity of a complex scientific methodology.<sup>150</sup>

The court in *Rubanick* was particularly concerned about a trial judge trying to second-guess an expert.

[T]he trial court here “independently reviewed” each of the thirteen studies on which [the expert] relied, and decided that they “do not say what plaintiff’s expert concludes.” In engaging in such an analysis, the court substituted its own assessment of the studies for that of an acknowledged expert. [However,] “[t]he interpretation of the data . . . is the function of the qualified expert . . . . [C]ourts should be loath to determine whether the particular expert has properly relied upon data which experts in the field generally rely on.”<sup>151</sup>

The actual inquiry should not be about the judge’s personal interpretation of the underlying scientific support for an expert’s opinion, but rather the reliability of the expert’s methodology.

Thus, the inquiry is not the reliability of the expert’s ultimate opinion nor is it whether the expert thought his or her own reliance on the underlying data was reasonable, nor whether the court thinks that the expert’s reliance was reasonable. The proper inquiry is whether comparable “experts in the field [would] actually rely” on that information.<sup>152</sup>

Not all courts have accepted defendants’ efforts to reduce an expert’s opinion and methodology *ad absurdum*. In *Ruff v. Ensign-Bickford Company*,<sup>153</sup> the plaintiffs had been diagnosed with non-Hodkins Lymphoma (NHL), allegedly due to chemicals in the water they drank.<sup>154</sup> The plaintiffs’ experts showed that the chemicals at issue could cause NHL, but the defendant argued that there are several subtypes of NHL, and plaintiffs should be required to show that the specific subtype at issue was caused by the chemicals to which they were

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150. *Rubanick v. Witco Chemical Corp.*, 593 A.2d 733, 748 (N.J. 1991) (citation omitted).

151. *Id.* at 749 (internal citations omitted).

152. *Id.* (internal citations omitted).

153. 168 F. Supp. 2d 1271 (D. Utah 2001).

154. *Id.* at 1273–74.

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exposed.<sup>155</sup> The court held that studies of the exact subtype of NHL were not necessary.<sup>156</sup> Rather, the defendant's argument could be used on cross-examination to challenge the weight of the testimony; it did not go to admissibility.<sup>157</sup>

Recognizing that Rule 702 was intended to relax traditional barriers to expert opinion testimony, the court in *Cook v. Rockwell International Corp.*<sup>158</sup> held that a liberal standard should be applied and doubts should be resolved in favor of admissibility.<sup>159</sup> The court noted that "epidemiology cannot objectively prove causation; rather causation is a judgment by epidemiologists and others interpreting epidemiological data."<sup>160</sup> The court then concluded that opinions based on studies showing even a weak association between exposure and disease are not unreliable per se as a matter of science or law.<sup>161</sup> Rather, the weakness of the association goes to the weight to be given to the opinion testimony.<sup>162</sup> Similarly, admissibility does not depend upon statistically significant results.<sup>163</sup> "The statistical significance or insignificance of [a study's] results may affect the weight given to [the expert's] testimony, but does not determine its admissibility under Rule 702."<sup>164</sup>

In *McClellan v. I-Flow Corp.*<sup>165</sup> the defendants argued that studies showing just an association between a condition and a disease (i.e., a RR <2) could not reliably support a causation opinion.<sup>166</sup> Rather, they demanded "conclusive" evidence of causation before an opinion could be admissible.<sup>167</sup> The court rejected this argument outright.<sup>168</sup> Expert testimony based on studies showing "only" an association should not be excluded where the expert can explain "why the association is valid and how causation can be inferred . . . ."<sup>169</sup> The court also permitted reliance upon *in vitro* and *in vivo* animal studies, as well as case reports, because scientists and doctors rely upon these types of studies, as evidenced by the use of these types of studies in the scientific literature.<sup>170</sup> Rule 702 does not impose on the court either the obligation or the authority to become

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155. *Id.* at 1279.

156. *Id.*

157. *Id.*

158. 580 F. Supp. 2d 1071 (D. Colo. 2006).

159. *Id.* at 1082.

160. *Id.* at 1095.

161. *Id.* at 1097–98.

162. *Id.*

163. *Id.* at 1103.

164. *Id.*

165. 710 F. Supp. 2d 1092 (D. Or. 2010).

166. *Id.* at 1100.

167. *Id.* at 1101.

168. *Id.*

169. *Id.* at 1102 (internal citations omitted).

170. *Id.* at 1110–11.

