# CLOSE THE GATE! A DAUBERT ARGUMENT FOR EXCLUDING INDUSTRY-FUNDED "SCIENCE"

# Dayna Smith\*

## **ABSTRACT**

Many people understand that industry and industry organizations lobby to promote their agendas. However, industry groups also fund scientific studies to support industry activity, generally exploiting the public's trust in science. Many industry-backed studies are plagued by improper influence and bias that skews the results in a positive direction on behalf of the company. This science ultimately gets published, and the public relies on it, causing harm and creating a breeding ground for litigation against industry members.

Then, when industry defendants enter the courtroom, they bring with them the same biased, industry-funded science through their experts. This Article argues that judges should use the Daubert standard to exclude improper, industry-funded science from the courtroom. It first describes the problem with industry-backed science. Then, it describes the evolution of the Daubert standard. Finally, this Article argues that plaintiffs' attorneys can use the Daubert standard to argue for the exclusion of industry-funded science from evidence. Specifically, it argues that judges should forgo their usual deference to cross-examination and examine the underlying science for unreliability due to bias.

#### TABLE OF CONTENTS

I.	Introduction	46
II.	Industry "Science"	47
	The Evolution of <i>Daubert</i>	
IV.	Challenging the "Science" in a Toxic Tort Case	56
	A. Examining the Underlying Basis of an Opinion	
	B. The Sixth Factor	
V.	Conclusion.	64

<sup>\*</sup> Dayna Smith is an Assistant Professor of Law at Vermont Law & Graduate School. The Authors thanks the student editors of *Drake Law Review* for their detailed review of the article.

Drake Law Review

[Vol. 71

#### I. INTRODUCTION

The general public has historically trusted scientists.<sup>1</sup> "[A] 2009 Pew Research Center [study found that] 84 percent of the public had a positive outlook on science and scientists."<sup>2</sup> Yet, in recent years, anti-science groups have grown in number, with science being subjected to a "morally charged antagonism."<sup>3</sup> However, despite recent skepticism of science in various demographic groups, confidence in scientific leaders in the United States has generally been stable over the last 30 years and most Americans have supported investment in research and a role for science in the public's life.<sup>4</sup>

This general trust in science can be manipulated though.<sup>5</sup> For example, industry groups often fund scientific research or provide gifts to scientists in exchange for the ability to influence what gets published.<sup>6</sup> The public ultimately relies on this science, resulting in harm and creating a breeding ground for litigation against industry members.<sup>7</sup> Trial opens up another opportunity for industry science to cause injustice through doubt and skewed results when it is presented by industry experts' testimony.<sup>8</sup>

- 1. Jim Wedeking & Brenten H. Williams, *Cultural Perceptions of Science: Trials and Regulatory Decision Making*, NAT. RES. & ENV'T, Spring 2017, at 31, 31 ("Scientists have long been trusted and admired, a perception that persists today.").
- 2. *Id.* (referencing PEW RSCH. CTR., PUBLIC PRAISES SCIENCE; SCIENTISTS FAULT PUBLIC, MEDIA (2009), https://www.pewresearch.org/politics/2009/07/09/section-1-public-views-of-science-and-scientists/ [https://perma.cc/5GQK-CD2Q] (follow directions to download complete report)).
- 3. MICHAEL GASTROW & N. ISHMAEL-PERKINS, PUBLIC PERCEPTIONS AND UNDERSTANDINGS OF SCIENCE: FROM INTERNATIONAL CONTEXTS TO INSTITUTIONAL RESPONSES 10 (Int'l Sci. Council 2021).
- 4. The Pub. Face of Sci. Initiative, Perceptions of Science in America vii (Am. Acad. of Arts & Scis. 2018).
- 5. See Anita Rao, Industry-Funded Research and Bias in Food Science, 20 QUANTITATIVE MKTG. & ECON. 39, 48 (2022) ("Engaging in scientific research is one way to increase credibility. Other means include citing scientific literature that supports the firm's health claims.").
- 6. See Sheryl Gay Stolberg, Gifts to Science Researchers Have Strings, Study Finds, N.Y. TIMES (Apr. 1, 1998), https://www.nytimes.com/1998/04/01/us/gifts-to-science-researchers-have-strings-study-finds.html (discussing survey of scientists that indicated one-third of researchers given gifts by industry have been asked to show their results before seeking publication); Dean A. Elwell, Note, Industry-Influenced Evidence: Bias, Conflict, and Manipulation in Scientific Evidence, 61 B.C. L. Rev. 2155, 2155–56 (2020) (noting 70 percent of research funding comes from industry sources).
  - 7. See infra Part II.
  - 8. See, e.g., Elwell, supra note 6, at 2181.

46

## 2024] *Close the Gate!* 47

This Article, through the lens of toxic tort litigation, argues that the *Daubert* standard should be used to exclude biased, improper industry-funded science from the courtroom. It first describes the problem with industry backed science. Then, it describes the evolution of the *Daubert* standard. Finally, this Article argues that the *Daubert* standard can be used to argue for the exclusion of industry-funded science from evidence by asking judges to stop deferring to cross-examination and instead examine the science underlying industry experts' opinions.

