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Industry-Influenced Evidence: Bias, Conflict, and Manipulation in Scientific Evidence

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INDUSTRY-INFLUENCED EVIDENCE: BIAS, CONFLICT, AND MANIPULATION IN SCIENTIFIC EVIDENCE

Abstract: In 2008, in *Exxon Shipping Co. v. Baker*, the U.S. Supreme Court refused to consider scientific studies that a litigant had funded. Despite this rejection, many courts have failed even to recognize the dangers of relying on such potentially biased research. As a result, standards for the admission of scientific evidence have evolved without accounting for the risks posed by industry-influenced evidence. This Note argues for meaningful admissibility reviews via mandatory disclosure of industry influence. In this context, the evidentiary fraud doctrine should guide applications of *Frye v. United States* and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*

INTRODUCTION

In 1980, the U.S. Supreme Court greenlit the patentability of life science research results[1] and Congress began encouraging public-private research partnerships.[2] Just over thirty years later, in 2013, private industry surpassed the federal government to become the leading funder of basic research in the United States.[3] Within the next four years, private industry funding increased

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[1] *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (expanding the scope of patentable subject matter by approving the patentability of a genetically engineered bacterium used to clear oil spills). *Diamond* spurred a dramatic increase in private agricultural research. Adanna Uwazurike, Note, *Remaking Making: Integrating Self-Replicating Technologies with the Exhaustion Doctrine*, 59 B.C. L. REV. 389, 408 (2018).

[2] Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980). The Bayh-Dole Act incentivizes public-private "technology transfer," the commercialization of publicly funded discoveries. *See* Margo A. Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217, 219–20 (2006) (discussing university-to-industry technology transfer). Prior to the Bayh-Dole Act, intellectual property rights stemming from publicly funded research vested automatically in the government. Jennifer A. Henderson & John J. Smith, *Financial Conflict of Interest in Medical Research: Overview and Analysis of Federal and State Controls*, 57 FOOD & DRUG L.J. 445, 445 (2002). The Bayh-Dole Act gave private entities the right to patent their discoveries, even if those discoveries were publicly funded. *Id.* at 446. In the following years, the United States saw dramatic increases in public-private funding and collaboration, university-owned patents, and university-licensed start-up companies. *Id.* From 1980 to 2000, industry funding of medical research grew from $1.5 billion to $22.4 billion. U.S. GOV'T ACCOUNTABILITY OFF., GAO-02-89, BIOMEDICAL RESEARCH: HHS DIRECTION NEEDED TO ADDRESS FINANCIAL CONFLICTS OF INTEREST 6 (2001). In that period alone, more than 2,200 companies formed around university-licensed inventions. COUNCIL ON GOVERNMENTAL RELATIONS, THE BAYH-DOLE ACT: A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS 9 (1999).

[3] Jeffrey Mervis, *Data Check: U.S. Government Share of Basic Research Funding Falls Below 50%*, SCI. MAG. (Mar. 9, 2017), https://www.sciencemag.org/news/2017/03/data-check-us-government-share-

to seventy percent of all research funding nationwide.[4] Today, the federal government broadly supports industry-led research.[5] Inherent in that private financial power is the potential to influence research.[6] For the purposes of this Note, industry influence describes the corporate sponsorship of scientific research through monetary contributions, in-kind donations, or the designation of research parameters.[7] Industry influence also describes scientific studies that have been ghostwritten by someone with a personal stake in the results.[8] Industry influence has the potential to create bias at the pre-study, study, and post-study stages.[9]

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basic-research-funding-falls-below-50 [https://perma.cc/GXA6-3P6Y]. The National Science Foundation defines "basic research" as activity having no immediate commercial value. *Id.* By contrast, "applied research" has a "specific commercial objective." *Id.*

[4] MARK BOROUSH, NAT'L CTR. FOR SCI. & ENG'G STATISTICS, RESEARCH AND DEVELOPMENT: U.S. TRENDS AND INTERNATIONAL COMPARISONS 7 (2020).

[5] *See, e.g.*, Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (modifying patent law to favor the patent filer rather than the inventor); Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (enabling "cooperative research and development agreements"); Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (requiring publicly funded laboratories to budget for and participate in technology transfers).

[6] *See* Darren E. Zinner et al., *Participation of Academic Scientists in Relationships with Industry*, 28 HEALTH AFF. 1814, 1814–15 (2009) (summarizing various types of university-industry relationships and the roles that researchers play, such as consultant, equity owner, paid speaker, scientific advisory board member, and scientist under grant or contract); Mhairi Ransom, Note, *Drugs & Money: The Impact of Industry "Donated" Money on Public Research and the Need for Stricter Conflict of Interest Standards*, 17 S. CAL. INTERDISC. L.J. 567, 570–71 (2008) (discussing industry financial support and its effects on scientific discoveries). Industry-led research has made significant contributions to both law and science. *See, e.g.*, Sheila Jasanoff, *Hidden Experts: Judging Science After* Daubert, *in* TRYING TIMES: SCIENCE AND RESPONSIBILITIES AFTER *DAUBERT* 30, 39 (Vivian Weil ed., 2001) (discussing National Research Council reports on DNA "fingerprint" evidence). Disputes over the reliability of DNA "fingerprinting" led the National Research Council to conduct intensive research into DNA and issue two reports to guide its evidentiary use. *See generally* COMM. ON DNA FORENSIC SCI., NAT'L RESEARCH COUNCIL, THE EVALUATION OF FORENSIC DNA EVIDENCE (1996); COMM. ON DNA TECH. IN FORENSIC SCI., NAT'L RESEARCH COUNCIL, DNA TECHNOLOGY IN FORENSIC SCIENCE (1992).

[7] *See* Leslie I. Boden & David Ozonoff, *Litigation-Generated Science: Why Should We Care?*, 116 ENVTL. HEALTH PERSP. 117, 118 (2008) ("Direct funding of a specific study by an interested party is not the only dimension of financial conflict of interest. Financial conflicts can be generated by funding of other studies, research-related gifts, board membership, and stock ownership."); Ransom, *supra* note 6, at 570–71 (describing the "strings" attached to purportedly altruistic gifts from private industry to researchers).

[8] Ghostwriting is the process of writing under the name of another. *Ghostwriter*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (Philip B. Gove ed., 1986). Once published, ghostwritten studies bear an imprimatur of neutrality. *See* Sheldon Krimsky & Carey Gillam, *Roundup Litigation Discovery Documents: Implications for Public Health and Journal Ethics*, 39 J. PUB. HEALTH POL'Y 318, 320–21 (2018) (summarizing ghostwritten research uncovered in recent litigation). The Superior Court of Pennsylvania has described ghostwriting as "polluting the scientific literature." Barton v. Wyeth Pharm., Inc., Nos. 694 EDA 2010, 695 EDA 2010, 2012 WL 112613, at *11 (Pa. Super. Ct. Jan. 3, 2012).

[9] *See generally* Christopher J. Pannucci & Edwin G. Wilkins, *Identifying and Avoiding Bias in Research*, 126 J. PLASTIC & RECONSTRUCTIVE SURGERY 619 (2010). When a particular result would

Critics in the media have expressed concern over the effects of industry influence on clinical trials, expert testimony, government decision making, and scientific literature.[10] This has spurred numerous books, congressional hearings, editorials, investigations, and lawsuits advocating for scientific neutrality.[11] For instance, when an investigative report by the *Los Angeles Times* discovered that employees of the National Institutes of Health (NIH) were personally profiting from cooperative research and development agreements with private industry, the newspaper accused the NIH of corruption.[12]

The U.S. Supreme Court has a long history of relying on empirical studies.[13] In 2008, in *Exxon Shipping Co. v. Baker*, the Supreme Court addressed

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benefit a study's sponsor, researchers could consciously or subconsciously design a study to obtain that result (a pre-study design flaw), probe the data purposefully to find that result (a study observation bias), or publish only the studies or portions of studies that reached that result (a post-study publication bias). *Id.* at 619–25. The presence of industry influence poses risks that warrant scrutiny. *See* Sheldon Krimsky & L.S. Rothenberg, *Financial Interest and Its Disclosure in Scientific Publications*, 280 JAMA 225, 225 (1998) (describing the potential for conflicts of interest in scientific research). It does not and should not automatically preclude the admission of industry-influenced evidence that is nevertheless reliable. *See In re* Orthopedic Bone Screw Prods. Liab. Litig., 1997 WL 230818, at *5–6 (E.D. Pa. May 5, 1997) (alteration in original) (refusing to assume the "wors[t] case scenario" when evidence of biased science was merely conjectural).

[10] *See, e.g.*, Lisa Girion, *J&J Kept a Guiding Hand on Talc Safety Research*, REUTERS (Dec. 14, 2018), https://www.reuters.com/article/us-johnson-johnson-cancer-research/jj-kept-a-guiding-hand-on-talc-safety-research-idUSKBN1OD1SW [https://perma.cc/RS7R-LXWG] (reporting on efforts to influence researchers investigating talc for asbestos); Andrew Joseph, *'We Owe Much to the Sackler Family': How Gifts to a Top Medical School Advanced the Interests of Purdue Pharma*, STAT (Apr. 9, 2019), https://www.statnews.com/2019/04/09/sackler-purdue-pharma-gifts-to-tufts-advanced-company-interests [https://perma.cc/GZY3-Y4EL] (reporting on monetary and personnel contributions from a pharmaceutical corporation to a private university medical school); Natasha Singer, *Medical Papers by Ghostwriters Pushed Therapy*, N.Y. TIMES (Aug. 4, 2009), https://www.nytimes.com/2009/08/05/health/research/05ghost.html [https://perma.cc/395U-J3WK] (reporting on twenty-six ghostwritten articles promoting the use of hormone therapies to prevent aging, heart disease, and dementia); Natasha Singer, *Senator Moves to Block Medical Ghostwriting*, N.Y. TIMES (Aug. 18, 2009), https://www.nytimes.com/2009/08/19/health/research/19ethics.html [https://perma.cc/7NHP-WPJ4] (reporting on a letter from Senator Charles E. Grassley to the National Institutes of Health (NIH) concerning ghostwriting).

[11] Sheldon Krimsky, *The Funding Effect in Science and Its Implications for the Judiciary*, 13 J.L. & POL'Y 43, 45 (2005).

[12] Editorial, *Subverting U.S. Health*, L.A. TIMES (Dec. 7, 2003), https://www.latimes.com/archives/la-xpm-2003-dec-07-ed-nunih7-story.html [https://perma.cc/AA8U-9S53]. The *Los Angeles Times* concluded that the NIH, once perceived as scientifically neutral, had been tainted by industry influence. *Id.* The NIH is not the only governmental agency to feel the effects of industry influence. *See* Krimsky, *supra* note 11, at 62–63. An investigative report into eighteen expert advisory committees at the Center for Drug Evaluation and Research, a division of the U.S. Food and Drug Administration, found that at least one committee member had a financial stake in the drug under review more than 90% of the time. *Id.*

[13] Adam Liptak, *From One Footnote, a Debate over the Tangles of Law, Science and Money*, N.Y. TIMES (Nov. 24, 2008), https://www.nytimes.com/2008/11/25/washington/25bar.html [https://perma.cc/F9QG-FQW6]. In *Muller v. Oregon*, then-litigator and eventual U.S. Supreme Court Justice Louis D. Brandeis filed a 113-page, primarily scientific brief about the effects of long working hours on women. *The Brandeis Brief—in Its Entirety*, LOUIS D. BRANDEIS SCH. L. LIBR., https://louisville.

the risks of such reliance in a footnote.[14] Following the 1989 Exxon Valdez oil spill in Prince William Sound, a jury in the U.S. District Court for the District of Alaska awarded $287 million in compensatory damages and five billion dollars in punitive damages, the greatest punitive damages award to date.[15] Exxon appealed, and the U.S. Court of Appeals for the Ninth Circuit eventually reduced the punitive damages award to $2.5 billion in light of a recent Supreme Court decision on the constitutional limits of punitive-to-compensatory damages ratios.[16] Exxon then challenged the reduced award and appealed the judgment to the Supreme Court.[17] In an amicus brief filed in support of Exxon, the Washington Legal Foundation (WLF) argued that the Supreme Court should further reduce the award because juries cannot be trusted to produce consistent and predictable punitive damages awards.[18] In support, the amicus brief cited a book and empirical studies that were funded by Exxon and published during the *Baker* litigation.[19] Writing for the majority, Justice David H. Souter stated that the Supreme Court was aware of no research that contradicted WLF's argument.[20] Justice Souter added a footnote to explain, however,

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edu/law/library/special-collections/the-louis-d.-brandeis-collection/the-brandeis-brief-in-its-entirety [https://perma.cc/3ZVV-QTY9]. *See generally* Muller v. Oregon, 208 U.S. 412 (1908). This winning brief has been memorialized as the "Brandeis Brief." *The Brandeis Brief—in Its Entirety*, *supra*. The U.S. Supreme Court has not always been so amenable to this empirical strategy. *See generally, e.g.*, McClesky v. Kemp, 481 U.S. 279 (1987) (deeming two statistical analyses of racially disparate punishments in more than 2,000 capital cases insufficient to support a petition for a writ of habeas corpus under the Eighth and Fourteenth Amendments).

[14] Exxon Shipping Co. v. Baker, 554 U.S. 471, 501 n.17 (2008).

[15] *In re* Exxon Valdez, 270 F.3d 1215, 1225 (9th Cir. 2001).

[16] *In re* Exxon Valdez, 472 F.3d 600, 602 (9th Cir. 2006). In 2003, in *State Farm Mutual Automobile Insurance Co. v. Campbell*, the U.S. Supreme Court stated that few punitive-to-compensatory damages ratios greater than ten-to-one are constitutionally permissible. 538 U.S. 408, 425 (2003). In *Baker*, taking for granted the district court's calculations of the total compensatory damages, the punitive-to-compensatory ratio was $5 billion to $507 million, or approximately five-to-one. 554 U.S. at 515.