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an amateur scientist in order to perform the gatekeeping function. “[A]nalogy, inference and extrapolation can be sufficiently reliable’ when the expert’s opinion is the ‘kind that a reasonable scientist or physician would make in a decision of importance arising in the exercise of his profession outside the context of litigation.’”<sup>171</sup>

*King v. Burlington Northern Santa Fe Railway Company*<sup>172</sup> is one of the best primers on the admissibility of epidemiologic evidence. It lays out in simple terms virtually every issue that might arise in considering an epidemiologist’s opinion testimony and explains how the courts should approach and resolve these questions.<sup>173</sup>

The court starts with the notion that “epidemiological studies cannot prove causation, they can [only] provide a foundation for an epidemiologist to infer and opine that a certain agent can cause a disease.”<sup>174</sup> Thus, contrary to defendants’ usual arguments, a study cannot objectively prove or disprove causation.<sup>175</sup> Rather, the strengths and weaknesses of associations found in epidemiological studies must be assessed.<sup>176</sup> This requires judgment as to how the findings fit with other scientific information.<sup>177</sup>

The court then discussed relative risk as one of the cornerstones for causal inferences.<sup>178</sup> Where a study shows a relative risk greater than 1.0, a positive association exists to support a causal inference.<sup>179</sup> The greater the relative risk, the greater the likelihood that the relationship is causal.<sup>180</sup> If the relative risk is greater than 2.0, this means a greater than fifty percent likelihood the agent caused the disease, permitting an inference of both general and specific causation.<sup>181</sup> But in considering relative risk, the questions of potential sources of error and statistical significance also arise.<sup>182</sup> The court noted that a poorly designed or executed study that is “statistically significant could be less reliable than a well-conceived and conducted study that is not statistically significant.”<sup>183</sup> Thus, the inquiry into causation is not just about whether or not there is a high enough relative risk that is statistically significant. Rather, “it involves subjective judgment. Experts consider several factors under different sets of criteria that can

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171. *Id.* at 1110.

172. 762 N.W.2d 24 (Neb. 2009).

173. *See generally id.*

174. *Id.* at 36.

175. *See id.*

176. *Id.*

177. *Id.*

178. *Id.*

179. *Id.*

180. *Id.*

181. *Id.* at 36–37.

182. *Id.* at 137.

183. *Id.* at 39.

point to causation. Relative risk presents only one factor that they consider.”<sup>184</sup>  
The court then concluded as to relative risk:

So we decline to set a minimum threshold for relative risk, or any other statistical measurement, above the minimum requirement that the study show a relative risk greater than 1.0. We agree that “it would be far preferable for the district court to instruct the jury on statistical significance and then let the jury decide whether many studies over the 1.0 mark have any significance in combination.” In short, the significance of epidemiological studies with weak positive associations is a question of weight, not admissibility.<sup>185</sup>

Regarding statistical significance, the court concluded:

We agree that statistical significance is the most obvious way for a court to determine that researchers properly ruled out random variations in the population sample accounting for the result. But those decisions requiring a study’s relative risk to be statistically significant have come under fire. Experts have pointed out that the lack of statistical significance does not demonstrate that there is no relationship. So not all courts impose a requirement of statistical significance. We also decline to impose a statistical significance requirement if an expert shows that others in the field would nonetheless rely on the study to support a causation opinion and that the probability of chance causing the study’s results is low.<sup>186</sup>

The court also considered the weight-of-the-evidence methodology, which “comprehensively analyzes the data from different scientific fields.”<sup>187</sup> As Justice Stevens had said, “it cannot be intrinsically ‘unscientific’ for experienced professionals to arrive at a conclusion by weighing all available scientific evidence.”<sup>188</sup> The court also recognized that there is no generally accepted method for determining how much weight to apply to different types of studies.<sup>189</sup> Yet the US EPA uses this methodology to assess risk,<sup>190</sup> showing that the methodology is applied by scientists functioning in the real world outside of the courtroom.

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184. *Id.*

185. *Id.* at 46.

186. *Id.* at 47.

187. *Id.* at 39.

188. *Id.*

189. *Id.* at 40.

190. *Id.* at 39–40.