## II. INDUSTRY "SCIENCE"

Many people understand that industry and industry organizations lobby to promote their agendas.<sup>13</sup> However, besides lobbying lawmakers, industry groups also fund scientific studies to support industry activity.<sup>14</sup> The studies might be used for lobbying, supporting industry during regulatory processes, and to win the support of the public.<sup>15</sup> This makes sense, since the public has historically trusted scientists. However, industry-funded science is highly susceptible to bias.<sup>16</sup> Then, the biased science gets published, and the public relies on it, causing harm and creating a breeding ground for litigation against industry members.<sup>17</sup>

- 9. *Tort*, BLACK'S LAW DICTIONARY (11th ed. 2019) ("A civil wrong arising from exposure to a toxic substance, such as asbestos, radiation, or hazardous waste.").
  - 10. See infra Part II.
  - 11. See infra Part III.
  - 12. See infra Part IV.
- 13. See Jake Frankenfield, Which Industry Spends the Most on Lobbying?, INVESTOPEDIA, https://www.investopedia.com/investing/which-industry-spends-most-lobbying-antm-so/ [https://perma.cc/EV7S-KAZW] (Sept. 29, 2022) (noting lobbying "is par for the course" in major industries); Lobbying, OPEN SECRETS, https://www.opensecrets.org/industries/ lobbying.php?cycle=All&ind=N00 [https://perma.cc/SCW7-GZCA] (select 2022 from the drop-down menu) (compiling data on top industry lobbying).
- 14. See, e.g., Lisa Bero, When Big Companies Fund Academic Research, the Truth Often Comes Last, THE CONVERSATION (Oct. 2, 2019, 4:04 PM), https://theconversation.com/when-big-companies-fund-academic-research-the-truth-often-comes-last-119164 [https://perma.cc/FTE2-4Q24] ("By 2011, industry funding... accounted for two-thirds of medical research worldwide.").
  - 15. See, e.g., Frankenfield, supra note 13; Rao, supra note 5, at 48.
- 16. See Stolberg, supra note 6, at 2 (discussing survey of scientists that indicated one-third of researchers given gifts by industry have been asked to show their results before seeking publication).
  - 17. See, e.g., infra Part III.

48 Drake Law Review [Vol. 71

Biased, industry-funded science is a potentially far-reaching problem. <sup>18</sup> Just over 30 years after Congress began encouraging public and private sector research partnerships, private industry became the leading funder of basic research in the United States. <sup>19</sup> A short time later, private industry funding increased to 70 percent of the total research funding. <sup>20</sup> Although the federal government generally supports industry-funded research, this research creates an environment for restriction and dishonesty. <sup>21</sup> For example, researchers have been prohibited from publishing their actual findings in industry-funded studies. <sup>22</sup> Additionally, industry funding has been used to "drive research agendas away from questions that are the most relevant for public health." <sup>23</sup>

One study analyzing 200 trials of vaccines, drugs, and devices with full industry funding found that "[i]n most trials, both funder and academic authors were involved in the design, conduct, and reporting."<sup>24</sup> Those "results show[ed] that data analysis was most often done by funder or [contract research organization] employees, without academic involvement."<sup>25</sup> Authors collaborating with industry funders often found the collaboration beneficial, but 11 percent "reported disagreements with the industry funder, mostly concerning trial design and reporting."<sup>26</sup>

Industry can manipulate the evidence in studies it funds through study design, conduct, and publication.<sup>27</sup> Possibly the most well-known example of this is the tobacco industry's "science."<sup>28</sup> Starting in the 1950s, when the first studies linked cigarettes to lung cancer, the tobacco industry hired scientists to question

- 18. Elwell, supra note 6, at 2156.
- 19. Id. at 2155.
- 20. Id. at 2155-56.
- 21. See id. at 2156.
- 22. Bero, supra note 14.
- 23. Alice Fabbri et al., *The Influence of Industry Sponsorship on the Research Agenda: A Scoping Review*, Am. J. Pub. HEALTH, Nov. 2018, at e9, e9.
- 24. Funder Involved in All Aspects of Most Industry-Funded Clinical Trials, EUREKALERT! (Oct. 3, 2018), https://www.eurekalert.org/news-releases/805802 [https://perma.cc/5PLF-9WNC] (referencing a study conducted by The BMJ).
- 25. *Id.* ("For example, data analysis involved the funder in 146 (73%) trials and the academic authors in 79 (40%).").
  - 26. Id.
  - 27. Bero, supra note 14.
- 28. See Truth Tobacco Industry Documents, UCSF, https://www.industrydocuments.ucsf. edu/tobacco/ [https://perma.cc/M2PX-6EQX] ("An archive of 14 million documents created by tobacco companies about their advertising, manufacturing, marketing, scientific research and political activities, hosted by the UCSF Library.").

# 2024] *Close the Gate!* 49

the science that showed tobacco made people sick.<sup>29</sup> If one of their funded studies showed harm to the public, the tobacco industry buried it.<sup>30</sup> Otherwise, the tobacco industry thrived by suggesting the science was not clear and the industry was doing more research to determine the health effects.<sup>31</sup> The industry's manipulation of science, which has been classified as a public relations operation, was calculated to attack studies that were a threat to the industry.<sup>32</sup> Ultimately, although it did not invent the technique entirely, the tobacco industry paved the way for other industries to create scientific doubt.<sup>33</sup>

Since the tobacco industry's relative success made this technique popular, other industries have used scientists to advance their agendas by manufacturing uncertainty in existing literature.<sup>34</sup> For instance, the pharmaceutical company, Merck, was involved in manipulation of studies for its prescription pain killer, Vioxx.<sup>35</sup> Merck tested the effectiveness through a randomized clinical trial that compared Vioxx to Naproxen (Aleve), and it found that Vioxx was effective at preventing pain and had a significant reduction in gastrointestinal complaints.<sup>36</sup> During the clinical trial, Merck was warned that Vioxx might increase the risk of blocked arteries.<sup>37</sup> Merck reanalyzed their clinical data and included the possible

- 30. *Id*.
- 31. *Id*.