[17] *Baker*, 554 U.S. at 490.

[18] Brief of Washington Legal Foundation as Amicus Curiae in Support of Petitioners at 23–27, *Baker*, 554 U.S. 471 (2008) (No. 07-219), 2007 WL 4618317, at *23–28.

[19] *Id.*; *see* David Schkade et al., *Deliberating About Dollars: The Severity Shift*, 100 COLUM. L. REV. 1139, 1139 (2000) (acknowledging funding from Exxon but maintaining that Exxon had no input in the analysis or conclusion); Cass R. Sunstein et al., *Do People Want Optimal Deterrence?* 29 J. LEGAL STUD. 237, 237 (2000) (same); Cass R. Sunstein et al., *Assessing Punitive Damages (with Notes on Cognition and Valuation in Law)*, 107 YALE L.J. 2071, 2071 (1998) [hereinafter Sunstein et al., *Assessing Punitive Damages*] (same). Several large corporations filed an amicus brief in *Campbell* that cited to these same sources. Brief of Certain Leading Business Corporations as Amici Curiae in Support of Petitioner, *Campbell*, 538 U.S. 408 (2003) (No. 01-1289), 2002 WL 1964582, at *11 n.18, *12 n.22, *17 n.30; *see* Alan Zarembo, *Funding Studies to Suit Need*, L.A. TIMES (Dec. 3, 2003), https://www.latimes.com/archives/la-xpm-2003-dec-03-me-exxon3-story.html [https://perma.cc/9C8N-ZUM6] (reporting on the filing of Exxon-funded studies in *Campbell* and in Exxon's appeals to the U.S. Court of Appeals for the Ninth Circuit).

[20] *See Baker*, 554 U.S. at 501 ("We are aware of no scholarly work pointing to consistency across punitive awards in cases involving similar claims and circumstances.").

that the Supreme Court would not rely on WLF's sources because Exxon had funded them.[21] Despite this unequivocal rejection, few courts have even recognized industry-influenced evidence, let alone excluded it.[22]

This Note analyzes existing evidentiary practices and proposes an approach for modernizing them.[23] Part I explains the relevant differences in scientific and legal epistemology.[24] Part II explores how narrowly applied admissibility standards have failed to account for industry influence.[25] Part III studies one such application in a recent case regarding the carcinogenicity of an herbicide.[26] Part IV argues that courts should assess industry-influenced evidence for fraud and proposes a procedural overlay to facilitate this assessment.[27]

I. Differences in Legal and Scientific Epistemology Prevent the Formulation of a Perfect Admissibility Standard

Both law and science are guided by the truth.[28] For the most part, their similarities end there.[29] First and foremost, advocacy—not objectivity—is the currency of the law.[30] There is no expectation that lawyers are neutral; in fact, lawyers have a professional duty to be biased in favor of their clients.[31] When lawyers present facts, they do so with their client's interests in mind.[32] No one

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[21] *Id.* at 501 n.17. ("The Court is aware of a body of literature running parallel to anecdotal reports, examining the predictability of punitive awards by conducting numerous 'mock juries,' where different 'jurors' are confronted with the same hypothetical case. Because this research was funded in part by Exxon, we decline to rely on it." (citations omitted)). *But see* Cooper Indus., Inc. v. Leatherman Tool Grp., Inc., 532 U.S. 424, 432 n.5 (2001) (quoting with approval Sunstein et al., *Assessing Punitive Damages*, *supra* note 19, at 2074). *See generally* Shireen A. Barday, Note, *Punitive Damages, Remunerated Research, and the Legal Profession*, 61 Stan. L. Rev. 711 (2008) (tracing the origins and use of industry-influenced research in punitive damages litigation).

[22] *See infra* notes 126–188 and accompanying text.

[23] *See infra* notes 24–255 and accompanying text.

[24] *See infra* notes 28–57 and accompanying text.

[25] *See infra* notes 58–125 and accompanying text.

[26] *See infra* notes 126–188 and accompanying text.

[27] *See infra* notes 189–255 and accompanying text.

[28] *See* Krimsky, *supra* note 11, at 46 ("It is fair to say that the judicial system and the scientific system are both about getting to the truth.").

[29] *See* Jasanoff, *supra* note 6, at 38 (stating that science and law approach truth in distinct ways).

[30] *See id.* (recognizing that the adversary system relies on advocacy and not objective truth-seeking).

[31] *See* Model Rules of Prof'l Conduct r. 1.3 cmt. 1 (Am. Bar Ass'n 1983) ("A lawyer must also act with commitment and dedication to the interests of the client and with zeal in advocacy upon the client's behalf."). *But see id.* r. 3.8(d) (requiring prosecutors to disclose to the defense all exculpatory evidence and information); *id.* r. 2.4 (describing the duties of lawyers who do not represent clients in a matter but instead serve as "third-party neutrals," such as arbitrators, mediators, and "in such other capacit[ies] as will enable the lawyer[s] to assist the parties to resolve the matter").

[32] *See* Krimsky, *supra* note 11, at 46 (stating that lawyers typically disclose harmful evidence only to challenge it). Though opposing lawyers may present identical facts and argue for contradictory conclusions, neither may knowingly misrepresent the facts nor proffer fraudulent evidence. *See infra* notes 192–208 and accompanying text (explaining the evidentiary fraud doctrine).

would expect (or pay for) anything else.[33] Scientists, on the other hand, are trained skeptics.[34] They are expected to acknowledge openly the limitations of their data and the falsifiability of their hypotheses.[35] In the scientific community, failing to disclose unfavorable data may be a sanctionable offense.[36]

Industry influence is well known among scientists.[37] Pharmaceutical manufacturers often solicit scientists to conduct their research.[38] For example, after a professor published data which showed greater benefits of two name-brand drugs over their generic counterparts, Flint Laboratories, a pharmaceutical manufacturer, contacted the professor.[39] Flint asked the professor to conduct a similar study on its name-brand drug.[40] The professor agreed and signed a contract that prohibited her from sharing her results absent Flint's written consent.[41] In 1990, when the professor's study showed that Flint's drug was no more effective than its generic counterparts, she submitted the study for publication but Flint threatened to sue her for breach of contract.[42] The professor subsequently withdrew her submission and did not publish it until 1997.[43] In response to the publication, Flint faced class action lawsuits alleging violations of state and federal law.[44] Flint subsequently agreed to pay consumers and in-

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[33] *See* Krimsky, *supra* note 11, at 46–47 (describing the public expectation that lawyers set forth narratives favorable to their clients).

[34] *See* ROBERT K. MERTON, *Science and the Social Order*, *in* SOCIAL THEORY AND SOCIAL STRUCTURE 591, 601 (enlarged ed. 1968) (explaining that organized skepticism is the systematic questioning of authoritative, institutional, and routine procedures).

[35] Krimsky, *supra* note 11, at 48.

[36] *Id.* The False Claims Act forbids the presentation of false information to the federal government, including research proposals, reports, and publications. NAT'L ACADS. OF SCI. ET AL., RESPONSIBLE SCIENCE: ENSURING THE INTEGRITY OF THE RESEARCH PROCESS 84 (1992). *See generally* 18 U.S.C. § 1001 (2018) (prohibiting the filing of false statements to the federal government). The False Claims Act has been used to prosecute pharmaceutical firms and at least one scientist. NAT'L ACADS. OF SCI. ET AL., *supra*, at 84. The Program Fraud Civil Remedies Act imposes civil penalties for the same conduct. 45 C.F.R. § 79.1 (2019). Congress broadly promotes objectivity in research and mandates disclosure of financial conflicts of interest. 42 C.F.R. §§ 50.601–.607 (2019). *See generally* James T. O'Reilly, *More Gold and More Fleece: Improving the Legal Sanctions Against Medical Research Fraud*, 42 ADMIN. L. REV. 393 (1990) (discussing legal sanctions for research fraud, including administrative enforcement, civil penalties, and criminal prosecution).

[37] *See* Krimsky, *supra* note 11, at 50 (stating that a publication restriction garnered international attention and sparked a discussion about industry-influenced research).

[38] *Id.*

[39] *Id.* at 48.

[40] *Id.* at 49.

[41] *Id.*

[42] *Id.*

[43] *Id.* at 49–50, 50 n.30. Flint allowed the professor to publish the study after Flint was accused of withholding unfavorable findings. *In re* Synthroid Mktg. Litig., 264 F.3d 712, 714 (7th Cir. 2001).

[44] *See In re Synthroid Mktg. Litig.*, 264 F.3d at 714 ("After the article's publication, lawyers across the country began filing class action suits. They sought relief under a variety of state and federal law theories, including antitrust, RICO, and state consumer-fraud statutes."). RICO is an acronym for the Racketeer Influenced and Corrupt Organizations Act. *See generally* Organized Crime Control

surers more than $130 million to settle the litigation.[45] Though the professor's case sparked outcry, similar restrictive covenants on industry-sponsored research are still commonplace in the pharmaceutical industry.[46]

No standard for the admission of scientific evidence has yet reconciled fundamental differences in legal and scientific epistemology.[47] The first difference is that the practice of science is ordinarily "disinterested," or neutral with respect to observers' desired outcomes.[48] The practice of litigation, by contrast, typically focuses on arguing for a client's preferred result.[49] Second is a difference in goals: the goal of scientific inquiry is to advance science, whereas the goal of litigation is to construct a winning evidentiary record.[50] The third difference concerns review of the results, which in science is left to knowledgeable peers but in law is left to judges during admissibility reviews and juries during deliberations.[51] Fourth is a difference in closure, which in science is revisable consensus but in law is a final judgment or mandate possibly subject to appeal.[52] Fifth is a disparity in certainty, which exists in science when data are replicable, but which has no analog in law; the legal system regularly sees similar cases reach dissimilar results.[53] Sixth is a variance in proof, which in science is statistical significance but in civil litigation is typically a preponder-

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Act of 1970, Pub. L. No. 91-452, tit. IX, 84 Stat. 922 (codified as amended at 18 U.S.C. §§ 1961–1968 (2018)).

[45] *In re Synthroid Mktg. Litig.*, 264 F.3d at 715.

[46] Krimsky, *supra* note 11, at 50. Some journals associated with the International Committee for Medical Journal Editors (ICMJE) require authors to affirm that their sponsors did not control their data. *Id.* Arguing that restrictive covenants prevent legitimate scientific inquiry and subject the journals to potential misrepresentation, the lead editors of these journals refuse to review or publish sponsor-controlled studies. Frank Davidoff et al., *Sponsorship, Authorship, and Accountability*, 345 NEW ENG. J. MED. 825, 825–26 (2001); *see also Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of Interest*, INT'L COMMITTEE MED. J. EDITORS, http://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities—conflicts-of-interest.html [https://perma.cc/Q5GS-TLDX] (describing disclosures required for publication in ICMJE journals).

[47] Epistemology is the study of knowledge. *Epistemology*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, *supra* note 8; *see* Boden & Ozonoff, *supra* note 7, at 120 ("As it is presented at trial, even normal science is integrated into an advocacy narrative and becomes unmoored from the discourse of science as practiced outside the litigation context."); Jasanoff, *supra* note 6, at 38 (listing seven major differences between legal and scientific approaches to truth).

[48] Jasanoff, *supra* note 6, at 37–38.

[49] *Id.*

[50] *Id.* Filling narrative gaps may make for good persuasion, but it may also diminish scientific accuracy. *Id.*

[51] *Id.* at 37, 40.

[52] *Id.* at 37, 41.

[53] *Id.* at 37, 42; *see, e.g.*, Erica Evans, *Similar Crime, Different Punishment: Campus Rape Echoes Brock Turner Case*, L.A. TIMES (July 22, 2016), https://www.latimes.com/nation/la-na-pennsylvania-sexual-assault-20160721-snap-story.html [https://perma.cc/2A9Q-YZZ2] (comparing a six-year prison sentence imposed for felony sexual assault on a college campus with a six-month prison sentence imposed for the same crime one month earlier).

ance of the evidence.[54] The seventh and final reason that there may never be a perfect standard for the admission of scientific evidence is a difference in norms, which in science is a commitment to truth but in law is a commitment to justice.[55] Despite these differences, admissibility standards have evolved to account for some of the growing complexities of the sciences.[56] They have not yet evolved, however, to account for industry influence.[57]

II. *FRYE*, *DAUBERT I*, AND *DAUBERT II*: HOW NARROWLY APPLIED ADMISSIBILITY STANDARDS FAIL TO ACCOUNT FOR INDUSTRY INFLUENCE

Section A of this Part explains how the general acceptance test—the prevailing standard in many state courts—has permitted the admission of industry-influenced evidence.[58] Section B explores how the five "reliability" factors governing the admission of scientific evidence in federal court have failed to account for industry influence.[59] Section C evaluates the utility of an influential sixth factor relevant to the admission of scientific evidence.[60]

A. Frye*: The General Acceptance Test*

In 1923, in *Frye v. United States*, the Court of Appeals of the District of Columbia rendered a two-page, citation-less decision rejecting the admissibility of the results of a systolic blood pressure test because the test had not gained sufficient recognition among the physiological and psychological communities.[61] To admit scientific evidence under *Frye*, a court must find that the relevant scientific communities generally accept the evidence.[62] Though

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[54] Jasanoff, *supra* note 6, at 37, 42–43.

[55] *Id.* at 37, 43.

[56] *See infra* notes 58–125 and accompanying text (tracking the development of increasingly complex standards for the admission of scientific evidence).