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Alternatively, the court considered the Bradford Hill factors used by epidemiologists to assess causation.<sup>191</sup> These factors include (1) temporal relationship, (2) strength of the association, (3) dose-response relationship, (4) replication of the findings, (5) biological plausibility, (6) consideration of alternative explanations, (7) cessation of exposure, (8) specificity of the association, and (9) consistency with other knowledge.<sup>192</sup> Yet these factors are not mandatory criteria etched in stone. One or more of the factors may be absent, they may be weighted differently depending upon the circumstances, and a subjective element is present in judging whether causation exists.<sup>193</sup>

The court next looked at dose-response, “a hallmark of toxicology.”<sup>194</sup> While some courts require proof that a plaintiff’s actual exposure to an agent was at a level proven to be dangerous, the court noted that a dose-response relationship is not essential to proof of causation.<sup>195</sup> Moreover, an expert may be able to infer the exposure level without precise exposure information.<sup>196</sup> In fact, rarely do exposures occur in a manner that permits a quantitative determination.<sup>197</sup> Thus, semiquantitative or qualitative estimates of exposure may be sufficient.<sup>198</sup>

Finally, the court noted that, at heart, an expert’s opinion must be based on good grounds, derived by the scientific method and supported by appropriate validation, not subjective belief or unsupported speculation.<sup>199</sup> “If the underlying data are so lacking in probative force and reliability that no reasonable expert could base an opinion on them, an opinion which rests entirely upon them must be excluded.<sup>200</sup>” The focus should be on “whether no reasonable expert would rely on the studies to find a causal relationship—not whether the parties dispute their force or validity.”<sup>201</sup> The court concluded that “while the trial court acts as the evidentiary gatekeeper, it is not a goalkeeper.”<sup>202</sup>

What started out as another case of slicing and dicing to reach summary judgment for a defendant, turned out on appeal to be a major victory for science in the courtroom and the generally-accepted methodology of looking at the whole picture. *Milward v. Acuity Specialty Product Group, Inc.*<sup>203</sup> involved a plaintiff who developed acute promyelocytic Leukemia (APL), a subtype of acute

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191. *Id.* at 40.

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.* at 41.

196. *Id.*

197. *Id.*

198. *Id.*

199. *Id.* at 43.

200. *Id.* at 45.

201. *Id.* at 49.

202. *Id.* at 43.

203. 664 F. Supp. 2d 137 (D. Mass. 2009), *rev’d* 639 F. 3d 11 (1st Cir. 2011).

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myeloid leukemia (AML), from benzene exposure.<sup>204</sup> Plaintiff's expert offered the opinion that a number of factors, taken together, showed a causal relationship between benzene and APL.<sup>205</sup> The expert noted that APL is just a subtype of AML; that all AML subtypes derive from genetically damaged stem cells; and that all AMLs involve transposition of chromosomes.<sup>206</sup> Moreover, most epidemiology studies do not differentiate between subtypes of AML.<sup>207</sup> The defendant and its experts, on the other hand, argued that while benzene has been shown to cause some types of AML, it has not been shown to cause all subtypes, such as APL.<sup>208</sup>

The plaintiff in *Milward* offered at the *Daubert* hearing, in addition to the testimony of its causation expert, the opinions of an expert on scientific methodology to support the methodology utilized by plaintiff's trial expert.<sup>209</sup> This has become a common tactic used by defendants to challenge plaintiffs' experts but has been a less common device utilized by plaintiffs. It was extremely effective and helpful in *Milward*.<sup>210</sup>

The methodology expert addressed in his initial report (and then a supplemental declaration responding to the defense experts) the basic principle that scientists not only disagree on ultimate conclusions but also often disagree on applicable theories, what evidence should be considered, and the weight to give the various matters considered.<sup>211</sup> Moreover, "quite respectable scientists may reasonably differ in their scientific judgments even if they agree on the same data and on considerations that guide theory choices."<sup>212</sup> The plaintiff's methodology expert then noted:

[A] scientist, in reviewing and assessing all the scientific evidence for a conclusion . . . must consider and *integrate all the available relevant evidence*, utilizing his or her professional judgment to come to a conclusion about the best explanation to account for an observed association. Moreover, this review should include consideration of all available and relevant human evidence, evidence from experimental animals, scientific reviews, chemical structure-biological activity evidence, various kinds of mechanistic evidence (which may or may not

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204. *Id.* at 140.

205. *Id.* at 142.

206. *Id.* at 143-44.

207. *Milward v. Acuity Specialty Prod. Group, Inc.*, 639 F.3d 11, 24 n.18 (1st Cir. 2011).

208. *Milward*, 664 F. Supp 2d at 146.

209. *Milward*, 639 F.3d at 19.

210. *See id.*

211. *Id.* at 21 n.14.

212. Supplemental Declaration of Carl F. Cranor, PH.D, M.S.L., at ¶ 4 *Milward v. Acuity Specialty Products Grp., Inc.*, 639 F.3d 11 (1st Cir. 2011).