- 33. Keith A. Spencer, *The Art of Scientific Deception: How Corporations Use* "*Mercenary Science*" to Evade Regulation, SALON (Feb. 2, 2020, 8:00 AM), https://www.salon.com/2020/02/02/the-art-of-scientific-deception-how-corporations-use-mercenary-science-to-evade-regulation/ [https://perma.cc/EP9K-JUCH].
- 34. See David Michaels on The Triumph of Doubt Dark Money and the Science of Deception, supra note 29 (providing a history of industry manipulating science to advance its agenda, with traceable results in legislation, courtrooms, and public perception).
- 35. *See* Spencer, *supra* note 33 (describing how Merck manipulated science to get Vioxx FDA approved).
- 36. *Id.*; Robert Burton, *How Merck Stacked the Vioxx Deck*, SALON (Apr. 1, 2005, 12:23 AM), https://www.salon.com/2005/04/01/vioxx\_2/ [https://perma.cc/VWY9-6F9P].
  - 37. Burton, supra note 36.

<sup>29.</sup> David Michaels on the Triumph of Doubt Dark Money and the Science of Deception, CORP. CRIME REP. (Mar. 25, 2020, 12:24 PM), https://www.corporatecrimereporter.com/news/200/david-michaels-on-the-triumph-of-doubt-dark-money-and-the-science-of-deception/[https://perma.cc/FY2G-4AE7].

<sup>32.</sup> *Id.*; see Mi-Kyung Hong & Lisa A. Bero, *How the Tobacco Industry Responded to an Influential Study of the Health Effects of Secondhand Smoke*, 325 BMJ 1413, 1413 (2002) (discussing how the tobacco industry refuted a 1981 study that showed an association between passive smoking and lung cancer).

50 Drake Law Review [Vol. 71

cardiovascular risk in its FDA application.<sup>38</sup> However, Merck never designed a study to further examine those cardiovascular risks.<sup>39</sup> Instead, it created a study, called the VIGOR study, which compared the incidence of gastrointestinal complications and followed its subjects for only nine months.<sup>40</sup>

Vioxx was ultimately approved by the FDA and went on the market. Its annual sales exceeded \$2.5 billion. PDA approval, a panel of independent scientists looked at the results of Merck's gastrointestinal study and found that patients taking Vioxx had over twice the cardiovascular incident rate of the people who took Naproxen. However, the incident rate may have been even higher had Merck not skewed the study's subjects. Merck's study, 80 percent of the patients were women, who develop cardiovascular disease 10 years later than men, on average. Additionally, only four percent of the subjects had a history of cardiovascular illness and were considered high risk. Because of the inclusion of that four percent, the higher cardiovascular incident rate was significant and the independent researchers were able to identify the risk. If Merck had eliminated those subjects, the cardiovascular impact of Vioxx may not have been discovered.

The Vioxx study also hid cardiovascular incidents by not having a control placebo group. <sup>49</sup> Merck relied on this lack of placebo group to discount the finding that Vioxx caused more cardiovascular incidents: "Because the VIGOR study compared two drugs[—]Vioxx and [N[aproxen[—]and did not contain a placebo arm, it was not possible to conclude, based on this study alone, whether [N]aproxen was having a beneficial [cardiovascular] effect or whether Vioxx was having a detrimental [cardiovascular] effect." <sup>50</sup> Although Merck tried to explain the lack of a placebo group by citing ethical concerns, other similar comparative studies use placebos. <sup>51</sup> Ultimately, Vioxx was removed from the shelves, and a class action

```
38. Id.
```

<sup>39.</sup> Id.

<sup>40.</sup> Id.

<sup>41.</sup> Id.

<sup>42.</sup> Id.

<sup>43.</sup> See Spencer, supra note 33.

<sup>44.</sup> See Burton, supra note 36.

<sup>45.</sup> *Id*.

<sup>46.</sup> *Id*.

<sup>47.</sup> *Id*.

<sup>48.</sup> Id.

<sup>49.</sup> Id.

<sup>50.</sup> Id. (quoting Peter S. Kim, president of Merck Research Laboratories).

<sup>51.</sup> Id.

2024] *Close the Gate!* 51

lawsuit was later filed.<sup>52</sup> "In the few short years since Vioxx was on the market, FDA scientists estimated it [caused] somewhere between 88,000 and 120,000 heart attacks."<sup>53</sup>

Sometimes, such as in the Vioxx example, industry funding tries to blind reputable scientists and the public to the truth of their studies.<sup>54</sup> However, there are also consulting firms who provide "mercenary science" to defend products and corporations.<sup>55</sup> Oftentimes, this mercenary science makes its way into legislatures and courtrooms.<sup>56</sup> "[T]his phrase . . . is used by these consulting companies whose business model is to provide some using reports and testimonies to corporations, so they can continue to market dangerous products or activities without being hindered by regulation or by compensating the people they've hurt."<sup>57</sup> Although there are a relatively small number of scientists and firms involved in mercenary science, their work has far-reaching implications, including in the courtroom.<sup>58</sup>

Of course, industry would emphasize the opposite. For example, industry would argue that government regulations, penalties for faulty reporting, and the threat of litigation, all incentivize disclosing any potential harms of their product to the public.<sup>59</sup> Additionally, industry representatives may point out that plaintiffs' firms can also hire mercenary scientists as expert witnesses too, thus raising the same concerns about scientific reliability.<sup>60</sup> Admittedly, there have been cases where plaintiffs have taken advantage of "junk science" to hold industry liable for harms outside of its control.<sup>61</sup>

- 52. Id.
- 53. See Spencer, supra note 33.
- 54. *Id*.
- 55. *Id*.
- 56. *Id*.
- 57. *Id*.
- 58. See id.
- 59. See James W. Conrad, Jr., Open Secrets: The Widespread Availability of Information about the Health and Environmental Effects of Chemicals, 69 L. & CONTEMP. PROBS. 141, 157–61 (2006).
- 60. See id. at 162–63 ("The point is not that scientists receiving funds from for-profit entities necessarily have a fatal conflict of interest, much less that their work is somehow less valid. Rather, the potential for conflict, or more likely bias, is present in both cases and justifies disclosure in order to allow adequate scientific assessment of the work.").
- 61. See, e.g., Doug Bandow, Galileo's Revenge: Junk Science in the Courtroom, FOUND. FOR ECON. EDUC. (Mar. 1, 1992), https://fee.org/articles/galileos-revenge-junk-science-in-the-courtroom/ [https://perma.cc/AKP7-S5E8] (describing cases where junk science resulted in questionable verdicts).