[57] *See infra* notes 189–255 and accompanying text (arguing that industry influence is a matter of admissibility and proposing mandatory disclosure of industry influence to facilitate meaningful admissibility reviews).

[58] *See infra* notes 61–76 and accompanying text.

[59] *See infra* notes 77–111 and accompanying text.

[60] *See infra* notes 112–125 and accompanying text.

[61] *See* Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923). Congress established the Court of Appeals of the District of Columbia in 1893. Act of Feb. 9, 1893, ch. 74, 27 Stat. 434. In 1934, Congress re-designated the court the U.S. Court of Appeals for the District of Columbia. *See Court of Appeals of the District of Columbia, 1893–1934*, FED. JUD. CTR., https://www.fjc.gov/history/courts/court-appeals-district-columbia-1893-1934 [https://perma.cc/8MHR-F6X6]. Fourteen years later, Congress changed the court's name to the U.S. Court of Appeals for the District of Columbia Circuit. *Id.*

[62] *Frye*, 293 F. at 1014 ("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 be-

simple at first glance, this "general acceptance test" has spawned more questions than it has answered.[63] Scholars have lambasted *Frye* for being both under- and over-inclusive of admissible evidence, but the decision has received less criticism for its overemphasis on scientific orthodoxy.[64]

In 2000, in *Blum ex rel. Blum v. Merrell Dow Pharmaceuticals, Inc.*, Justice Ronald D. Castille of the Supreme Court of Pennsylvania based his dissent on the consequences of *Frye*'s overemphasis.[65] In *Blum*, the plaintiffs claimed that Merrell Dow's drug Bendectin had caused a birth defect in their child.[66] The trial judge admitted testimony from the plaintiffs' expert, whose non-epidemiological conclusions linking Bendectin to birth defects had contradicted more than thirty published epidemiological studies.[67] On appeal, the Supreme Court of Pennsylvania ruled in favor of Merrell Dow, holding that the testimony of the plaintiffs' expert was inadmissible under *Frye* because the expert had used methods that were not generally accepted.[68]

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longs."). In *Frye*, the court conceded that it is difficult to trace the line between scientific theory and scientific truth. *See id.* ("Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define.").

[63] *See generally, e.g.*, Paul C. Giannelli, *The Admissibility of Novel Scientific Evidence:* Frye v. United States*, a Half-Century Later*, 80 COLUM. L. REV. 1197, 1208–23 (1980) (exploring the questions left in *Frye*'s wake). In addition to delineating the "general acceptance test" that would govern the admission of scientific evidence for the following seventy years, *Frye* spurred a presumption against the admissibility of polygraph results. *See* United States v. Scheffer, 523 U.S. 303, 311 n.7 (1998) (recognizing the uniform presumption against the admission of polygraph evidence in state and federal courts). For an introduction to the admission of scientific evidence before *Frye*, see generally David L. Faigman et al., *Check Your Crystal Ball at the Courthouse Door, Please: Exploring the Past, Understanding the Present, and Worrying About the Future of Scientific Evidence*, 15 CARDOZO L. REV. 1799, 1803–05 (1994).

[64] *See* 1 MCCORMICK ON EVIDENCE § 203, at 1145 (Kenneth S. Broun ed., 7th ed. 2013) (criticizing the ambiguity of key phrases in *Frye* and the decision's overall vagueness); Giannelli, *supra* note 63, at 1208–23 (describing difficulties in the application of *Frye*); Edward J. Imwinkelried, *A New Era in the Evolution of Scientific Evidence—A Primer on Evaluating the Weight of Scientific Evidence*, 23 WM. & MARY L. REV. 261, 264–68 (1981) (summarizing criticisms of *Frye*).

[65] *See generally* Blum *ex rel.* Blum v. Merrell Dow Pharm., Inc., 764 A.2d 1, 6–17 (Pa. 2000) (Castille, J., dissenting).

[66] *Id.* at 2–3 (majority opinion).

[67] *Id.* at 4 n.5. Epidemiology is defined as "the field of public health and medicine that studies the incidence, distribution, and etiology of disease in human populations." FED. JUDICIAL CTR. ET AL., *Reference Guide on Epidemiology*, *in* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 549, 551 (3d ed. 2011).

[68] *Blum*, 764 A.2d at 4 n.5. The *Blum* majority cited other cases in which the testimony of the plaintiffs' expert had been rejected, including one case where the expert had been deemed a "professional plaintiff's witness." *Id.*; *see* Lust *ex rel.* Lust v. Merrell Dow Pharm., 89 F.3d 594, 597 (9th Cir. 1996) ("Although [the expert] published the 1984 article prior to this litigation, he was at that time already a professional plaintiff's witness. It is not unreasonable to presume that [the expert]'s opinion . . . was influenced by a litigation-driven financial incentive."). In his dissent, Justice Ronald D. Castille asserted that Merrell Dow's experts were "equally 'professional defendant's witnesses'" because Merrell Dow had compensated them not only for their testimony but also for their favorable research, provided them with high-ranking positions at the company, and permitted them to base their conclusions on unreliable sources. *Blum*, 764 A.2d at 12–14 (Castille, J., dissenting).

Justice Castille dissented, asserting that the majority had overlooked the fact that Merrell Dow had created and distorted the supposedly neutral scientific community.[69] In support of this assertion, Justice Castille pointed to the plaintiffs' evidence that, faced with a potential multi-million dollar loss, Merrell Dow had employed its vast financial resources to manufacture studies for litigation purposes.[70] Justice Castille adopted the trial court's factual findings, which recognized that Merrell Dow had paid for and published scientific studies in peer-reviewed journals and had assigned as editors lawyers litigating those issues.[71]

The effect of this industry-influenced orthodoxy was to preclude scientific evidence contrary to Merrell Dow's pecuniary interests.[72] In particular, Merrell Dow had created and supervised a "scientific subdiscipline" intended both to vindicate Bendectin and to suppress contrary findings.[73] Justice Castille expressed concern over the ability to purchase scientific consensus and thus dictate case outcomes.[74] Nevertheless, Justice Castille felt constrained by the presumption that scientific consensus ends the *Frye* inquiry, and posited that accommodating his concern required a specific exception to *Frye*.[75] In the two decades since *Blum*, no such exception has gained traction.[76]

B. Daubert I*: The Rules of Reliability*

Enacted in 1975, Federal Rule of Evidence 702 governs the admission of expert testimony in federal court.[77] In 1993, in *Daubert v. Merrell Dow Phar-*

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[69] *See Blum*, 764 A.2d at 16 (Castille, J., dissenting) ("Merrell Dow's role in virtually creating, and then slanting, the 'scientific community' should be a relevant factor in the *Frye* analysis.").

[70] *Id.* at 14.

[71] *Id.* at 8.

[72] *Id.* at 16. Justice Castille was troubled by the majority's approval of the manufacture of slanted scientific orthodoxy and the subsequent ability to silence experts with differing views. *See id.* at 17 ("Where the would-be relevant scientific community is a community beholden to the defendants' litigation interests, that biased community should not be permitted to squelch dissenting opposing opinions.").

[73] *Id.* at 14.

[74] *Id.*

[75] *See id.* at 16–17 (contemplating "a limited exception to *Frye* that would permit the introduction of expert opinions contrary to those opinions generally held by the 'scientific community,' when those opinions are a result of proprietary research influenced by an interested party").

[76] *See, e.g.*, Betz v. Pneumo Abex LLC, 998 A.2d 962, 974–75 n.19 (Pa. Super. Ct. 2010) (recognizing that the defendants had funded some of the studies offered into evidence, and that Justice Castille had admonished courts to scrutinize such evidence, but nevertheless applying *Frye*), *rev'd on other grounds*, 44 A.3d 27 (Pa. 2012).

[77] *See generally* FED. R. EVID. 702 (providing for the admission of testimony by a "witness who is qualified as an expert by knowledge, skill, experience, training, or education" when the witness's testimony "will help the trier of fact to understand the evidence or to determine a fact in issue," "is based on sufficient facts or data," "is the product of reliable principles and methods," and is based on a reliable application of "the principles and methods to the facts of the case"); *see also* Act of Jan. 2, 1975, Pub. L. No. 93-595, 88 Stat. 1926 (enacting the Federal Rules of Evidence). In enacting Federal

maceuticals, Inc. (*Daubert I*), the U.S. Supreme Court held that Rule 702 had superseded *Frye*.[78]

The plaintiffs in *Daubert I*, like the plaintiffs in *Blum*, alleged that Merrell Dow's drug Bendectin had caused a birth defect in their children.[79] In response, Merrell Dow filed a motion for summary judgment supported by an expert affidavit.[80] In the affidavit, Merrell Dow's expert stated that he had reviewed more than thirty published studies involving more than 130,000 patients, none of which had connected Bendectin to birth defects.[81] Based on these data, the expert concluded that Bendectin did not cause the alleged birth defects.[82] In response, the plaintiffs proffered eight experts who reached the opposite conclusion based on animal cell testing, live animal observation, chemical structure evaluation, and an unpublished reanalysis of epidemiological studies.[83]

The U.S. District Court for the Southern District of California ruled that in light of the vast epidemiological data available, expert testimony based on any other type of data was inadmissible.[84] The district court therefore rejected the plaintiffs' animal and chemical evidence.[85] The district court also rejected the plaintiffs' unpublished reanalysis because although it was based on epide-

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Rule of Evidence 702, the Advisory Committee recognized that expert witness testimony may be necessary where "[a]n intelligent evaluation of facts is . . . difficult or impossible without the application of some scientific, technical, or other specialized knowledge." FED. R. EVID. 702 advisory committee's notes to 1972 proposed rules.

[78] Daubert v. Merrell Dow Pharm., Inc. (*Daubert I*), 509 U.S. 579, 587 (1993). *See generally* FED. R. EVID. 702 (providing for the qualification of expert testimony). In 1993, in *Daubert I*, the U.S. Supreme Court granted certiorari "in light of sharp divisions among the courts regarding the proper standard for the admission of expert testimony." 509 U.S. at 585. In *Daubert I*, the Supreme Court recognized that "[t]he merits of the *Frye* test have been much debated, and scholarship on its proper scope and application is legion." *Id.* at 586. At issue in the case, however, was "the continuing authority of the [*Frye*] rule" after the enactment of the Federal Rules of Evidence in 1975. *Id.* at 587. Interpreting "the legislatively enacted Federal Rules of Evidence as [it] would any statute," the Supreme Court stated that the legislative history of Rule 702 "makes no mention of *Frye*, and a rigid general acceptance requirement would be at odds with the liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to opinion testimony." *Id.* at 588 (internal quotation marks omitted) (quoting Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 169 (1988)). "Given the Rules' permissive backdrop and their inclusion of a specific rule on expert testimony that does not mention 'general acceptance,'" the Supreme Court rejected "the assertion that the Rules somehow assimilated *Frye*." *Id.* at 589.

[79] *Daubert I*, 509 U.S. at 582; *Blum*, 764 A.2d at 2–3.

[80] *Daubert I*, 509 U.S. at 582.

[81] *Id.*

[82] *Id.*

[83] *Id.* at 583. A chemical structure evaluation is an examination of the "molecular architecture" of a compound. *See* Jonathan Brecher, *Graphical Representation of Stereochemical Configuration*, 78 PURE & APPLIED CHEMISTRY 1897, 1900 (2006).

[84] Daubert v. Merrell Dow Pharm., Inc., 727 F. Supp. 570, 575 (S.D. Cal. 1989), *aff'd*, 951 F.2d 1128 (9th Cir. 1991), *rev'd*, 509 U.S. 579 (1993).

[85] *Id.*

miological data, the reanalysis had no support in published scientific literature.[86] Discerning no triable issue, the district court granted Merrell Dow's motion for summary judgment.[87] On appeal, the U.S. Court of Appeals for the Ninth Circuit affirmed, stating that a method that deviates significantly from those used by authorities in the field is not generally accepted and is thus inadmissible under *Frye*.[88]

In reversing the Ninth Circuit, the U.S. Supreme Court emphasized that scientific evidence must be both relevant and "reliable."[89] The Supreme Court interpreted Rule 702 as imposing a "gatekeeping" duty on federal judges to decide the admissibility of scientific evidence.[90] The Supreme Court delineated five factors to guide applications of the Rule.[91] Like the critics of *Frye*, critics of *Daubert I* find the decision both under- and over-inclusive of admissible

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[86] *Id.*

[87] *Id.* at 576.

[88] Daubert v. Merrell Dow Pharm., Inc., 951 F.2d 1128, 1130 (9th Cir. 1991), *rev'd*, 509 U.S. 579 (1993).

[89] *Daubert I*, 509 U.S. at 589 (holding that under Rule 702, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable").

[90] *Id.* at 597; *see* FED. R. EVID. 702 advisory committee's notes to 2000 amendments ("In *Daubert* [*I*] the Court charged trial judges with the responsibility of acting as gatekeepers to exclude unreliable expert testimony . . . ."). Some scholars have suggested that this "gatekeeping" duty predates *Daubert I*. *See* Richard Marcus, *Reviving Judicial Gatekeeping of Aggregation: Scrutinizing the Merits on Class Certification*, 79 GEO. WASH. L. REV. 324, 324 (2011) ("Judges have always been gatekeepers, but their gatekeeping tasks have changed a good deal over time."). The *Daubert I* Court recognized that the admissibility of expert testimony is a "preliminary question" under Federal Rule of Evidence 104(a). 509 U.S. at 592 (citing FED. R. EVID. 104(a)). The burden of proving such admissibility is therefore a preponderance of the evidence. *See id.* at 592 n.10 ("These matters should be established by a preponderance of proof." (citing Bourjaily v. United States, 483 U.S. 171, 175–76 (1987)).