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be available), a range of experimental studies that could assist inferences and so on.<sup>213</sup>

As the methodology expert stated, the weight-of-the-evidence methodology is used by the IARC and the US Toxicology Program “for determining whether a substance is a known or probable human carcinogen.”<sup>214</sup> He also explained:

As part of a review of the science, whether for assessing claims in physics or human health, scientific judgment is critically involved not only for drawing the ultimate conclusions, but also for a number of steps along the way . . . . An expert reviews the body of data that appear to bear on causal judgments, selects the scientifically relevant data, assesses and weighs studies for their quality, weighs the importance of different kinds of data vis-à-vis one another (e.g., animal studies versus human studies versus short-term studies versus structure-activity relationships versus mechanistic evidence versus any case studies and so on), and brings her background understanding of biology and toxicology, as well as her understanding of the phenomena, to the causal issues. Scientific judgment also enters into integrating all the data and how it bears on evaluating different possible explanations in light of all the evidence and the particular phenomena to be explained (e.g., a disease).<sup>215</sup>

The expert then analyzed the defense experts’ opinions at length, accusing them of “an impoverished conception of scientific evidence” contrary to national and international scientific approaches.<sup>216</sup> He showed how the defense disregarded scientific evidence contrary to procedures at NTP and IARC, misused the Bradford Hill considerations (not mandatory criteria as defendants would have the court believe), and ignored selection bias in the studies they relied upon.<sup>217</sup>

Thus, plaintiff’s methodology expert was able to give the court an overview of the weight-of-the-evidence scientific methodology, an appraisal of what the plaintiff’s expert had done and why it was consistent with scientific processes used nationally and internationally, and a critique of the defense experts’ bias and misuse of accepted methodology.<sup>218</sup> As seen from the result in *Milward*, using a separate expert from the testifying expert offering the substantive opinions for trial can be an effective and persuasive strategy.<sup>219</sup>

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213. *Id.* at ¶ 5.

214. *Id.*

215. *Id.* at ¶ 6 (footnote omitted).

216. *Id.* at ¶ 8.

217. *Id.* at ¶ 9–10, 14–15.

218. *See supra* notes 134–137 and accompanying text.

219. *Milward v. Acuity Specialty Product Group, Inc.*, 664 F. Supp. 2d 137 (D. Mass. 2009), *rev’d* 639 F.

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In spite of all the plaintiff's expert's testimony, the trial court held that plaintiff's expert could not extrapolate from general benzene studies or studies of other subtypes to APL because the chromosome translocations were not identical.<sup>220</sup> Nor was the expert permitted to testify based upon the totality of similarities among AML subtypes.<sup>221</sup> The trial court also noted the absence of epidemiology studies showing a causal connection between benzene and APL even though there are not enough cases of APL to support a statistically significant epidemiology study.<sup>222</sup> The result was that the defendants were able to exclude expert testimony by slicing and dicing the disease into subtypes for which it is impossible to conduct epidemiology studies, and then convinced the court that in the absence of epidemiology studies there can be no proof of causation. The First Circuit Court of Appeals reversed in what must be viewed as a major victory for plaintiffs.<sup>223</sup> Recognizing this, the defendants have petitioned the United States Supreme Court for certiorari.<sup>224</sup>

The Court of Appeals began its analysis by noting that courts are not "empowered to determine which of several competing theories has the best provenance."<sup>225</sup> It then noted, quoting *Daubert*, "So long as an expert's scientific testimony rests upon 'good grounds,' based on what is known, it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities."<sup>226</sup> If all courts followed this tenet, the admissibility of expert testimony would be less about slicing and dicing an expert's opinion and methodology and more about whether the expert followed practices relied upon real scientists functioning in the real world.

Milward's expert had applied the weight-of-the-evidence methodology by applying the Bradford Hill "viewpoints"<sup>227</sup> for determining causation to five bodies of evidence.<sup>228</sup> The Court of Appeals recognized that scientific judgment is

3d 11 (1st Cir. 2011).

220. *Id.* at 144.

221. *Id.*

222. *Id.* at 146.

223. 639 F.3d 11 (1st Cir. 2011).

224. *U.S. Steel Corp. v. Milward*, 639 F.3d 11 (1st Cir. 2011), *cert. denied*, 2012 U.S. Lexis 229 (U.S. Jan. 9, 2012) (No. 11-316).

225. *Milward*, 639 F.3d at 15 (internal citations and quotations omitted).