## 52 Drake Law Review [Vol. 71

Yet, with private industry funding making up approximately 70 percent of research funding, several studies have shown the impact of industry funding on the resulting science.<sup>62</sup> For instance, an anonymous survey showed that "more than half of the university scientists who received gifts from drug or biotechnology companies admitted that the donors expected to exert influence over their work."<sup>63</sup> This influence included reviewing papers before publication.<sup>64</sup> In fact, one-third of the scientists surveyed said their industry funders expected to review the scientists' papers before they were submitted for publication.<sup>65</sup> The gifts provided by the various industries were reported to be "either important or very important" to the researchers' work, often constituting biomaterials, laboratory equipment, trips, or money.<sup>66</sup>

Thus, knowing the potential far-reaching impacts of industry funding on science raises the question of how industry science can impact the courtroom. The outcomes of many trials rely on experts to distill the existing scientific literature into plain English for the jury.<sup>67</sup> Therefore, it is not surprising that industry defendants hire experts (who are often from the same group of mercenary scientists that wrote the misleading science) to use industry backed science to manufacture uncertainty in the jurors' minds.<sup>68</sup> Particularly in toxic tort cases, where the connection between the injury and the exposure must be carefully explained, experts play a vital role in determining the outcome.<sup>69</sup>

- 64. *Id*.
- 65. *Id.* at 2.
- 66. Id.

<sup>62.</sup> See Elwell, supra note 6, at 2155–56; Ned Miltenberg, Myths About "Neutral" Scientific Experts, TRIAL, Jan. 2000, at 62, 63–64 (2000) (discussing the results of industry-funded studies on resulting science).

<sup>63.</sup> Stolberg, supra note 6.

<sup>67.</sup> See, e.g., Anjelica Cappellino, Expert Witnesses in High-Profile Litigation: Three Defining Trials, EXPERT INST. (July 29, 2021), https://www.expertinstitute.com/resources/insights/expert-witnesses-high-profile-litigation-three-defining-trials/ [https://perma.cc/P844-JDRB] ("Expert witness testimony can oftentimes make or break a case.").

<sup>68.</sup> See DAVID MICHAELS, DOUBT IS THEIR PRODUCT: HOW INDUSTRY'S ASSAULT ON SCIENCE THREATENS YOUR HEALTH 50–53 (Oxford Univ. Press 2008) (discussing how one mercenary scientist could be involved in research, lobbying, and litigation); David Michaels on the Triumph of Doubt Dark Money and the Science of Deception, supra note 29 (noting that the tobacco industry would combine their studies with public relations and raise doubts "to the public, to regulators, to the courts").

<sup>69.</sup> MICHAELS, supra note 68, at 161.

2024] *Close the Gate!* 53

## III. THE EVOLUTION OF DAUBERT

The Federal Rules of Evidence form the basis for admitting expert testimony. 70 Federal Rule of Evidence 702 reads:

## Rule 702. Testimony by Expert Witnesses

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based upon sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.<sup>71</sup>

## Rule 703 provides additional guidance:

## Rule 703. Bases of an Expert's Opinion Testimony

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted. But if the facts or data would otherwise be inadmissible, the proponent of the opinion may disclose them to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect.<sup>72</sup>

Because admissible evidence must be relevant and unreliable evidence is not relevant, courts had to establish a standard for reliability of expert testimony.<sup>73</sup> The federal judiciary initially established a standard in *Frye v. United States*.<sup>74</sup>

<sup>70.</sup> Although this Article focuses on the Federal Rules of Evidence, many state courts have adopted a similar evidentiary standard. *See* MARTIN S. KAUFMAN & ATL. LEGAL FOUND., THE STATUS OF *DAUBERT* IN STATE COURTS (Atl. Legal Found. 2006), http://www.iapsych.com/iqmr/daubertstates.pdf [https://perma.cc/8CSF-26ZG] (summarizing states that have adopted *Daubert*).

<sup>71.</sup> FED. R. EVID. 702.

<sup>72.</sup> FED. R. EVID. 703.

<sup>73.</sup> Learned Hand, *Historical and Practical Considerations Regarding Expert Testimony*, 15 HARV. L. REV. 40, 55–56 (1901).

<sup>74. 293</sup> F. 1013 (D.C. Cir. 1923).

In *Frye*, the trial court refused to admit evidence of the defendant's systolic blood pressure to show his truthfulness in a murder trial.<sup>75</sup> After the defendant was convicted, the D.C. Circuit Court of Appeals heard the issue of whether the court should have admitted the test.<sup>76</sup> The court noted:

Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.<sup>77</sup>

Thus, the *Frye* court identified a two-step process of determining reliability that resulted in "general acceptance": (1) the scientific community creates a theory and (2) the results of that theory are subjected to peer review.<sup>78</sup> Thus, lawyers seeking admission of expert testimony under *Frye* had to demonstrate general acceptance of a theory by offering scientific publications, other judicial decisions, and testimony by a scientist's peers.<sup>79</sup> As a result, new theories and evidence were unlikely to pass the *Frye* test, raising concerns about its application.<sup>80</sup>

In the landmark case of *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the U.S. Supreme Court took the opportunity to review and overturn the *Frye* standard.<sup>81</sup> In *Daubert*, the primary question was whether an anti-nausea drug caused birth defects.<sup>82</sup> The defendant introduced expert testimony that the drug did not cause birth defects.<sup>83</sup> The plaintiff sought to introduce expert testimony interpreting epidemiological studies performed by other scientists.<sup>84</sup> Based on the defendant's expert, the plaintiff's experts were rejected by both the trial court and the Ninth Circuit Court of Appeals, using the *Frye* standard.<sup>85</sup>

<sup>75.</sup> *Id.* at 1013–14.