[91] *See Daubert I*, 509 U.S. at 593–94 ("Many factors will bear on the inquiry, and we do not presume to set out a definitive checklist or test. But some general observations are appropriate."). The five *Daubert I* factors are whether the method has been tested; whether the method has been subjected to peer review and publication; the method's known and potential rates of error; the maintenance of standards controlling the method; and whether the relevant scientific community generally accepts the method. *Id.*; *see* FED. R. EVID. 702 advisory committee's notes to 2000 amendments (listing the five "specific factors explicated by the *Daubert* [*I*] Court"). Six years after deciding *Daubert I*, the U.S. Supreme Court held that the five *Daubert I* factors apply to "all expert testimony," including that which is "based on 'technical' and 'other specialized' knowledge." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147 (1999); *see* FED. R. EVID. 702 advisory committee's notes to 2000 amendments ("[T]he Court in *Kumho* clarified that this gatekeeper function applies to all expert testimony, not just testimony based in science.").

evidence.[92] These critics, however, have largely overlooked the effect of *Daubert I* on the admission of industry-influenced evidence.[93]

Although described as "flexible,"[94] the *Daubert I* factors do not explicitly account for industry influence.[95] The first factor asks whether the method has been tested.[96] This factor assumes that whoever conducts the tests will report unbiased results, an assumption which scholars reject.[97] The second factor prioritizes peer review and publication.[98] Scholars assert that this factor ignores

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[92] *See generally* Sophia I. Gatowski et al., *Asking the Gatekeepers: A National Survey of Judges on Judging Expert Evidence in a Post-*Daubert *World*, 25 LAW & HUM. BEHAV. 433 (2001) (surveying 400 judges about their understanding of the *Daubert I* factors); David H. Kaye, *How* Daubert *and Its Progeny Have Failed Criminalistics Evidence and a Few Things the Judiciary Could Do About It*, 86 FORDHAM L. REV. 1639 (2018) (arguing that applications of *Daubert I* have failed to regulate adequately the admission of scientific and pseudoscientific evidence).

[93] *See infra* notes 95–111 and accompanying text.

[94] *See Daubert I*, 509 U.S. at 594 ("The inquiry envisioned by Rule 702 is, we emphasize, a flexible one."); FED. R. EVID. 702 advisory committee's notes to 2000 amendments (explaining that the *Daubert I* factors are "neither exclusive nor dispositive"); *In re* Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994) (holding that district courts should apply the *Daubert I* factors "as well as any others that are relevant"). "Courts both before and after *Daubert* [*I*] have found other factors relevant in determining whether expert testimony is sufficiently reliable to be considered by the trier of fact." FED. R. EVID. 702 advisory committee's notes to 2000 amendments (collecting cases).

[95] *See* Mark R. Patterson, *Conflicts of Interest in Scientific Expert Testimony*, 40 WM. & MARY L. REV. 1313, 1345–61 (1999) ("Notably absent from this list is any mention of the possible biases or conflicts of interest of the expert."). Two federal appellate courts have delineated another factor that partially addresses the risks posed by industry influence. *See* Adams v. Lab. Corp. of Am., 760 F.3d 1322, 1334 (11th Cir. 2014); Stagl v. Delta Air Lines, Inc., 117 F.3d 76, 81 (2d Cir. 1997). In 1997, in *Stagl v. Delta Air Lines, Inc.*, the U.S. Court of Appeals for the Second Circuit held that in applying Rule 702, district courts should consider whether there are other, more qualified experts who are not principally employed by the proffering party or its competitors. 117 F.3d at 81. The *Stagl* court warned against allowing industry litigants to define their own duties of care and thus dictate case outcomes. *Id.* at 81 n.2. In 2014, in *Adams v. Laboratory Corp. of America*, the U.S. Court of Appeals for the Eleventh Circuit reversed the decision of a trial court that had effectively delegated its gatekeeping function to private industry. 760 F.3d at 1334. The *Adams* court warned against permitting industry litigants to define the contours of admissibility and thus set unreachable standards of proof. *Id.*

[96] *Daubert I*, 509 U.S. at 593 ("Ordinarily, a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested.").

[97] *See* Patterson, *supra* note 95, at 1355 ("Researchers also may have incentives to reach particular results in other contexts, though, as when their research is funded by a sponsor from whom the researcher might reasonably expect future support.").

[98] *See Daubert I*, 509 U.S. at 593–94 ("Another pertinent consideration is whether the theory or technique has been subjected to peer review and publication. Publication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability, and in some instances well-grounded but innovative theories will not have been published. Some propositions, moreover, are too particular, too new, or of too limited interest to be published. But submission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected. The fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised." (citations omitted)).

the fact that peer reviewers may be just as vulnerable to industry influence.[99] The third factor focuses on quantitative reassurances,[100] overlooking the potential for cherry-picking favorable data, scholars claim.[101] The fourth factor relies on industry standards and controls,[102] so scholars argue that this factor misses the fact that the industry might slant those metrics in its favor.[103] The fifth and final factor incorporates the *Frye* general acceptance test.[104] Scholars therefore repeat their concerns about *Frye*, emphasizing that the relevant scientific community may not be as disinterested as courts assume.[105]

Scholars suggest that Federal Rule of Evidence 706, which provides for court-appointed expert witnesses, is not a sufficient prophylactic.[106] In his con-

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[99] *See* Valentine v. Pioneer Chlor Alkali Co., 921 F. Supp. 666, 674 (D. Nev. 1996) (scrutinizing the value of peer review after *Daubert I*). *See generally* Richard Smith, *Peer Review: A Flawed Process at the Heart of Science and Journals*, 99 J. ROYAL SOC'Y MED. 178 (2006) (discussing the substantive and procedural risks of overreliance on peer review in scientific publishing); M. Sun, *Peer Review Comes Under Peer Review*, 244 SCI. 910 (1989) (same); Lawrence K. Altman, *The Doctor's World; Errors Prompt Proposals to Improve 'Peer Review' at Science Journals*, N.Y. TIMES (June 6, 1989), https://www.nytimes.com/1989/06/06/science/doctor-s-world-errors-prompt-proposals-improve-peer-review-science-journals.html [https://perma.cc/4D3D-CD79] (same).

[100] *See Daubert I*, 509 U.S. at 594 ("Additionally, in the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error . . . .").

[101] *See* Patterson, *supra* note 95, at 1350–51 ("To the extent that the defendant can choose to fund research that focuses only on satisfactory aspects of the product, therefore, it may be able to create a misleading record for the product."). In another context, Chief Justice William H. Rehnquist posited that the malleability of data ought to draw suspicion, borrowing a quotation often attributed to Benjamin Disraeli, "[T]here are three kinds of lies: lies, damned lies and statistics." Procter & Gamble Mfg. Co. v. Fisher, 449 U.S. 1115, 1118 (1981) (Rehnquist, C.J., dissenting from denial of certiorari).

[102] *See Daubert I*, 509 U.S. at 594 ("Additionally, in the case of a particular scientific technique, the court ordinarily should consider . . . the existence and maintenance of standards controlling the technique's operation." (citations omitted)).

[103] *See* Patterson, *supra* note 95, at 1351 ("The defendant might fund studies that are relevant to the issue in the case, but that are designed to be unlikely to detect a problem, even if one exists.").

[104] *See Daubert I*, 509 U.S. at 594 ("Finally, 'general acceptance' can yet have a bearing on the inquiry. A 'reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community.' Widespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique which has been able to attract only minimal support within the community' may properly be viewed with skepticism." (citations omitted) (quoting United States v. Downing, 753 F.2d 1224, 1238 (3d Cir. 1985))).

[105] *See supra* notes 61–76 and accompanying text.

[106] *See* FED. R. EVID. 706; Krimsky, *supra* note 11, at 64 ("[I]t is worth questioning whether the standards for impartiality were as high for the selection of jurors as they were for the members of the expert panel."); Patterson, *supra* note 95, at 1370 ("[N]o expert is truly unbiased . . . any biases of a court-appointed expert—who necessarily comes with the imprimatur of the court—will perhaps be more insidious."). Courts often appoint experts "when the parties' experts offer[] directly conflicting testimony on topics . . . beyond the comprehension of the court." Joe S. Cecil & Thomas E. Willging, *Accepting* Daubert*'s Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995, 1010 (1994). "[I]t is not uncommon for two scientists to interpret the same study very differently." Boden & Ozonoff, *supra* note 7, at 119. In this way, court-appointed experts may help to resolve "battles" between opposing experts. Cecil & Willging, *supra*, at 1010, 1060. For other criticisms of Federal Rule of Evidence 706, see generally Sophia Cope, Comment,

currence in *General Electric Co. v. Joiner*, a decision holding that federal courts review evidentiary rulings under Rule 702 for abuse of discretion, Justice Stephen G. Breyer stated that applications of Rule 706 would facilitate applications of Rule 702.[107] Court-appointed experts, however, might still rely on industry-influenced evidence whether or not they, the attorneys, or the judge are aware of that fact.[108] At trial, for instance, a Rule 706 expert could offer testimony that is knowingly or unknowingly based on industry-influenced research.[109] A litigant seeking to exclude this testimony faces a steep uphill climb because the expert would have been either approved by the litigants or handpicked by the judge.[110] Either way, the challenger confronts an imprimatur of neutrality that a court is unlikely to reverse.[111]

C. Daubert II*: Taking Aim at Hired Guns*

On remand from the U.S. Supreme Court, *Daubert I* returned to the very same three-judge panel of the U.S. Court of Appeals for the Ninth Circuit.[112] In 1995, in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (*Daubert II*), the Ninth Circuit stated that the responsibility of federal courts is to ascertain whether an expert's methodology falls within a range of generally accepted methodologies.[113] Interpreting *Daubert I* as setting out five non-exhaustive factors, the Ninth Circuit added a sixth: whether the expert formed their opinion in anticipation of litigation.[114] The Ninth Circuit intended this factor to ensure that ex-

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Ripe for Revision: A Critique of Federal Rule of Evidence 706 and the Use of Court-Appointed Experts, 39 GONZ. L. REV. 163 (2003–2004).

[107] *See* Gen. Elec. Co. v. Joiner, 522 U.S. 136, 150 (1997) (Breyer, J., concurring) ("Given this kind of offer of cooperative effort, from the scientific to the legal community, and given the various Rules-authorized methods for facilitating the courts' task, it seems to me that *Daubert*'s gatekeeping requirement will not prove inordinately difficult to implement . . . .").

[108] *See* Patterson, *supra* note 95, at 1369 (arguing that the only available experts for court appointment might have conflicts of interests).

[109] *See Daubert I*, 509 U.S. at 595 (recognizing that, under Federal Rule of Evidence 703, the basis for an expert's testimony need not be admissible on its own).

[110] *See* FED. R. EVID. 706(a) (providing the methods of expert appointment); Patterson, *supra* note 95, at 1370 n.198 ("Indeed, courts sometimes intentionally avoid cross-examination of their experts.").

[111] Patterson, *supra* note 95, at 1370.

[112] *See* Daubert v. Merrell Dow Pharm., Inc. (*Daubert II*), 43 F.3d 1311 (9th Cir. 1995).

[113] *Id.* at 1317. The *Daubert II* court suggested that methodologies "practiced by (at least) a recognized minority of scientists in the[] field" could fall within the range of generally accepted methodologies. *Id.* at 1319.

[114] *See id.* at 1316–17 ("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."); *supra* note 91 (listing the five *Daubert I* factors). This sixth factor has been influential in many circuits, where courts have adopted the Ninth Circuit's holding that in the absence of independent research, an expert's testimony is inadmissible unless the expert offers other evidence to establish that the testimony is based on reliable science. *Daubert II*, 43 F.3d at 1317–18 ("If the proffered ex-

pert testimony is based on disinterested science.[115] The court explained that experts whose research predates the filing of a complaint are more trustworthy than experts whose research postdates a litigant's promise of remuneration.[116] The Ninth Circuit reasoned that pre-litigation research commits an expert to their work, thereby reducing the expert's ability to tailor their testimony to a litigant's interests.[117] Therefore, the *Daubert II* court concluded, expert testimony based on pre-litigation research is inherently more reliable than research conducted during or after litigation.[118]

This sixth factor excludes the testimony of "hired gun" experts, those who have abandoned scientific neutrality in favor of the highest bidder.[119] In the context of industry-influenced research, however, it is not necessarily true that pre-litigation studies are more disinterested than studies conducted during or after litigation.[120] First, scholars maintain that pre-litigation science can be

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pert testimony is not based on independent research, the party proffering it must come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'" (quoting *Daubert I*, 509 U.S. at 597)); *accord* Johnson v. Manitowoc Boom Trucks, Inc., 484 F.3d 426, 435 (6th Cir. 2007); Lauzon v. Senco Prods., Inc., 270 F.3d 681, 687 (8th Cir. 2001). In these courts, plaintiffs who rely solely on a "hired gun" expert will not survive summary judgment. *See Johnson*, 484 F.3d at 435–36 (affirming summary judgment for the defendant where the plaintiff's expert was a "quintessential expert for hire"). In 2007, in *Johnson v. Manitowoc Boom Trucks, Inc.*, the U.S. Court of Appeals for the Sixth Circuit noted that most experts are neither "quintessentially" biased nor perfectly untainted by industry influence. *Id.* at 435 n.2.

[115] *See Daubert II*, 43 F.3d 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.").

[116] *See id.* ("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 . . . .").

[117] *See id.* ("[W]hen 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.").

[118] *See id.* ("That the testimony proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were 'derived by the scientific method.'" (quoting *Daubert I*, 509 U.S. at 590). The Ninth Circuit went on to note that because so few experts will fit this mold for any given case, the ability to cherry-pick experts based on their findings will be naturally constrained. *See id.* ("[T]here 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.").