226. *Id.*

227. The Bradford Hill "viewpoints" involve consideration of nine factors, none of which are conclusive and not all need be present. Moreover, the various criteria cannot be ranked into any kind of hierarchy of significance. The Bradford Hill factors are:

[T]he strength or frequency of the association; the consistency of the association in varied circumstances; the specificity of the association; the temporal relationship between the disease and the posited cause; the dose response curve between them; the biological plausibility of the causal explanation given existing scientific knowledge; the coherence of the explanation with generally known facts about the disease; the experimental data that relates to it; and the existence of analogous causal relationships.

*Id.* at 17.

228. These included "the fact that benzene causes AML as a class, that all subtypes of AML likely have a

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necessary to conduct the weight-of-the-evidence analysis. Quoting Comment (c) to the Third Restatement of Torts §28, the court noted, “No algorithm exists for applying the Hill guidelines to determine whether an association truly reflects a causal relationship or is spurious. Because “[n]o scientific methodology exists for this process . . . reasonable scientists may come to different judgments about whether such an inference is appropriate.”<sup>229</sup> Thus, the evaluation of scientific evidence requires judgment and interpretation similar to that used in a differential diagnosis. The court recognized:

The fact that the role of judgment in the weight of the evidence approach is more readily apparent than it is in other methodologies does not mean that the approach is any less scientific. No matter what methodology is used, “an evaluation of data and scientific evidence to determine whether an inference of causation is appropriate requires judgment and interpretation.” [Thus], [n]o serious argument can be made that the “weight of the evidence approach is inherently unreliable.”<sup>230</sup>

The trial court had looked at all the evidentiary components of the expert’s analysis atomistically, requiring the ultimate opinion to be supported by each piece of evidence independently. But under the weight-of-the-evidence approach,

no body of evidence was itself treated as justifying an inference of causation. Rather, each body of evidence was treated as grounds for the subsidiary conclusion that it would, if combined with other evidence, support a causal inference. The district court erred in reasoning that because no one line of evidence supported a reliable inference of causation, an inference of causation based on the totality of the evidence was unreliable . . . . The hallmark of the weight of the evidence approach is reasoning to the best explanation for all of the available evidence.<sup>231</sup>

The court noted that the fact that there might be another explanation for the evidence is not a sufficient basis for excluding the expert testimony.<sup>232</sup> Any alleged flaws go to the weight to be given the opinion, not its admissibility.<sup>233</sup>

Lastly, the court looked at the epidemiological evidence that the plaintiff’s expert had relied upon. The court concluded that the paucity of epidemiological

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common etiology, that benzene is known to cause the general types of cellular damage that are known to cause APL, that benzene is known to inhibit an enzyme whose inhibition is known to cause APL, and that APL has been reported in benzene-exposed workers in a number of epidemiological studies.” *See id.* at 20.

229. *Id.* at 18 (citing RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 28 reporters’ note cmts. c(3) and c(4) (2010).

230. *Id.* at 18–19.

231. *Id.* at 23.

232. *Id.* at 22.

233. *Id.*

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studies did not make it “almost impossible” for the expert’s opinion to be admissible, as the defendants had argued.<sup>234</sup> “Epidemiological studies are not per se required as a condition of admissibility regardless of context.”<sup>235</sup> Here, the rarity of the disease makes it very difficult to perform an epidemiological study of the causes of APL.<sup>236</sup> Moreover, the lack of statistically significant studies was not a deviation from sound scientific methodology under these circumstances.<sup>237</sup> The fact that APL has been observed in studies of exposed workers was a piece of the total weight-of-the-evidence puzzle, indicating that the epidemiological evidence was at least consistent with the expert’s conclusion that benzene causes APL.<sup>238</sup>

Thus, the appellate court found that plaintiff’s expert had reasonably applied a reliable methodology.<sup>239</sup> Questions about the sufficiency of the evidence to support the ultimate opinion go to the weight of the opinion, not its admissibility.<sup>240</sup> This is how it should be.

Unfortunately, upon remand, the trial court found that the plaintiff’s specific causation expert, though board certified in occupational medicine, pathology, and hematology was not qualified to interpret epidemiological studies.<sup>241</sup> She therefore could not offer a reliable opinion to address cumulative exposure as a cause of increased risk of leukemia.<sup>242</sup> Without a specific causation expert to link the plaintiff’s exposures to his illness, the court granted summary judgment to the defendant.<sup>243</sup>

Finally in this regard, the West Virginia Supreme Court recently conducted a lengthy and thoughtful analysis of the *Daubert* process in *Harris v. CSX Transportation, Inc.*<sup>244</sup> The court emphasized that the court’s gatekeeper role is simply to determine whether the expert’s science is reliable, not whether it is right: “right or wrong is not an issue of the admissibility of scientific evidence.”<sup>245</sup>

Noting that the purpose of *Daubert* was to “liberalize the rules governing the admissibility of expert testimony” and that Rule 702 “is one of admissibility

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234. *Id.* at 24.