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

<sup>77.</sup> Id. at 1014.

<sup>78.</sup> Id.

<sup>79.</sup> Allan Kanner & M. Ryan Casey, Daubert and the Disappearing Jury Trial, 69 U. PITT. L. REV. 281, 287 (2007).

<sup>80.</sup> Id.

<sup>81. 509</sup> U.S. 579, 597 (1993).

<sup>82.</sup> See id. at 582.

<sup>83.</sup> *Id*.

<sup>84.</sup> Id. at 583.

<sup>85.</sup> Id. at 583-84.

2024] *Close the Gate!* 55

The plaintiff appealed to the U.S. Supreme Court. <sup>86</sup> Relying on the adoption of Rules 702 and 703, the Court noted that the adoption of rules on expert testimony that did not mention *general acceptance* sought to overrule the *Frye* test. <sup>87</sup> Because the drafters of the Rules of Evidence did not include the *Frye* general acceptance test as a prerequisite for admissibility, the Court sought to establish a new standard in accordance with the rules. <sup>88</sup>

Ultimately, this led to the *Daubert* standard. Under this standard, a trial court judge must determine whether the expert will testify to scientific knowledge that will assist the trier of fact in understanding or determining a fact at issue.<sup>89</sup> Some factors the Court included, although it did not intend for the factors to be an exhaustive list, are:

(1) whether the expert's theory can be or has been tested; (2) whether the theory has been subject to peer review and publication; (3) the known or potential rate of error of a technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) the degree to which the technique or theory has been generally accepted in the scientific community.<sup>90</sup>

Later, in *Daubert v. Merrell Dow Pharmaceuticals, Inc. (Daubert II)*, the Ninth Circuit further examined expert testimony. <sup>91</sup> Significantly, the Ninth Circuit addressed experts who form opinions in anticipation of litigation. <sup>92</sup> The court added this consideration as a sixth factor to the *Daubert* reliability test, intending for expert testimony to be based on disinterested science. <sup>93</sup> This additional factor is often used to challenge studies performed during and after litigation. <sup>94</sup>

In subsequent related cases, the U.S. Supreme Court noted that, although this standard would allow a trial judge to admit a broader range of testimony than *Frye*, the trial court judge still maintains their "gatekeeper" role.<sup>95</sup> The Court also

<sup>86.</sup> Id. at 585.

<sup>87.</sup> See id. at 588, 595.

<sup>88.</sup> Id. at 588–89.

<sup>89.</sup> *Id.* at 597.

<sup>90.</sup> Moore v. Ashland Chem. Inc., 151 F.3d 269, 275 (5th Cir. 1998) (citing *Daubert*, 509 U.S. at 593–95); *see also* Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141 (1999).

<sup>91. 43</sup> F.3d 1311, 1315 (9th Cir. 1995).

<sup>92.</sup> *Id.* at 1316–17.

<sup>93.</sup> *Id.* at 1317 ("That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science.").

<sup>94.</sup> See Elwell, supra note 6, at 2171.

<sup>95.</sup> Gen. Elec. Co. v. Joiner, 522 U.S. 136, 142 (1997).

determined that *Daubert* applies to all expert testimony, rather than just scientific testimony. <sup>96</sup>

The drafters of the Federal Rules of Evidence also later commented on the *Daubert* standard. 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 the proponent demonstrates to the court that it is more likely than not that: . . . (b) the testimony is based upon sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the witness has applied the principles and methods reliably to the facts of the case. <sup>97</sup>

In sum, Rule 702 is considered a "trilogy of restrictions on expert testimony." The judge must consider an expert's qualification, reliability, and fit. For reliability, the "focus [is] not on the expert's conclusions, but [rather upon] his or her principles and methodology." The issue is whether the evidence should be excluded because the "flaw is large enough that the expert lacks 'good grounds' for his or her conclusions." The *Daubert* standard guides this inquiry. <sup>102</sup>

#### IV. CHALLENGING THE "SCIENCE" IN A TOXIC TORT CASE

Imagine a community impacted by a pollutant from a facility nearby. This pollutant is necessary to certain manufacturing processes, and there is a strong industry group behind the companies that perform that process. The industry group regularly engages a group of mercenary scientists to demonstrate how safe the manufacturing process and the pollutant are. Industry is using this science to influence lawmakers and regulators.

The community, realizing they are being harmed by the facility, organizes and brings a tort action against the owner, who is an active member of the industry group. The case makes its way towards trial and the facility owner engages an

<sup>96.</sup> Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147-48 (1999).

<sup>97.</sup> FED. R. EVID. 702.

<sup>98.</sup> Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (citing *In re* Paoli R.R. Yard PCB Litig., 35 F.3d 717, 741–43 (3d Cir. 1994)).

<sup>99.</sup> *Id*.

<sup>100.</sup> In re Paoli R.R., 35 F.3d at 746.

<sup>101.</sup> Id.

<sup>102.</sup> *Id.* at 742 n.8; *see also* Daubert v. Merrel Dow Pharms., Inc., 509 U.S. 579, 595 (1993).

2024] *Close the Gate!* 57

expert witness. This expert witness is a member of the group of scientists that the industry has previously engaged to conduct studies about the pollutant and process. The expert report shows that the expert relied on those same studies to support their opinion. What can the plaintiffs' attorney do? Object under the *Daubert* standard.