[119] *Hired Gun*, BLACK'S LAW DICTIONARY (11th ed. 2019); *see* David E. Bernstein, *Expert Witnesses, Adversarial Bias, and the (Partial) Failure of the* Daubert *Revolution*, 93 IOWA L. REV. 451, 454 n.13 (2008) (summarizing the role of hired guns in litigation).

[120] *See* Jasanoff, *supra* note 6, at 34 ("[T]he assumption that science is more biased if it emerges from post-litigation than from pre-litigation research remains, at the very least, more doubtful than [*Daubert II*] suggested."); Krimsky, *supra* note 11, at 61–62 ("[T]here is no evidence that pre-litigation research is more dependable or objective than post-litigation research."); Patterson, *supra* note 95, at 1322–23 ("[I]t is not clear that research conducted independent of litigation is more reliable, as presented in court, than research conducted in connection with litigation."). Scholars caution against this sort of black-and-white cognitive line-drawing, as comforting as it may be. *See* Jasanoff, *supra* note 6, at 34. One scholar thus harkens back to *Frye*'s ambiguities, asserting that the Ninth Circuit oversimplified what is actually a nuanced distinction based on complex socio-cultural negotia-

equally susceptible to industry influence.[121] In sub-disciplines with significant commercial potential, the pressure to generate research that benefits the sub-discipline economically resembles the pressure to generate research that benefits the sub-discipline legally.[122] Second, scholars note that timing alone does not necessarily bias a study conducted during or after litigation.[123] In an economy that rewards bringing new products to market, there are few incentives—other than litigation—to conduct research after a product has been released to consumers.[124] Scholars submit that *Daubert II* therefore underestimates the potential for bias in pre-litigation studies and overestimates the potential for bias in studies conducted during and after litigation.[125]

III. MONSANTO, THE GHOSTWRITER: A CASE STUDY IN INDUSTRY INFLUENCE

Narrow applications of *Frye v. United States*, *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (*Daubert I*), and *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (*Daubert II*) have led to a default assumption that industry influence is a matter of weight and not admissibility.[126] On this assumption, the few courts that have recognized industry influence have admitted the evidence subject only to cross-examination and the presentation of other evidence that purports to expose the influence.[127] These techniques fall short of adequate protection against the risks of industry influence.[128]

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tions. *See id.* ("In any legal proceeding involving scientific and technical evidence, it is far from self-evident where (if at all) the space of law ends and the space of science begins.").

[121] Jasanoff, *supra* note 6, at 38.

[122] *Id.*

[123] *Id.*; Krimsky, *supra* note 11, at 62 (arguing that distinctions based on publication timing are not as important as any underlying conflicts of interests).

[124] *See* Jasanoff, *supra* note 6, at 38 ("[I]n a scientific-industrial system geared toward putting new products on the market, the research base for assessing postmarket consequences may not preexist litigation in any meaningful way; not until litigation develops will researchers identify many issues worth investigating, and there is nothing inherently illegitimate about such motivation."). *But see* Boden & Ozonoff, *supra* note 7, at 119 (recognizing that an industry could sponsor research as part of a product marketing campaign).

[125] *See* Jasanoff, *supra* note 6, at 38 (arguing that the *Daubert II* presumption against post-litigation research is inherently problematic).

[126] *See id.* at 42 (stating that industry influence is a matter of uncertainty and analyzing it as a matter of weight rather than admissibility); *see also* Patterson, *supra* note 95, at 1352 (discussing the "incorrect result" of an application of *Daubert I*). *See generally* Daubert v. Merrell Dow Pharm., Inc. (*Daubert I*), 509 U.S. 579 (1993); Daubert v. Merrell Dow Pharm., Inc. (*Daubert II*), 43 F.3d 1311 (9th Cir. 1995); Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

[127] *See, e.g.*, Kammerer v. Wyeth, No. 8:04CV196, 2012 WL 13033732, at *1 (D. Neb. Jan. 31, 2012) (denying the defendant's motion to preclude reference to the defendant's ghostwritten studies in the evidentiary record); *In re* Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prods. Liab. Litig., No. 3:09-CV-10012-DRH, 2011 WL 6740391, at *9 (S.D. Ill. Dec. 22, 2011) (same); Torkie-Tork v. Wyeth, No. 1:04CV945, 2010 WL 11431846, at *2 (E.D. Va. Nov. 17, 2010) (same); *In re* Seroquel Prods. Liab. Litig., No. 6:06MD1769-ORL-22DAB, 2009 WL 223140, at *2–3 (M.D. Fla.

The default remedy for witness bias is cross-examination.[129] Cross-examination may be sufficient to expose the bias of hired gun experts,[130] but industry influence presents a special problem and deserves special treatment.[131] 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.[132] Second, many expert witnesses may not know the extent of industry influence on the research undergirding their conclusions.[133] In this

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Jan. 30) (same), *aff'd*, 601 F. Supp. 2d 1313 (M.D. Fla. 2009). Under *Daubert I*, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 596.

[128] *See infra* notes 129–188 and accompanying text.

[129] Patterson, *supra* note 95, at 1320. In 1984, in *United States v. Abel*, the U.S. Supreme Court held that although the Federal Rules of Evidence do not expressly contemplate impeachment on the basis of bias, the Rules also do not preclude it. 469 U.S. 45, 51 (1984). Impeachment is appropriate for experts as well as fact witnesses. *See* United States v. Salerno, 505 U.S. 317, 328–29 (1992) (Stevens, J., dissenting) (stating that although cross-examination may not be a panacea, it remains the primary means of discrediting a witness); Ford v. Wainwright, 477 U.S. 399, 415 (1986) (recognizing that "[c]ross-examination . . . is beyond any doubt the greatest legal engine ever invented for the discovery of truth" (quoting JOHN HENRY WIGMORE, 5 WIGMORE ON EVIDENCE § 1367 (James H. Chadbourn rev. 1974))).

[130] *See* Patterson, *supra* note 95, at 1320 ("Courts generally handle biases of expert witnesses in the same way they handle biases of fact witnesses, by permitting cross-examination about the biases and allowing the fact finder to assess the overall credibility of the witnesses.").

[131] *See id.* at 1364, 1367 (arguing that conflicts of interest are particularly hard to ferret out on cross-examination and that such "bias might appropriately factor into an admissibility decision"). *But see* Boden & Ozonoff, *supra* note 7, at 121 ("With their own experts as consultants, attorneys have become adept at deconstructing the research and arguments of opposing experts. They also can point out to the jury when research presented by an expert has been funded by and controlled by a party to the litigation."). Scholars suggest that such special treatment has an explicit basis in *Daubert I*. *See* Patterson, *supra* note 95, at 1320 ("It is, of course, exactly that sort of distinct treatment of scientific expert testimony that the Supreme Court established in *Daubert* [*I*] when it wrote that, in regard to such testimony, '*evidentiary reliability* will be based on *scientific validity*.'" (internal quotation marks omitted) (quoting *Daubert I*, 509 U.S. at 590–91 n.9)).

[132] *See* FED. R. EVID. 702 advisory committee's notes to 2000 amendments ("The use of the term 'expert' in the Rule does not, however, mean that a jury should actually be informed that a qualified witness is testifying as an 'expert.' Indeed, there is much to be said for a practice that prohibits the use of the term 'expert' by both the parties and the court at trial. Such a practice 'ensures that trial courts do not inadvertently put their stamp of authority' on a witness's opinion, and protects against the jury's being 'overwhelmed by the so-called "experts."'" (quoting Charles R. Richey, *Proposals to Eliminate the Prejudicial Effect of the Use of the Word "Expert" Under the Federal Rules Evidence in Civil and Criminal Jury Trials*, 154 F.R.D. 537, 559 (1994))); *see also* Patterson, *supra* note 95, at 1368, 1368 n.190 (recognizing that the credibility of expert testimony depends on the expert's professional credentials and experiences); *id.* at 1375 ("Cross-examination in this context is not likely to be entirely effective because lay fact finders are likely to find it difficult to assess the significance of conflicts in research."). *But see* Boden & Ozonoff, *supra* note 7, at 121 (recognizing that although jurors might find the relevant science to be complex, "most understand conflicts of interest and can judge the science presented to them with that in mind" during cross-examination).

[133] *See* Patterson, *supra* note 95, at 1345 ("Even if a litigant's selection of an expert was unbiased and the expert himself had no conflict, the expert's testimony might still be biased. This is possible because the scientific knowledge about which the expert testifies may itself be biased."). Scholars argue that one way this might occur is when an industry distorts scientific consensus by controlling

situation, cross-examination will likely prove ineffective because there is no way to elicit the damaging information.[134] Finally, it may not be clear when or to what extent an expert witness has relied on a particular study or series of studies.[135] Expert witnesses may testify based on their experience without relying on a specific study.[136] In this way, an expert's background familiarity with industry-influenced research could taint the expert's testimony.[137] In any event, a judge is likely to terminate this line of cross-examination if it delves too deeply into research that the witness did not personally conduct.[138]

The presentation of other evidence that purports to expose the industry influence is similarly inadequate.[139] In *In re Roundup Products Liability Litigation* (*Monsanto MDL*), a multidistrict jury trial in the U.S. District Court for the Northern District of California, the plaintiffs alleged that Roundup, a popular glyphosate-based herbicide manufactured by Monsanto Company, had caused their non-Hodgkin's lymphoma.[140] The plaintiff in the bellwether case

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the publication of research results. *Id.*; *see, e.g.*, *supra* notes 39–46 and accompanying text (discussing a restrictive covenant that governed the publication of an industry-funded study). Another way that an expert might not realize the extent of industry influence on their testimony is when an industry distorts scientific consensus by funding only studies that focus on the positive aspects of a product. Patterson, *supra* note 95, at 1345, 1351; *see, e.g.*, *infra* notes 139–188 and accompanying text (discussing studies that an industry member funded, ghostwrote, and relied upon when sued).

[134] *See* Patterson, *supra* note 95, at 1375 (arguing that cross-examination is "even more ineffective when the witness did not conduct the research and therefore may not be able to respond to questions about it"). A survey of North American medical journal editors discovered that, prior to publication, only 28% of medical journals required authors to disclose their institutional affiliations, 26% required a list of funding sources, 13% required a list of past and present consultancy positions, and just 10% required disclosure of stock ownership. Krimsky & Rothenberg, *supra* note 9, at 226. Editors are required to disclose their conflicts of interest in less than 40% of all original research journals. Xavier Bosch et al., *Financial, Nonfinancial and Editors' Conflicts of Interest in High-Impact Biomedical Journals*, 43 EUR. J. CLINICAL INVESTIGATIONS 660, 660 (2013).

[135] *See* FED. R. EVID. 705 (permitting an expert to state and explain an opinion without first describing foundational facts or data).

[136] *See* FED. R. EVID. 703 (permitting an expert to testify based on supplied facts or data which the expert observed personally).

[137] *See* Pannucci & Wilkins, *supra* note 9, at 619–24 (discussing the insidious nature of pre-study, study, and post-study biases).

[138] *See* Patterson, *supra* note 95, at 1364 (recognizing the hesitancy of trial judges to allow substantial probing of research conducted by someone other than the testifying witness). *But see* FED. R. EVID. 602 (providing that expert testimony may be admissible even if it is not based on "personal knowledge").

[139] *See infra* notes 140–188 and accompanying text.

[140] *See In re* Roundup Prods. Liab. Litig. (*Monsanto MDL*), MDL No. 2741, 214 F. Supp. 3d 1346, 1347–48 (J.P.M.L. Oct. 4, 2016). Multidistrict litigation refers to the statutory consolidation of civil actions involving common questions of fact. 28 U.S.C. § 1407(a) (2018). For an introduction to this unique process, see generally Thomas D. Rowe, Jr. & Kenneth D. Sibley, *Beyond Diversity: Federal Multiparty, Multiforum Jurisdiction*, 135 U. PA. L. REV. 7 (1986) (explaining the need for multidistrict consolidation and the attendant problems). For an introduction to multidistrict litigation within state courts, see generally George T. Conway III, Note, *The Consolidation of Multistate Litigation in State Courts*, 96 YALE L.J. 1099 (1987) (exploring the potential for the transference of federal multidistrict proceedings to state courts). Non-Hodgkin's lymphoma is a cancer of the lymphatic system. *What Is*

was seventy-year-old Edwin Hardeman, who had sprayed more than six thousand gallons of Roundup over the course of twenty-six years.[141]

Monsanto filed a motion to bifurcate the trial into a causation phase and a liability and damages phase.[142] In opposing the motion, Hardeman argued that bifurcation would complicate rather than simplify the trial.[143] In pertinent part, Hardeman argued that his evidence demonstrating Monsanto's ghostwritten research was relevant to both causation and liability.[144] On January 3, 2019, Judge Vince G. Chhabria granted Monsanto's motion, bifurcating the trial into Phase 1 (causation) and Phase 2 (liability and damages).[145] In Phase 1, the jury would decide only whether Roundup could cause non-Hodgkin's lymphoma.[146] If the jury found in Hardeman's favor, the trial would proceed to Phase 2, where the jury would decide whether Roundup actually caused Hardeman's non-Hodgkin's lymphoma, and if so, to what extent Hardeman was entitled to recov-

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Non-Hodgkin Lymphoma?, AM. CANCER SOC'Y, https://www.cancer.org/cancer/non-hodgkin-lymphoma/about/what-is-non-hodgkin-lymphoma.html [https://perma.cc/C7A5-DQTX].