235. *Id.*

236. *Id.* at 17.

237. *Id.* at 24.

238. *Id.* at 25.

239. *Id.* at 26.

240. *See id.*

241. 2013 U.S. Dist. LEXIS 1285 at \*36 (September 6, 2013).

242. *Id.*

243. *Milward v. Acuity Specialty Prods. Grp.*, No. 07-11944-DPW, 2013 U.S. Dist. LEXIS 127473, at \*4025 (D. Mass. September 6, 2013).

244. No. 12-1135, 2013 W. Va. LEXIS 1285 (W.V. Nov. 13, 2013).

245. *Id.* at \*11.

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rather than exclusion,<sup>246</sup> the court accused litigants of abusing the process and crowding dockets with unnecessary *Daubert* hearings.<sup>247</sup> The court held instead,

[W]hen a trial court is called upon to determine the admissibility of scientific expert testimony, in deciding the “reliability” prong of admissibility the focus of the trial court’s inquiry is limited to determining whether the expert employed a methodology that is recognized in the scientific community for rendering an opinion on the subject under consideration. If the methodology is recognized in the scientific community, the court should then determine whether the expert correctly applied the methodology to render his or her opinion. If these two factors are satisfied, and the testimony has been found to be relevant, and the expert is qualified, the expert may testify at trial.<sup>248</sup>

The court went on to conclude that courts should take judicial notice of generally recognized scientific methodologies and reserve *Daubert* evidentiary hearings for new scientific and technical methodologies that cannot be judicially noticed and require a hearing to test reliability.<sup>249</sup> *Daubert* hearings should not be held where qualified experts simply disagree about the interpretation of data obtained through standard methodologies.<sup>250</sup>

Unfortunately, it is this author’s experience that defendants all too often file *Daubert* motions and seek evidentiary hearings where both sides’ experts apply the same methodologies but reach different conclusions. Too many courts then hold evidentiary hearings and allow challenges to underlying facts, interpretations of data, and opinions that are at variance from the defendants’ experts’ opinions, even though none of these are grounds for exclusion of expert testimony.

PART IV: A FRAMEWORK FOR PRESENTING A PLAINTIFF’S EPIDEMIOLOGY  
EXPERT ON CAUSATION

The cases addressed above, both favorable and unfavorable, suggest an approach for plaintiffs going into a *Daubert* hearing on the admissibility of the opinions of an expert epidemiologist. There are, of course, no guarantees, and there is bad law, and at times bad facts, to be overcome.

First, it is incumbent upon the plaintiff to fully explain to the court the weight-of-the-evidence and Bradford Hill methodologies. This should be briefed at length, and the expert should be prepared to address it both at deposition and in

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246. *Id.* at \*5.

247. *Id.* at \*97.

248. *Id.* at \*96.

249. *Id.* at \*97.

250. *Id.* at \*98.

live testimony. It is critically important to show to the court how the various factors to be considered are “viewpoints” and not “criteria.” As Austin Bradford Hill wrote, “None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a *sine qua non*.”<sup>251</sup>

It is also important to emphasize that the weight-of-the-evidence methodology is used by American and international regulatory and standard-setting agencies such as the EPA, OSHA, ATSDR, NTP, IARC and WHO.<sup>252</sup> If the purpose of Rule 702 is to make sure that the expert witness uses the same rigor in an analysis in the courtroom as in the real world,<sup>253</sup> then this evidence should be persuasive.

A thorough discussion of the *Milward* and *King* cases and the evidentiary reliability of the weight-of-the-evidence methodology, because of its scientific validity, is imperative. It is also helpful to discuss those cases, such as *U.S. v. W.R. Grace*<sup>254</sup> and *Rubanick*,<sup>255</sup> which emphasize the court’s duty to take a “holistic approach” to expert testimony and not try to dissect the underlying data the expert relies upon.<sup>256</sup>

Second, it is important to explain in the brief to the court, as well as through the expert’s testimony, the key principles of epidemiology and how epidemiologists apply them outside of the courtroom. This means discussing relative risk, statistical significance, dose-response, healthy worker effect, selection bias, biological plausibility, and the other terms that will arise. This allows you to show that the defendants’ views on these concepts are not mainstream science but distortions and misapplications of epidemiological principles. Discussing the *King*<sup>257</sup> case can be particularly helpful in this regard.