According to the *Daubert* standard it is up to the trial judge to examine an expert's testimony and determine admissibility. <sup>103</sup> However, since the modification of Rule 702 and the implementation of the *Daubert* standard, courts have taken different levels of leniency in applying the standard to expert testimony. <sup>104</sup> This particularly creates an issue with industry-backed science and experts. <sup>105</sup>

A common default for alleged expert witness bias is cross-examination, rather than gatekeeping. Although cross-examination can expose potential bias of mercenary scientists, there are potential hurdles that complicate the situation:

First, juries will likely find it difficult to appreciate the significance of unreliable research if the well-credentialed, so-called "expert" witness seems otherwise credible. Second, many expert witnesses may not know the extent of industry influence on the research undergirding their conclusions. In this situation, cross-examination will likely prove ineffective because there is no way to elicit the damaging information. Finally, it may not be clear when or to what extent an expert witness has relied on a particular study or series of studies. Expert witnesses may testify based on their experience without relying on a specific study. <sup>107</sup>

<sup>103.</sup> See In re Paoli R.R., 35 F.3d at 742; Daubert, 509 U.S. at 589.

<sup>104.</sup> See Kanner & Casey, supra note 79, at 295–96 (discussing how the U.S. Supreme Court and appellate courts have applied Daubert).

<sup>105.</sup> *See id.* at 297–98 (discussing the "battle underway for the soul of science" and proindustry judges that use Daubert to eliminate non-industry science).

<sup>106.</sup> Elwell, *supra* note 6, at 2172; *see*, *e.g.*, *In re* Yasmin & YAZ (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig., No. 3:09-md-02100-DRH-PMF, 2011 WL 6302573, at \*17 (S.D. Ill. Dec. 16, 2011) (using cross-examination to qualify plaintiffs' expert, rather than using gatekeeping in response to the defense's *Daubert* challenge); *In re* Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proc., No. 14 C 1748, 2017 WL 1833173, at \*10 (N.D. Ill. May 8, 2017) (declining to use the court's gatekeeping role to exclude the defendant's expert because "[a]t this stage, it is not the Court's role to choose between competing studies" (internal citation omitted)). *But see* Kanner & Casey, *supra* note 79, at 296 (discussing pro-industry judges gatekeeping non-industry science).

<sup>107.</sup> Elwell, *supra* note 6, at 2172–73.

58 Drake Law Review [Vol. 71

These considerations all suggest that judges should forgo relying on cross-examination and instead use *Daubert* to help exclude industry-backed science. <sup>108</sup> This Article argues that the proper remedy, within a judge's gatekeeping power, would specifically be to inquire into the literature forming the basis of the expert's opinion and then to exclude it based on unreliability and *Daubert II*'s sixth factor: a preference for disinterested science. <sup>109</sup>

# A. Examining the Underlying Basis of an Opinion

There is existing precedent supporting a judge's ability to examine the underlying basis of an opinion, rather than relying on cross-examination. Following *Daubert*, the U.S. Supreme Court considered the case *General Electric Co. v. Joiner*, where an electrician sued his workplace for exposure to polychlorinated biphenyls (PCB) that allegedly resulted in small-cell lung cancer. The District Court granted summary judgment for General Electric in part because the plaintiffs' experts' testimony "failed to [establish] . . . a link between exposure to PCB's and small-cell lung cancer." Specifically, the District Court determined the specific studies that the expert relied on did not support the link:

The studies involved infant mice that had developed cancer after being exposed to PCB's.... Joiner was an adult human whose alleged exposure to PCB's was far less than the exposure in the animal studies.... No study demonstrated that adult mice developed cancer after being exposed to PCB's. One of the experts admitted that no study had demonstrated that PCB's lead to cancer in any other species. <sup>112</sup>

The appellate court overruled the district court's decision, but the Supreme Court determined that the appellate court applied the incorrect standard of review and reversed. The Supreme Court did not criticize the district court's examination of the individual studies behind the expert's opinion, and it was not swayed by plaintiff's argument that the district court improperly excluded the

<sup>108.</sup> See F.E.I. Co. v. United States, 409 F. Supp. 3d 305, 317 (M.D. Pa. 2019) (noting that expert testimony has high potential to be misleading).

<sup>109.</sup> See Daubert v. Merrell Dow Pharms., Inc. (Daubert II), 43 F.3d 1311, 1317 (9th Cir. 1995).

<sup>110. 522</sup> U.S. 136, 140 (1997).

<sup>111.</sup> *Id*.

<sup>112.</sup> Id. at 144.

<sup>113.</sup> *Id.* at 146–47.

evidence based on the conclusion, rather than the methodology.<sup>114</sup> This lends support to asking judges to forgo leaving the debate about the underlying science to cross-examination.

Additionally, since *Joiner*, lower courts have used *Daubert* to exclude expert testimony and scientific evidence from the courtroom because of the unreliability of the underlying science and methodology for an opinion, rather than relying on cross-examination.<sup>115</sup> In one instance, the Southern District of Texas barred a plaintiff's expert from testifying in a case where the plaintiff sued Mobil and Chevron for the decedent's acute myelogenous leukemia, which was allegedly caused by exposure to benzene. 116 The plaintiff hired several experts to testify to the issue of causation. 117 The defendant challenged each of the plaintiff's experts on the basis that their opinions were unsupported in science, could not reach the requirement of good science, and could not assist the jury. 118 Specific to the issue here, the defendants argued that one of the plaintiff's experts improperly relied on modeling to determine the decedent's cumulative exposure to benzene when he worked at a gas station.<sup>119</sup> The court noted that it was not persuaded that the underlying modeling was an acceptable scientific methodology in a tort claim, despite the plaintiff submitting publications advocating for the model. 120 Thus, despite evidence that modeling was an appropriate methodology, which could have been challenged on cross-examination by calling into question the underlying assumptions, the judge chose to exclude the experts' testimony entirely. 121

In another case, *Chambers v. Exxon Corp.*, the plaintiff's expert testimony was found inadmissible for lack of reliability. <sup>122</sup> In *Chambers*, the plaintiff sued

<sup>114.</sup> *Id.* at 146 ("But conclusions and methodology are not entirely distinct from one another. . . . But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

<sup>115.</sup> Because the plaintiff generally has the burden of proof, plaintiffs have generally been more impacted by the judge's gatekeeping role. Kanner & Casey, *supra* note 79, at 306. Therefore, the listed examples are those where the plaintiff's expert's opinion has been disqualified under *Daubert*. For additional information on how the *Daubert* standard can harm plaintiffs, *see* MICHAELS, *supra* note 68, at 161–75.