[141] *See* Ross Todd, *First Bellwether Trial in* Roundup MDL *Reaches End of Initial Science-Heavy Phase*, THE RECORDER (Mar. 12, 2019), https://www.law.com/therecorder/2019/03/12/first-bellwether-trial-in-roundup-mdl-reaches-end-of-initial-science-heavy-phase [https://perma.cc/KU7A-TPBP] (summarizing the facts and travel of *Monsanto MDL*). In cases involving many plaintiffs, courts sometimes begin with single-plaintiff bellwether trials to simplify the proceeding and provide a foundation for settlement of the remaining cases. Alexandra D. Lahav, *Bellwether Trials*, 76 GEO. WASH. L. REV. 576, 577–78 (2008).

[142] Monsanto Company's Motion to Reverse Bifurcate the Group 1 Trials at 1, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Dec. 10, 2018). Bifurcation is a procedural tool employed to streamline a case by dividing the proceedings into discrete phases. FED. R. CIV. P. 42(b).

[143] Plaintiffs' Opposition to Issue Bifurcation at 15, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Dec. 13, 2018). The *Monsanto MDL* court dismissed as a "relatively minor concern" the plaintiffs' argument that "bifurcation is unfair because jurors will be left wondering, during the causation phase, how glyphosate could possibly be dangerous if it has gone largely unregulated for decades." Pretrial Order No. 61 Re: Bifurcation at 1, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Jan. 3, 2019) [hereinafter Bifurcation Order]. The court stated that the plaintiffs' concern "is best addressed by an instruction to jurors that they must not defer to regulatory agencies, and must instead reach their own judgment based on the evidence presented at trial." *Id.*

[144] Plaintiffs' Opposition to Issue Bifurcation, *supra* note 143, at 10–15. The *Monsanto MDL* court agreed with the plaintiffs' assertion that "[a]ny such evidence will likely overlap with evidence of liability" but disagreed with the plaintiffs' argument that it would therefore be "impossible . . . to separate evidence of causation from evidence of liability." Bifurcation Order, *supra* note 143, at 2.

[145] *See* Bifurcation Order, *supra* note 143, at 1 ("A significant portion of the plaintiffs' case involves attacks on Monsanto for attempting to influence regulatory agencies and manipulate public opinion regarding glyphosate. These issues are relevant to punitive damages and some liability questions. But when it comes to whether glyphosate caused a plaintiff's NHL, these issues are mostly a distraction, and a significant one at that."). Judge Chhabria also ordered bifurcation of the subsequent bellwether trials, concluding that "this is the fairest way to proceed in a trial addressing the carcinogenicity of glyphosate." *Id.* at 2 n.1.

[146] *Id.* at 1. When Hardeman's counsel discussed Phase 2 issues in her Phase 1 opening statement, Judge Chhabria sanctioned her $500. Pre-Trial Order No. 91: Order Sanctioning Mr. Hardeman's Counsel at 1–2, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Feb. 26, 2019). Judge Chhabria ordered Hardeman's counsel to disclose the names of every attorney who had participated even minimally in the preparation of the opening statement. *Id.* at 3.

er damages.[147] Judge Chhabria excluded from Phase 1 all evidence of Monsanto's influence on regulatory decisions, but left the proverbial Phase 1 door open to evidence concerning Monsanto's influence on scientific studies.[148]

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[147] Bifurcation Order, *supra* note 143, at 1.

[148] *See id.* at 1–2 ("[I]f the plaintiffs have evidence that Monsanto manipulated the outcome of scientific studies, as opposed to agency decisions or public opinion regarding those studies, that evidence may well be admissible at the causation phase."). Hardeman sought to admit two categories of evidence concerning Monsanto's influence on regulatory decisions. Plaintiffs' Opposition to Issue Bifurcation, *supra* note 143, at 10–15. First, Hardeman sought to expose Monsanto's lobbying of the U.S. Environmental Protection Agency (EPA) to accord its review of glyphosate with those of Canadian and European regulators. Plaintiffs' Motion to Compel the Deposition of Jess Rowland, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Mar. 14, 2017), ECF No. 189-5 ("Goal: Persuade EPA to follow Europe and Canada in defending the science behind a determination that glyphosate is not carcinogenic . . . ."). *See generally* CAN. PEST MGMT. REGULATORY AGENCY, RE-EVALUATION DECISION RVD2017-01, GLYPHOSATE (2017) (finding that there is insufficient evidence to establish a causal connection between glyphosate and cancer in humans); European Food Safety Authority, *Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate*, 13 EUR. FOOD SAFETY AUTHORITY J. 4302 (2015) (same). In support, Hardeman pointed to the relationship between Monsanto employees and Jess Rowland, then-deputy division director at EPA. Plaintiffs' Motion to Compel the Deposition of Jess Rowland, *supra*, at 1. In April 2015, Daniel Jenkins, U.S. Agency Lead at Monsanto, informed other Monsanto employees that Rowland called him to brag about his efforts to prevent a glyphosate review by the Agency for Toxic Substances and Disease Registry (ATSDR), a division of the U.S. Department of Health and Human Services. *See id.* at ECF No. 189-4 ("[H]e wanted to establish some saying 'If I can kill this I should get a medal.'"). Jenkins concluded that Monsanto's efforts to influence Rowland were finally bearing fruit, though he thought that ATSDR would still conduct its review. *See id.* ("[I]t's good to know they are going to actually make the effort now to coordinate due to our pressing . . . ."). A few months later, Jenkins wrote another internal email about Rowland's upcoming retirement, stating that Rowland could be useful in future glyphosate defense. *See id.* at ECF No. 189-6 ("Jess will be retiring from EPA in ~5–6 [months] and could be useful as we move forward with ongoing glyphosate defense."). Based on this evidence, Hardeman moved to exclude three EPA reports on the carcinogenicity of glyphosate from 2016 and 2017. Plaintiffs' Notice of Motion and Motion in Limine No. 5 to Exclude Certain U.S. EPA Documents Relating to Glyphosate Carcinogenicity at 4, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Jan. 30, 2019). The *Monsanto MDL* court partially granted Hardeman's motion, excluding the written reports from both Phases but allowing Monsanto to mention that EPA had approved the pesticide for consumer use. Pretrial Order No. 81: Ruling on Motions in Limine at 6, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Feb. 18, 2019) ("Particularly during Phase 1, discussion of EPA approval will be restricted under Rule 403 to avoid wasting time or misleading the jury, because the primary inquiry is what the scientific studies show, not what the EPA concluded they show."). Relatedly, Monsanto filed a motion "to exclude evidence of the company's lobbying activities," which the court granted for Phase 1 but denied for Phase 2. *Id.* at 4 (citing FED. R. EVID. 401, 403). Second, Hardeman proffered evidence concerning Monsanto's efforts to undermine a monograph by the International Agency for Research on Cancer (IARC), a division of the World Health Organization, which concluded that there is sufficient evidence to support a causal connection between glyphosate and cancer in humans. Plaintiffs' Motion to Compel the Deposition of Jess Rowland, *supra*, at ECF No. 189-4 ("As you know, we are considering the value/advisability of doing more work to help us deal with the IARC fallout . . . ."). According to a report submitted to the U.S. House of Representatives, Monsanto attempted to "undermine" the IARC monograph by orchestrating "outrage" to it, "amplifying" its disagreement with it on social media, and attempting to "neutralize" its effects with industry-influenced studies. MINORITY STAFF OF H. COMM. ON SCI., SPACE & TECH., 115TH CONG., SPINNING SCIENCE & SILENCING SCIENTISTS: A CASE STUDY IN HOW THE CHEMICAL INDUSTRY ATTEMPTS TO INFLUENCE SCIENCE 5 (Comm. Print 2018). These industry-

In response, Monsanto filed a motion to exclude evidence of ghostwriting as being both irrelevant and unduly prejudicial, serving only to evoke an emotional reaction from the jury.[149] Monsanto asserted that such a reaction would be unwarranted because Monsanto had done no wrong.[150] According to the company, the studies that Monsanto anticipated Hardeman would claim were ghostwritten actually acknowledged the company's influence.[151] Moreover, Monsanto averred that its involvement in the research process did not affect the empirical question of carcinogenicity.[152]

Hardeman filed a response to Monsanto's motion, disputing Monsanto's relevancy and undue prejudice arguments and asserting that Monsanto employees had referred to ghostwritten studies as "invaluable assets" for "regulatory reviews" and "product defense."[153] He pointed to three of the studies that Monsanto had anticipated in its motion.[154]

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influenced studies included five ghostwritten articles in *Critical Reviews in Toxicology*. *See infra* note 154 and accompanying text.

[149] Monsanto Company's Notice of Motion and Motion *in Limine* No. 2 Re: "Ghostwriting" at 4, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Jan. 30, 2019) [hereinafter Monsanto's Ghostwriting Motion].

[150] *Id.* at 5.

[151] *See id.* ("More broadly, the review articles at issue transparently reflect the extent of Monsanto's involvement, which means they were not ghostwritten in any relevant sense."); *id.* at 4 n.1 (listing studies that Monsanto anticipated Hardeman would allege were ghostwritten).

[152] *Id.* at 4 ("[W]hether Monsanto 'ghostwrote' any of the review articles would not have changed any of the primary data . . . .").

[153] *See* Plaintiffs' Response to MIL No. 2 Re: "Ghostwriting" at 2, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Jan. 30, 2019) [hereinafter Plaintiffs' Ghostwriting Response] ("Monsanto's own scientists acknowledge that they have ghostwritten papers that were 'invaluable assets to regulatory reviews' and for purposes of 'product defense.'").

[154] Plaintiffs' Ghostwriting Response, *supra* note 153, at 3–5; *see* Monsanto's Ghostwriting Motion, *supra* note 149, at 4 n.1 (anticipating "'ghostwriting' allegations" about certain studies). In its motion, Monsanto acknowledged its involvement in one study examining the carcinogenic potential of glyphosate. Monsanto's Ghostwriting Motion, *supra* note 149, at 4 n.1. *See generally* Helmut Greim et al., *Evaluation of Carcinogenic Potential of the Herbicide Glyphosate, Drawing on Tumor Incidence Data from Fourteen Chronic/Carcinogenicity Rodent Studies*, 45 CRITICAL REVS. TOXICOLOGY 185 (2015) [hereinafter *Evaluation of Carcinogenic Potential of the Herbicide Glyphosate*]. That study's four authors were listed as employed by Monsanto (David Saltmiras), retained by an independent consulting group (Helmut Greim and Volker Mostert), or as a member of the Glyphosate Task Force (Christian Strupp). *See Evaluation of Carcinogenic Potential of the Herbicide Glyphosate* at 206; *see also infra* note 158 (describing the Glyphosate Task Force). At least seventy-six other studies have cited this study. *Results*, GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C22&q=Evaluation+of+Carcinogenic+Potential+of+the+Herbicide+Glyphosate%2C+Drawing+on+Tumor+Incidence+Data+from+Fourteen+Chronic%2FCarcinogenicity+Rodent+Studies&btnG= [https://perma.cc/7J2X-SH35]. Monsanto also acknowledged its involvement in five other studies published consecutively in *Critical Reviews in Toxicology*. Monsanto's Ghostwriting Motion, *supra* note 149, at 4 n.1; *see* John Acquavella et al., *Glyphosate Epidemiology Expert Panel Review: A Weight of Evidence Systematic Review of the Relationship Between Glyphosate Exposure and Non-Hodgkin's Lymphoma or Multiple Myeloma*, 46 CRITICAL REVS. TOXICOLOGY 28, 28–43 (2016); David Brusick et al., *Genotoxicity Expert Panel Review: Weight of Evidence Evaluation of the Genotoxicity of Glyphosate, Glyphosate-Based Formulations, and Aminomethylphosphonic Acid*, 46

First, in November 2010, Monsanto employee Donna Farmer updated an author of a favorable study on Farmer's ghostwriting progress.[155] In an email, Farmer explained that she had finished writing the first forty-six pages of the study, added a section on genotoxicity, cut and pasted summaries from other favorable studies, and was drafting a response to a recent unfavorable study.[156]

CRITICAL REVS. TOXICOLOGY 56, 56–74 (2016); K.R. Solomon, *Glyphosate in the General Population and in Applicators: A Critical Review of Studies on Exposures*, 46 CRITICAL REVS. TOXICOLOGY 21, 21–27 (2016); Gary M. Williams et al., *A Review of the Carcinogenic Potential of Glyphosate by Four Independent Expert Panels and Comparison to the IARC Assessment*, 46 CRITICAL REVS. TOXICOLOGY 3, 3–20 (2016) [hereinafter Williams et al., *IARC*]; Gary M. Williams et al., *Glyphosate Rodent Carcinogenicity Bioassay Expert Panel Review*, 46 CRITICAL REVS. TOXICOLOGY 44, 44–55 (2016) [hereinafter Williams et al., *Rodent*]. In response to these articles, the editor in chief and the publisher of *Critical Reviews in Toxicology* requested additional disclosures of Monsanto's involvement. *Expression of Concern – 26 September 2018*, 48 CRITICAL REVS. TOXICOLOGY 891, 891 (2018). Two months later, the article authors released a corrigendum to make the disclosures. *Corrigendum*, 48 CRITICAL REVS. TOXICOLOGY 893, 893–94 (2018). In response, the editor in chief and publisher noted that the disclosures were "in some places in contradiction to the statements originally supplied" and that the journal had "not received an adequate explanation as to why the necessary level of transparency was not met on first submission . . . ." *Expression of Concern – 30 November 2018*, 48 CRITICAL REVS. TOXICOLOGY 903, 903 (2018). The editor in chief and publisher "recommend[ed] that readers take the additional context the corrected disclosures provide into account when reading the articles." *Id.* Collectively, as of the publication of this Note, at least 172 studies have cited these five publications. *See Results of Acquavella et al.*, GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C22&q=Glyphosate+Epidemiology+Expert+Panel+Review%3A+A+Weight+of+Evidence+Systematic+Review+of+the+Relationship+Between+Glyphosate+Exposure+and+Non-Hodgkin%E2%80%99s+Lymphoma+or+Multiple+Myeloma&btnG= [https://perma.cc/VTM2-PG3T] (finding twenty-nine citations); *Results of Brusick et al.*, GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C22&q=Genotoxicity+Expert+Panel+Review%3A+Weight+of+Evidence+Evaluation+of+the+Genotoxicity+of+Glyphosate%2C+Glyphosate-based+Formulations%2C+and+Aminomethylphosphonic+Acid&btnG= [https://perma.cc/5B5C-WMHX] (finding thirty-three citations); *Results of Solomon*, GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C22&q=Glyphosate+in+the+General+Population+and+in+Applicators%3A+A+Critical+Review+of+Studies+on+Exposures&btnG= [https://perma.cc/9LDW-H32S] (finding thirty-one citations); *Results of Williams et al., IARC*, GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C22&q=A+Review+of+the+Carcinogenic+Potential+of+Glyphosate+by+Four+Independent+Expert+Panels+and+Comparison+to+the+IARC+Assessment&btnG= [https://perma.cc/72JM-E5ZB] (finding fifty-six citations); *Results of Williams et al., Rodent*, GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C22&q=Glyphosate+Rodent+Carcinogenicity+Bioassay+Expert+Panel+Review&btnG= [https://perma.cc/DAN3-W6FF] (finding twenty-three citations).