The court in *King* recognized a number of important principles that should be presented to the court in your case. First, epidemiological studies cannot prove causation but they can be the foundation for an opinion that an agent can cause a disease. To do this, the epidemiologist must determine how a “study’s findings fit with other scientific knowledge on the subject.”<sup>258</sup>

Second, a plaintiff’s claim should not fail simply because the medical literature has not yet conclusively proven the connection between an agent and a disease. A plaintiff need only produce sufficient evidence for a reasonable person

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251. Sir Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 PROC. ROYAL SOC’Y OF MED. 295, 297 (1965).

252. See EPA, Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33992, 33996 (1986).

253. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

254. 639 F.3d 11 (1st Cir. 2011).

255. 593 A.2d 733 (N.J.1991).

256. See, e.g., *W.R. Grace*, 639 F.3d at 41 (noting Rule 702’s “holistic focus on an expert’s testimony”).

257. 762 N.W. 2d 24. (Neb. 2009).

258. *Id.* at 36.

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to conclude that the exposure caused the injury.<sup>259</sup> Only where “the underlying data are so lacking in probative force . . . that no reasonable expert could base an opinion on [that data] should an opinion be excluded.”<sup>260</sup>

All an epidemiological study can do is show the strength of an association between an agent and an outcome.<sup>261</sup> The strength of that association is reported as the relative risk.<sup>262</sup> If the relative risk is greater than 1.0, a positive association exists because the risk to the exposed group is greater than the risk to the unexposed population.<sup>263</sup> A relative risk greater than 1.0 thus supports a causal inference.<sup>264</sup>

Where the relative risk is 2.0, the agent will have caused an equal number of injuries as all other background causes.<sup>265</sup> Thus, if the relative risk is greater than 2.0, this establishes a greater than 50% likelihood that the agent caused the injury.<sup>266</sup> By showing that it is more likely than not that the agent caused the injury, a relative risk greater than 2.0 not only proves general causation, but many courts accept it as evidence of specific causation as well.<sup>267</sup>

Some courts improperly exclude an expert’s opinion on general as well as specific causation where the expert relies on a study with a relative risk less than 2.0.<sup>268</sup> Other courts more properly recognize that any relative risk greater than 1.0 is at least some evidence of a causal association and is thus relevant to the general causation inquiry.<sup>269</sup> Just because a relative risk is less than 2.0 does not mean it is irrelevant: “weak associations can indicate a causal relationship, depending upon the presence of other factors.”<sup>270</sup> Many workplace studies, for example, underestimate the relative risk.<sup>271</sup> This is why the court in *King* refused to set a minimum threshold for relative risk, other than that a study must show a relative risk greater than 1.0 as some evidence of a causal association.<sup>272</sup> Thus, “the significance of epidemiological studies with weak positive associations is a question of weight, not admissibility.”<sup>273</sup> This principle is of paramount importance and must be emphasized to the court.

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259. *Id.* at 41.

260. *Id.* at 45.

261. *Id.* at 36.

262. *Id.*

263. *Id.*

264. *Id.* at 36–37.

265. *Id.* at 37.

266. *Id.*

267. *Id.*

268. *See generally* Merck & Co., Inc. v. Garza, 277 S.W.3d (Tex. 2008).

269. *King*, 762 N.W. 2d at 37.

270. *Id.* at 46.

271. *See id.* at 37 n.131.

272. *Id.* at 46.

273. *Id.* at 46–47.

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Defendants often seek to exclude epidemiological studies on the grounds that they are not statistically significant. Statistical significance measures the risk of random variations or chance causing the study's results; a statistically significant result is not likely the result of chance.<sup>274</sup> The risk can be shown as a p-value (which measures the probability that a positive association resulted from sampling error) or as a confidence interval (showing the magnitude and stability of the association).<sup>275</sup>

However, there are confounding errors other than chance that could affect a study's results but are not measured by statistical significance. For example, a data collection error, an underestimate or overestimate of exposure, or an improper comparison group could all impact a study's results without showing up in a measure of statistical significance. Thus, a "poorly conceived or conducted study that is statistically significant could be far less reliable than a well-conceived and conducted study that is not statistically significant."<sup>276</sup>

While many courts prohibit reliance on studies that lack strong statistical significance, that does not mean a study with a weaker statistical significance does not show a causal relationship. Because of this, some courts refuse to impose a requirement for statistical significance where the expert can show that others in the field would rely on the study to support an opinion on causation.<sup>277</sup>