<sup>116.</sup> Castellow v. Chevron USA, 97 F. Supp. 2d 780, 782 (S.D. Tex. 2000).

<sup>117.</sup> Id.

<sup>118.</sup> *Id*.

<sup>119.</sup> *Id.* at 786.

<sup>120.</sup> *Id.* at 789.

<sup>121.</sup> See id. at 793.

<sup>122. 81</sup> F. Supp. 2d 661, 665 (M.D. La. 2000).

his employer, a refinery owner, alleging that the exposure to benzene caused his chronic myelogenous leukemia. 123 The court determined that the expert's opinion that the plaintiff's exposure to benzene caused his illness was not supported in the underlying literature:

The disease from which Mr. Chambers suffers, chronic myelogenous leukemia, develops in the general population. It develops in those that have been exposed to benzene and those that have not. Without a controlled study, there is no way to determine if CML is more common in people who are exposed to benzene than those who are not. Therefore, in a case such as this, the most conclusive type of evidence of causation is epidemiological evidence. 124

Because the plaintiff's experts did not produce an underlying study concluding that exposure to benzene caused his type of leukemia, the judge deemed the expert's opinions on the matter unreliable. Yet, as the plaintiff pointed out in their motion in opposition to the defendant's *Daubert* challenge:

Defendants repeatedly argue that there is an absence of *statistically significant* epidemiological data demonstrating benzene/CML causation. Infante explains that [t]his is so because leukemias generally are relatively rare forms of cancer, and that therefore subdividing them into different types of leukemia hinders the ability to analyze cause and effect on statistics alone. He therefore emphasizes the need to look at other factors. <sup>126</sup>

The court was not convinced, finding the plaintiff's experts' conclusions unreliable and, thus, inadmissible. 127 These same principles may be applied to industry-backed experts. 128 The above opinions illustrate that a judge may find an opinion unreliable based on the underlying methodology and research that supports the expert's opinion. 129 In our hypothetical case, then, the court would be able to examine the industry-backed studies underlying the expert's opinion. 130 In doing

<sup>123.</sup> Id. at 663.

<sup>124.</sup> *Id.* at 663–64.

<sup>125.</sup> Id. at 665.

<sup>126.</sup> Id. at 664 n.3.

<sup>127.</sup> Id. at 665–66.

<sup>128.</sup> *Cf. In re* Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proc., No. 14 C 1748, 2017 WL 1833173, at \*5 (N.D. Ill. May 8, 2017).

<sup>129.</sup> *See*, *e.g.*, Castellow v. Chevron USA, 97 F. Supp. 2d 780, 793 (S.D. Tex. 2000); *Chambers*, 81 F. Supp. 2d at 665–66.

<sup>130.</sup> Cf. Castellow, 97 F. Supp. 2d at 793; Chambers, 81 F. Supp. 2d at 665–66.

2024] *Close the Gate!* 61

so, the court might find the shortcomings in the industry-backed studies with the help of the plaintiff's attorneys.<sup>131</sup>

Using Vioxx as an example, Merck designed the comparative Vioxx study without a placebo arm even though similar comparative studies include a control group. If a judge were to examine the Vioxx study underlying Merck's expert's opinion and compare it to similar studies, the judge may conclude that the Vioxx study's methodology and design were unreliable because there was no control group. This would form a basis for the judge to exclude this study and possibly the expert's opinion that Vioxx does not cause cardiovascular incidents, from evidence. Is a supplementation of the property of the property

When using a *Daubert* motion to challenge industry-backed science under an unreliability argument, plaintiffs' attorneys should invite the judge to examine the underlying studies and methodology behind the industry expert's opinion.<sup>135</sup> Then, they must direct the judge to the biases and misdirection that often underlie industry-backed studies.<sup>136</sup>

#### B. The Sixth Factor

A key argument plaintiffs' attorneys should make when asking a judge to examine the underlying science is bias. *Daubert II*'s sixth factor forms a compelling argument against industry-funded science: the research used in litigation should be conducted independently of litigation.<sup>137</sup> The Ninth Circuit added this consideration as a sixth factor of the *Daubert* reliability test, intending for expert testimony to be based on disinterested science.<sup>138</sup>

The Ninth Circuit "read the Supreme Court as instructing us to determine whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their

<sup>131.</sup> Cf. Castellow, 97 F. Supp. 2d at 793; Chambers, 81 F. Supp. 2d at 665-66.

<sup>132.</sup> Burton, supra note 36.

<sup>133.</sup> *Id.* at 7; see Chambers, 81 F. Supp. 2d at 665.

<sup>134.</sup> Burton, supra note 36, at 7; see Chambers, 81 F. Supp. 2d at 665.

<sup>135.</sup> Cf. Castellow, 97 F. Supp. 2d at 793; Chambers, 81 F. Supp. 2d at 665–66.

<sup>136.</sup> See Bero, supra note 14 (outlining ways industry impacts studies).

<sup>137.</sup> See, e.g., Daubert v. Merrel Dow Pharms., Inc. (Daubert II), 43 F.3d 1311, 1317 (9th Cir. 1995).

<sup>138.</sup> *Id.* ("That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science.").