[155] Plaintiffs' Ghostwriting Response, *supra* note 153, at 4. *See generally* Amy L. Williams et al., *Developmental and Reproductive Outcomes in Humans and Animals After Glyphosate Exposure: A Critical Analysis*, 15 J. TOXICOLOGY & ENVTL. HEALTH 39 (2012) (finding that there is insufficient evidence to establish a causal connection between glyphosate and cancer in humans). Monsanto pointed out that the Williams et al. study discloses Monsanto's support in an unnumbered footnote. Monsanto's Ghostwriting Motion, *supra* note 149, at 5 (noting that the Williams et al. study "similarly acknowledges Monsanto 'for funding and for providing its unpublished glyphosate and surfactant toxicity study reports'" (quoting Williams et al., *supra*, at 39)).

[156] Plaintiffs' Ghostwriting Response, *supra* note 153, at 4. Farmer referred to the unfavorable study as "gasiner," likely a misspelling of Gasnier, the last name of an author who had recently reported a strong causal connection between glyphosate and cancer in humans. *Id. See generally* Céline

When the favorable study was published, however, Farmer was not listed as an author.[157]

Second, in July 2012, Monsanto employee David Saltmiras attempted to co-write a favorable study but was unable to counter contradictory studies, despite drawing from the Glyphosate Task Force's confidential research.[158] Monsanto then decided that it could enhance the credibility of the study by replacing Saltmiras' name with that of a well-known expert, David Kirkland.[159] Monsanto paid Kirkland £14,000 to publish the study under his name.[160] Saltmiras was not listed as an author of the study.[161]

Third, in February 2015, Monsanto employee William Heydens emailed Farmer, his coworker and coauthor on another favorable study, to inform her that hiring experts to contribute to the study would cost at least $250,000.[162] To save money, Heydens suggested that he and Farmer ghostwrite certain sections and retain experts for other sections.[163] Heydens then proposed paying certain

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Gasnier et al., *Glyphosate-Based Herbicides Are Toxic and Endocrine Disruptors in Human Cell Lines*, 262 TOXICOLOGY 184, 190 (2009) ("[Glyphosate]-based herbicides present DNA damages and [carcinogen, mutagen, and reprotoxic] effects on humans cells and *in vivo*.").

[157] Williams et al., *supra* note 155, at 39. At least 108 studies have cited the Williams et al. study. *Results of Williams et al.*, GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C22&q=Developmental+and+Reproductive+Outcomes+in+Humans+and+Animals+After+Glyphosate+Exposure%3A+A+Critical+Analysis&btnG= [https://perma.cc/PR8U-6DXS].

[158] Plaintiffs' Ghostwriting Response, *supra* note 153, at 4–5 ("[T]he Kier and Kirkland study was originally written by Monsanto's David Saltmiras as a valuable resource in future product defense against claims that glyphosate is mutagenic or genotoxic." (internal quotation marks omitted)). *See generally* L.D. Kier & D.J. Kirkland, *Review of Genotoxicity Studies of Glyphosate and Glyphosate-based Formulations*, 43 CRITICAL REVS. TOXICOLOGY 283 (2013) (finding that there is insufficient evidence to establish a causal connection between glyphosate and cancer in humans). Monsanto pointed out that the Kier and Kirkland study acknowledges David Saltmiras's contributions. Monsanto's Ghostwriting Motion, *supra* note 149, at 5. The Kier and Kirkland study also thanks Saltmiras "for his invaluable service in providing coordination with individual companies and the Glyphosate Task Force" and acknowledges that listed authors Larry Kier and David Kirkland "were paid consultants of the Glyphosate Task Force for the preparation of this review." Kier & Kirkland, *supra*, at 311. The Glyphosate Task Force, now the Glyphosate Renewal Group, is an industry group aimed at renewing glyphosate registration in the European Union. *What Is the Glyphosate Renewal Group?*, GLYPHOSATE RENEWAL GROUP, https://www.glyphosate.eu/ [https://perma.cc/Q7GS-2T8N]. Monsanto's parent company Bayer Agriculture is a member of the industry group. *Id.* Kier is a former Monsanto employee. Kier & Kirkland, *supra*, at 311.

[159] Plaintiffs' Ghostwriting Response, *supra* note 153, at 5. As one federal judge has suggested, a more forthright way to leverage the credibility of a well-known expert may be to list the real authors and have the expert draft a forward or summary endorsing the study. *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prods. Liab. Litig.*, 2011 WL 6740391, at *9.

[160] Plaintiffs' Submission in Response to Pretrial Order No. 8 at 2, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Mar. 14, 2017).

[161] Kier & Kirkland, *supra* note 158, at 238. At least 81 studies have cited the Kier and Kirkland study. *Results of Kier & Kirkland*, GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C22&q=Review+of+Genotoxicity+Studies+of+Glyphosate+and+Glyphosate-based+Formulations&btnG= [https://perma.cc/LT65-CVQ9].

[162] Plaintiffs' Submission in Response to Pretrial Order No. 8, *supra* note 160, at 4.

[163] *Id.*

well-known experts to publish the study under their names, just as Monsanto had done in an earlier study.[164] Neither Heydens nor Farmer was listed as an author of the earlier study.[165]

In his response, Hardeman also reminded the court that over a year earlier, Judge Chhabria had indicated the strong relevance of these three studies on the Phase 1 causation inquiry.[166] At the time, Judge Chhabria pressed Monsanto on how its efforts to ghostwrite studies showing a lack of causation were irrelevant to the question of causation.[167] Hardeman's response relied primarily on a Superior Court of California case in which evidence of Monsanto's ghostwriting was deemed sufficient to support a jury finding that Monsanto had sought to influence glyphosate research for litigation and public relations purposes.[168] Hardeman also cited evidentiary rulings in four other federal cases.[169] As in *Monsanto MDL*, each of these rulings followed a defendant's mo-

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[164] *Id.* at ECF No. 187-12 ("A less expensive/more palatable approach might be to involve experts only for the areas of contention . . . and we ghost-write the Exposure Tox & Genotox sections. An option would be to add Greim and Kier or Kirkland to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall that is how we handled Williams Kroes & Munro, 2000."). *See generally* Gary M. Williams et al., *Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans*, 31 REGULATORY TOXICOLOGY & PHARMACOLOGY 117 (2000) [hereinafter Williams et al., *Safety*] (finding that there is insufficient evidence to establish a causal connection between glyphosate and cancer in humans). Monsanto pointed out that the Williams et al. study identifies William Heydens and Donna Farmer as contributors. Monsanto's Ghostwriting Motion, *supra* note 149, at 5.

[165] Williams et al., *Safety*, *supra* note 164, at 117. At least 832 studies have cited the Williams et al. study. *Results of Williams et al., Safety*, GOOGLE SCHOLAR, https://scholar.google.com/scholar?hl=en&as_sdt=0%2C22&q=Safety+Evaluation+and+Risk+Assessment+of+the+Herbicide+Roundup+and+Its+Active+Ingredient%2C+Glyphosate%2C+for+Humans&btnG= [https://perma.cc/P8Q6-83LZ].

[166] Plaintiffs' Ghostwriting Response, *supra* note 153, at 2.

[167] *Id.* In a hearing on August 24, 2017, Judge Chhabria was unequivocal about his position. *Id.* In pertinent part, Judge Chhabria stated that he was confused as to how Monsanto could contend, on the one hand, that scientific studies show no causal connection between glyphosate and cancer in humans, and on the other hand argue against the relevance of Monsanto's ghostwriting those studies. *See id.* ("I don't understand how you could have taken the position that the issue of Monsanto drafting reports for allegedly independent experts on whether glyphosate causes non-Hodgkin's lymphoma could be irrelevant to the question of whether there's evidence that glyphosate causes non-Hodgkin's lymphoma. I just don't understand how you could take that position.").

[168] Plaintiffs' Ghostwriting Response, *supra* note 153, at 3. In 2018, in *Johnson v. Monsanto Co.*, the jury returned a verdict for the plaintiff, a school groundskeeper, awarding more than $289 million. No. CGC-15–550128, 2018 WL 4261442, at *6–7 (Cal. Super. Ct. Aug. 23, 2018). The Superior Court of California ultimately reduced the award to approximately $78 million. Johnson v. Monsanto Co., No. CGC-16–550128, 2018 WL 5246323, at *8 (Cal. Super. Ct. Oct. 22, 2018).

[169] Plaintiffs' Ghostwriting Response, *supra* note 153, at 2–3 (citing *Kammerer*, 2012 WL 13033732; *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prods. Liab. Litig.*, 2011 WL 6740391; *Torkie-Tork*, 2010 WL 11431846; *In re Seroquel Prods. Liab. Litig.*, 2009 WL 223140.

tion to exclude evidence of ghostwriting.[170] In all four cases, the courts denied the defendants' motions.[171] Critically, however, neither Hardeman nor the plaintiffs in these cases challenged testimonial reliance on the ghostwritten studies, so the courts never addressed the issue.[172] Hardeman's only option was to discredit the evidentiary weight of the studies by attempting to show the extent of Monsanto's influence on them.[173]

Monsanto MDL exemplifies the consequences of narrow applications of admissibility standards.[174] There, the court was bound to apply Federal Rule of Evidence 702 as interpreted in *Daubert I*.[175] As the *Monsanto MDL* court recognized, there is no such thing as a perfect scientific study.[176] *Daubert I* excludes only those studies that are based on unreliable methods.[177] In *Monsanto*

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[170] *Kammerer*, 2012 WL 13033732, at *1; *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prods. Liab. Litig.*, 2011 WL 6740391, at *9; *Torkie-Tork*, 2010 WL 11431846, at *2; *In re Seroquel Prods. Liab. Litig.*, 2009 WL 223140, at *2–3.

[171] *Kammerer*, 2012 WL 13033732, at *1; *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prods. Liab. Litig.*, 2011 WL 6740391, at *9; *Torkie-Tork*, 2010 WL 11431846, at *2; *In re Seroquel Prods. Liab. Litig.*, 2009 WL 223140, at *2–3.

[172] *See generally Kammerer*, 2012 WL 13033732; *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Prods. Liab. Litig.*, 2011 WL 6740391; *Torkie-Tork*, 2010 WL 11431846; *In re Seroquel Prods. Liab. Litig.*, 2009 WL 223140. On February 12, 2019, Judge Chhabria granted without a hearing Monsanto's motion to exclude evidence of ghostwriting for Phase 1 and denied it for Phase 2. Pretrial Order No. 78: Guidance for the Parties Re: Motions in Limine at 2, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. Feb. 12, 2019). Six days later, Judge Chhabria explained that he considered the evidence of ghostwriting essentially or completely irrelevant to causation but highly relevant to liability and damages. Pretrial Order No. 81: Ruling on Motions in Limine, *supra* note 148, at 1–2 ("This evidence is not relevant (or, at best, is marginally relevant) to causation, so its admission during Phase 1 would be unduly prejudicial and would waste the jury's time. During Phase 2, however, this evidence is far more relevant, and its admission would not be unduly prejudicial, particularly in light of the term's use by Monsanto employees.").

[173] *See supra* notes 126–138 and accompanying text (describing the two most common protections against industry influence, cross-examination and the presentation of evidence purporting to expose the influence). On March 19, 2019, the *Monsanto MDL* jury returned a verdict in Hardeman's favor in Phase 1, and the trial proceeded to Phase 2. *See* Mihir Zaveri, *Monsanto Weedkiller Roundup Was 'Substantial Factor' in Causing Man's Cancer, Jury Says*, N.Y. TIMES (Mar. 19, 2019), https://www.nytimes.com/2019/03/19/business/monsanto-roundup-cancer.html [https://perma.cc/DW5A-WHMD] (summarizing Phase 1). On March 27, 2019, the jury returned a verdict in Hardeman's favor in Phase 2, awarding him more than $5 million dollars in compensatory damages and $75 million in punitive damages. *See* Pretrial Order No. 145: Judgment at 1, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. May 3, 2019) (entering judgment in Hardeman's favor in the amount of $80,267,634.10).

[174] *See infra* notes 175–188 and accompanying text.

[175] *See* FED. R. EVID. 101(a) ("These rules apply to proceedings in United States courts.").

[176] Pre-Trial Order No. 45: Summary Judgment and *Daubert* Motions at 2, *Monsanto MDL*, MDL No. 2741, No. 3:16-md-02741-VC (N.D. Cal. July 10, 2018) ("All the studies leave certain questions unanswered, and every study has its flaws.").