In the end, any expert opinion on causation involves a subjective judgment. Contrary to what defendants most vociferously argue, proving causation is not an objective inquiry depending solely upon a statistically significant relative risk greater than 2.0.<sup>278</sup> As the court noted in *King*, "a weight-of-the-evidence methodology . . . comprehensively analyzes data from different scientific fields, primarily animal tests and epidemiological studies, to assess carcinogenic risks."<sup>279</sup> This methodology is permissible even though there are no agreed-upon standards for how to weigh the particular pieces of evidence being considered.<sup>280</sup> Alternatively, many epidemiologists utilize the Bradford Hill "viewpoints" to assess causation, finding a causal relationship even where one or more of the factors are missing.<sup>281</sup>

[S]ince causal actions of exposures are neither observable nor provable, a subjective element is present in judging whether, for a given exposure, such an action exists. As a result, scientists may differ both in terms of

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274. *Id.*

275. *Id.* at 37–38.

276. *Id.* at 39.

277. *Id.* at 41.

278. *Id.* at 39.

279. *Id.*

280. *Id.* at 39–40.

281. *Id.* at 40.

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interpretation of available evidence in support of criteria used to aid causal inference, and in relative weight assigned to each criteria.<sup>282</sup>

Plaintiffs must show courts that the focus should only be on whether the expert used a valid methodology and has good grounds for the opinions offered.<sup>283</sup> Even studies that do not draw a definitive conclusion on causation may be utilized where reasonable experts would rely on such a study.<sup>284</sup> The fact that experts may disagree with the conclusions and opinions being offered is not a basis for exclusion but rather goes to the weight to be given to the evidence at trial.<sup>285</sup>

Third, consider using an expert on scientific methodology at the *Daubert* hearing to bolster the testimony of your causation expert. Not only can this expert help with explaining the weight-of-the-evidence methodology, but he can also help explain where and how the defense experts misuse or misapply epidemiological concepts to mislead the court about how epidemiology is practiced in the real world.

Whether or not you use a separate expert on methodology, your causation expert needs to initially prepare a detailed report that addresses each opinion and sub-opinion, discuss the scientific literature in support of the opinions being offered and show why any contrary literature is inapplicable, unreliable, or otherwise insufficient to alter his or her opinion. This report should also explain the weight-of-the-evidence methodology and how the various considerations, such as the Bradford Hill factors, were taken into account and balanced. Showing that the methodology used is comparable to what other experts have employed, particularly in a non-litigation setting, is imperative. Your trial expert must then be thoroughly prepared for deposition, making sure to be comfortable answering questions about all the scientific literature relied upon or deemed inapplicable. Again, being able to explain how various factors were considered and weighed can go a long way to preserving the admissibility of the ultimate opinions.

If the expert reaches additional opinions, or relies upon new materials not addressed in his or her initial report, consider submitting a supplemental report, even if the new opinions or materials were addressed at deposition. All too often courts exclude some or all of an expert's opinions where they have not been presented in a timely filed report or supplement.<sup>286</sup>

Lastly, where you know you have a court disinclined to accept your explanation of epidemiology, consider moving under FRE 706 to have the court appoint a truly independent expert with no ties to industry to advise the court on

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282. *Id.*

283. *Id.* at 49.

284. *Id.* at 48–49.

285. *Id.* at 49.

286. *See, e.g., Baker v. Chevron USA, Inc.*, 680 F. Supp. 2d 865, 879 (S.D. Ohio 2010).

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scientific processes, methods, and terms as applied in the laboratory and real world outside the courtroom. In this regard, it could be helpful to remind the court that Rule 702 does not require the judge to become an amateur scientist or to second guess an expert's interpretation of underlying studies and data. The only relevant issue is whether the methodology employed by the expert is scientifically valid and relied upon by scientists in the field.

## CONCLUSION

Epidemiology is often essential to proving a toxic tort case. It is critical that the court and counsel understand the role of the epidemiologist and the applicable standards to admit such an expert's testimony. There is a growing body of law that supports the use of this kind of expert testimony in a reasonable and effective manner. It should be made clear that the court must look at scientific evidence as scientists do, taking all of the pieces as a whole, and not slice and dice to decide if each separate piece is sufficient in and of itself to support the overall opinion of the expert. As the court in *King* noted, "while the trial court acts as the evidentiary gatekeeper, it is not a goalkeeper."<sup>287</sup>

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287. *Id.* at 43.