## 62 Drake Law Review [Vol. 71

conclusions."<sup>139</sup> Specifically, the court noted: "One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying."<sup>140</sup>

Yet, despite its focus on unbiased science, the court did not consider the possibility of industry-backed studies in its decision:

For one thing, experts whose findings flow from existing research are less likely to have been biased toward a particular conclusion by the promise of remuneration; when an expert prepares reports and findings before being hired as a witness, that record will limit the degree to which he can tailor his testimony to serve a party's interests. Then, too, independent research carries its own indicia of reliability, as it is conducted, so to speak, in the usual course of business and must normally satisfy a variety of standards to attract funding and institutional support. Finally, there is usually a limited number of scientists actively conducting research on the very subject that is germane to a particular case, which provides a natural constraint on parties' ability to shop for experts who will come to the desired conclusion. <sup>141</sup>

This factor would certainly exclude industry-backed studies conducted for litigation. However, because incentives other than litigation, such as legislative lobbying and marketability, cause a lot of industry-backed research to be published before litigation begins, some scholars believe that *Daubert II* underestimates the potential bias in studies published before litigation begins. <sup>142</sup> But, applying the underlying reasoning behind *Daubert II*'s sixth factor—a desire for unbiased science—plaintiffs may argue that industry-backed science is the type of science the Ninth Circuit intended to exclude. <sup>143</sup>

In applying the sixth factor, plaintiffs' attorneys should point out the source of funding for the underlying studies. The Ninth Circuit expressed concern over the influence of remuneration on an expert's opinion. Additionally, a court should also be concerned when a defendant's industry group funded a study in support of a process or chemical, even if it is prior to litigation.

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

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

<sup>141.</sup> *Id*.

<sup>142.</sup> Elwell, *supra* note 6, at 2171.

<sup>143.</sup> See Daubert II, 43 F.3d at 1317.

<sup>144.</sup> *Id*.

## 2024] *Close the Gate!* 63

Using our hypothetical, an industry group the defendant belongs to funding a study being relied on by an expert would likely cast doubt on the study as biased. It could further cast doubt on the study if the industry group subsequently used it to lobby lawmakers and regulators regarding the safety of the manufacturing process because this would suggest that the industry undertook the study with this biased purpose in mind. Attorneys should couple this information with data on industry-funded research. For instance, the motion may include information "that industry-funded [research is] more likely to give a positive result" for the sponsor and is more likely to overstate their results. 146

Although not a *Daubert* analysis, the U.S. Supreme Court followed a similar process in *Exxon Shipping Co. v. Baker*. <sup>147</sup> In that case, which considered the punitive damages assessed by a jury, the Court considered the consistency of punitive award claims in similar cases. <sup>148</sup> Although the Court identified studies conducted before litigation discussing this very issue, it declined to rely on them because they were funded by Exxon, who was a party to the case. <sup>149</sup>

Industry defendants may respond by pointing to the journals publishing the studies.<sup>150</sup> Specifically, the defendants may direct the judge's attention to the impact factor of the journals, since industry-funded studies tend to be published in higher impact journals.<sup>151</sup> However, although high-impact journals are generally

<sup>145.</sup> See, e.g., Burton, supra note 36 (discussing Merck's biased comparative study of Vioxx as the basis for FDA approval); see also Spencer, supra note 33 (noting industry hires mercenary scientists "to influence regulation").

<sup>146.</sup> *See, e.g.*, Ben Goldacre, *Funding and Findings: The Impact Factor*, THE GUARDIAN (Feb. 13, 2009), https://www.theguardian.com/commentisfree/2009/feb/14/bad-science -medical-research [https://perma.cc/F5G2-ZAP5]; Rao, *supra* note 5, at 39 (finding food "industry-funded research is 3.2% more positive compared to non-industry funded research").

<sup>147. 554</sup> U.S. 471, 500 (2008).

<sup>148.</sup> Id. at 500.

<sup>149.</sup> *Id.* at 500 n.17 ("Because this research was funded in part by Exxon, we decline to rely on it.").

<sup>150.</sup> *See*, *e.g.*, Daubert v. Merrell Dow Pharms., Inc. (*Daubert II*), 43 F.3d 1311, 1318 (9th Cir. 1995) (indicating publication and peer review can help validate a study as reliable).

<sup>151.</sup> See High Impact Journals, NAT'L INST. OF ENV'T HEALTH SCI., https://tools.niehs.nih.gov/srp/publications/highimpactjournals.cfm [https://perma.cc/SE8N-RYQC] ("A journal's impact factor is a measure of the frequency with which an average article in a journal has been cited in a particular year."); Rao, supra note 5, at 40 ("[I]ndustry-funded articles are more likely to be published in journals with slightly higher impact factors."); see also Goldacre, supra note 146 ("The average journal impact factor for the 92 government-funded studies was 3.74; for the 52 studies wholly or partly funded by industry, the average

## 64 Drake Law Review [Vol. 71

given more deference, a study found that only a few industry-backed studies published in high-impact journals had independent analysis by the authors. Thus, in the case of industry-backed science, publication in a high-impact journal does not equal an unbiased study, which the sixth factor demands.

## V. CONCLUSION

In sum, judges may forgo the ordinary reliance on cross-examination and instead exclude biased, industry-backed science from the courtroom. By looking critically at the underlying science of an expert's opinion for bias and unreliability, judges could help stop industry's manipulation of the public's trust in science and help put injured parties on equal footing as well-funded industry defendants.

impact factor was 8.78."); T. Jefferson et al., *Relation of Study Quality, Concordance, Take Home Message, Funding, and Impact in Studies of Influenza Vaccines: Systemic Review*, BRIT. MED. J., Feb. 2009, at 1, 6 (indicating vaccine studies funded partially or wholly by industry were generally in higher-impact journals).

<sup>152.</sup> Funder Involved in All Aspects of Most Industry-Funded Clinical Trials, supra note 24.