[177] *Daubert I*, 509 U.S. at 589. Case law supplies a gloss: epidemiological studies must account for confounding variables and potential biases. Pre-Trial Order No. 45: Summary Judgment and *Daubert* Motions, *supra* note 176, at 15. When they do, they may form the basis of an expert's testimony. *Id.* Confounding occurs when a factor unaccounted for helps to explain an apparent association. *Id.* Confounding skews the observed strength of associations and may produce false positive or false

MDL, the plaintiffs did not argue that the methods used in the ghostwritten studies were unreliable, but rather that the authors' impartiality was questionable.[178] Under a narrow application of *Daubert I*, however, impartiality does not matter.[179] It makes no difference that the authors and peer reviewers of the ghostwritten studies—all members of the glyphosate industry—may have been biased.[180] Their work remains a permissible basis for expert testimony despite the fact that they created the testing methods, peer reviewed and published the methods, calculated the methods' rates of error, maintained the standards controlling the methods, and comprised the relevant scientific community that had generally accepted the methods.[181] Under *Daubert I*, these potential biases affect the evidentiary weight of the expert testimony, not its admissibility.[182]

The result would have been the same under the *Frye* general acceptance test.[183] Under *Frye*, scientific evidence is inadmissible only when the relevant scientific communities do not generally accept it.[184] Monsanto's ghostwritten studies would have passed this test because each used industry-standard methods, such as live human studies, epidemiological observations, and animal testing.[185] *Frye* demands nothing more.[186] As Justice Ronald D. Castille acknowledged in dissent in *Blum ex rel. Blum v. Merrell Dow Pharmaceuticals, Inc.*, the *Frye* general acceptance test is not necessarily offended by the fact that a litigant is an influential member of the supposedly neutral scientific community.[187] Under a narrow application of *Frye*, industry influence does not render evidence inadmissible.[188]

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negative results. *Id.* at 15–16 (citing KENNETH J. ROTHMAN ET AL., MODERN EPIDEMIOLOGY 129–34 (3d ed. 2008)). Bias occurs when non-random error infects a study at the pre-study, study, or post-study stage. *Id.* at 16. Judge Chhabria found that the studies undergirding the experts' testimonies satisfied this standard. *See id.* at 29 (recognizing that the litigants' epidemiological evidence was open to differing interpretations, none of which were "categorically unreliable").

[178] *See generally* Plaintiffs' Ghostwriting Response, *supra* note 153 (arguing that the *Monsanto MDL* court should admit evidence of Monsanto's efforts to influence research but not that the court should disallow expert testimony based on the influenced research).

[179] *See* Patterson, *supra* note 95, at 1319 ("Notably absent from [the *Daubert I* factors] is any mention of the possible biases or conflicts of interest of the expert.").

[180] *Id.*

[181] *Id.*; *see supra* notes 77–111 and accompanying text (evaluating the *Daubert I* factors in the context of industry-influenced evidence).

[182] Jasanoff, *supra* note 6, at 42; *see supra* notes 126–127 and accompanying text (discussing the prevailing view that industry influence is a matter of weight and not admissibility).

[183] *See supra* notes 61–76 and accompanying text (assessing *Frye* in the context of industry-influenced evidence).

[184] *Frye*, 293 F. at 1014.

[185] *See* Pre-Trial Order No. 45: Summary Judgment and *Daubert* Motions, *supra* note 176, at 63–67 (summarizing the testimonies of Monsanto's experts).

[186] *See Frye*, 293 F. at 1014.

[187] Blum *ex rel.* Blum v. Merrell Dow Pharm., Inc., 764 A.2d 1, 16 (Pa. 2000) (Castille, J., dissenting); *see* Boden & Ozonoff, *supra* note 7, at 119 (noting that in toxic tort litigation, "the vast majority of—or all—research on a product's hazards may be conducted under the sponsorship of its

IV. That Goes to Weight: How Current Doctrine Permits Evidentiary Fraud and What to Do About It

Section A of this Part argues that a knowing presentation of industry-influenced evidence may be fraud sufficient to justify relief from a final judgment and that narrow applications of admissibility standards are therefore incompatible with the judicial duty to prevent evidentiary fraud.[189] Section B suggests a method of applying existing admissibility standards to evaluate the risks posed by industry-influenced evidence.[190] Section C proposes a procedural overlay to facilitate meaningful admissibility reviews.[191]

A. Evidentiary Fraud: A Matter of Judicial Integrity

A lawyer's knowing presentation of fraudulent or misrepresented evidence can be so egregious that it justifies extraordinary relief from a final judgment.[192] Such a presentation may violate ethical duties to the court, opposing counsel, and third parties.[193] But the duty to avoid evidentiary fraud does not rest solely with attorneys.[194] In 1944, in *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, the U.S. Supreme Court made clear that courts have an affirmative, independent duty to guard against evidentiary fraud.[195] In *Hazel-Atlas Glass Co.*, the fraudulent proffer was an article that Hartford-Empire had ghostwritten in its favor and published in a trade journal.[196] The Supreme

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manufacturers or by researchers with industry ties"); *supra* notes 65–76 (summarizing Justice Ronald D. Castille's dissent in *Blum ex rel. Blum v. Merrell Dow Pharmaceuticals, Inc.*).

[188] *See Blum*, 764 A.2d at 16–17 (Castille, J., dissenting) (contemplating a limited exception to *Frye* that would allow the admission of "unorthodox" expert testimony when "orthodox" science is industry influenced).

[189] *See infra* notes 192–208 and accompanying text.

[190] *See infra* notes 209–219 and accompanying text.

[191] *See infra* notes 220–255 and accompanying text.

[192] *See, e.g.*, Fed. R. Civ. P. 60(b)(3) (permitting relief from a final judgment when a litigant has engaged in fraud, misrepresentation, or misconduct); Aoude v. Mobil Oil Corp., 892 F.2d 1115, 1118–19 (1st Cir. 1989) (explaining the evidentiary fraud doctrine). The evidentiary fraud standard is very demanding. *See Aoude*, 892 F.2d at 1118. To obtain dismissal, the movant must establish by clear and convincing evidence that another party knowingly engaged in an "unconscionable scheme" that was intended to sway the trier improperly or to obstruct the presentation of a claim or defense unfairly. *Id.*

[193] *See generally* David S. Caudill, *Advocacy, Witnesses, and the Limits of Scientific Knowledge: Is There an Ethical Duty to Evaluate Your Expert's Testimony?*, 39 Idaho L. Rev. 341 (2003) (exploring the ethical questions arising out of the presentation of scientific evidence). As officers of the court, attorneys have duties of candor toward the tribunal, material truthfulness to others, good faith advocacy, and avoiding the presentation of false evidence. Model Rules of Prof'l Conduct r. 3.1 (Am. Bar Ass'n 1983) (good faith advocacy); *id.* r. 3.3 (candor toward the tribunal); *id.* r. 3.4 (presentation of false evidence); *id.* r. 4.1 (truthfulness to others).

[194] *See* Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 246 (1944) (clarifying that courts share the responsibility of preventing evidentiary fraud).

[195] *Id.*

[196] *Id.* at 240–42. In 1926, Hartford-Empire Company decided to kick-start its stalled patent application by publishing a ghostwritten article under the name of a widely known expert in the field. *Id.*

Court explained that evidentiary fraud injures not only the opposing party but also the judiciary, which cannot tolerate such attacks.[197] In pertinent part, the Supreme Court stated that lower courts have a duty to question litigants' motives to avoid falling victim to evidentiary fraud.[198] Nevertheless, in presuming that industry influence does not bear on admissibility, courts neglect their *Hazel-Atlas Glass Co.* duty.[199] In *Hazel-Atlas Glass Co.*, a lawyer had ghostwritten an industry article under the name of a well-known authority in the field.[200] Similarly, in *In re Roundup Products Liability Litigation*, Monsanto employees had ghostwritten scientific studies under the names of well-known authorities in the field.[201] The point is not that the knowing proffer of industry-influenced evidence *is* evidentiary fraud, but rather that courts are obliged to determine *whether it is* evidentiary fraud.[202]

This is not to say that judicial scrutiny of industry-influenced evidence is a panacea.[203] First, some industry-influenced evidence may be innocuous, so extra scrutiny might prove unnecessary.[204] Second, scientific evidence can be complex, and opposing expert witnesses often espouse differing interpretations, neither of which may be fraudulent.[205] Third, judges—like juries—have no independent knowledge of the science at issue; they must rely on the evidence proffered by the litigants.[206] Judges, however, have experience sorting—

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at 240. The article, which referred to Hartford-Empire's design as a groundbreaking advance in the field, was subsequently published and attached to Hartford-Empire's patent application. *Id.* The application was granted less than two years later. *Id.* at 241.

[197] *Id.* at 246.

[198] *Id.*

[199] *See infra* notes 200–208 and accompanying text.

[200] *Hazel-Atlas Glass Co.*, 322 U.S. at 240–42.

[201] *See supra* notes 155–165 and accompanying text (describing three allegedly ghostwritten studies in *In re Roundup Products Liability Litigation*).

[202] *See Hazel-Atlas Glass Co.*, 322 U.S. at 246 (forbidding judicial acquiescence where there exists the potential for evidentiary fraud).

[203] *See* Boden & Ozonoff, *supra* note 7, at 121 (stating that "[d]isclosure is not a panacea" in scientific journalism because "[s]ponsors with control over publication" can still choose which studies to publish and which to leave unpublished, "thus biasing the overall literature").

[204] *See* Jasanoff, *supra* note 6, at 39 ("Litigation . . . can be a significant driver of high-quality scientific research and assessment . . . ."); Patterson, *supra* note 95, at 1378 (stating that under *Daubert v. Merrell Dow Pharm., Inc.* (*Daubert II*), 43 F.3d 1311 (9th Cir. 1995) courts may fail to recognize the fact-specific issues or nonissues associated with industry influence).

[205] *See* Scott Brewer, *Scientific Expert Testimony and Intellectual Due Process*, 107 YALE L.J. 1535, 1595 (1998) (recognizing that inexperienced jurors are expected to piece together a cogent resolution of conflicting expert testimonies).

[206] *Id.*; *see* Jasanoff, *supra* note 6, at 40 ("[J]udges review science in accordance with their personal understandings of scientific methodology. These may be informed by widely varied external sources, such as briefs by the litigants, briefs by *amici curiae*, representations by court-appointed experts or special masters, judicial precedents, and pretrial hearings."). Amici briefs may pose a heightened risk of unreliability when their authors have an interest in the outcome of the litigation. *See, e.g.*, Exxon Shipping Co. v. Baker, 554 U.S. 471, 501 n.17 (2008) (refusing to rely on studies cited in amici briefs because a litigant had funded the studies). Reports by special masters may be

and, at least in jurisdictions where reliability is the touchstone of admissibility, are required to sort—"good" science from "bad" science.[207] Rather than allow potentially fraudulent evidence to reach an impressionable jury, judges should evaluate the extent of industry influence in determining admissibility.[208]

B. Applying Frye *and* Daubert I *to Industry-Influenced Evidence*

It is possible to account for industry influence within existing admissibility standards.[209] As an initial matter, such accounting must stay within the bounds of the applicable admissibility standard, whether *Frye v. United States* or *Daubert v. Merrell Dow Pharmaceuticals, Inc.* (*Daubert I*).[210] But judges have discretion in applying these standards.[211] Their decisions will be reviewed, if at all, for abuse of that discretion.[212] This is an ideal environment for modernizing *Frye* and *Daubert I*, both of which ask whether the relevant scientific community generally accepts the methods undergirding the proffered evidence.[213] Accounting for industry influence requires only one additional step: consider, upon motion, whether and to what extent an entity with interests similar to one of the litigants influenced the scientific community's decision to accept or reject the method.[214] A variation on the evidentiary fraud doctrine

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more reliable than proffered evidence, but they are rare. Gordon J. Beggs, *Novel Expert Evidence in Federal Civil Rights Litigation*, 45 AM. U. L. REV. 1, 69–71 (1994). One scholar has analogized this relatively uniformed gatekeeping to the editorial process of scientific publications, although scientific editors usually have specialized expertise in the subject under review. Jasanoff, *supra* note 6, at 40.

[207] *See* Daubert v. Merrell Dow Pharm., Inc. (*Daubert I*), 509 U.S. 579, 592–93 (1993) ("This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. We are confident that federal judges possess the capacity to undertake this review."). *But see* Jasanoff, *supra* note 6, at 40 (arguing that the inferences that a judge draws from reliance on external sources "are filtered through the judge's own, largely unreviewable sensibility concerning the reliability of claims and claimants").

[208] *See infra* notes 209–219 and accompanying text (proposing a method of accounting for the risks of industry-influenced evidence within existing admissibility standards).

[209] *See* Patterson, *supra* note 95, at 1366–93 (proposing approaches to evaluating industry influence within admissibility standards).

[210] *See id.* (explaining the processes by which *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) and *Daubert I* jurisdictions would assess industry influence as matters of admissibility).

[211] *See* Gen. Elec. Co. v. Joiner, 522 U.S. 136, 141–42 (1997) ("[T]he question of admissibility of expert testimony is . . . reviewable under the abuse-of-discretion standard.").

[212] *Id.*

[213] *See Daubert I*, 509 U.S. at 594–95 ("Finally, 'general acceptance' can yet have a bearing on the inquiry."); *Frye*, 293 F. at 1014 (providing for the admission of scientific evidence that the relevant scientific community generally accepts).

[214] *See* Adams v. Lab. Corp. of Am., 760 F.3d 1322, 1334 (11th Cir. 2014) (noting the impropriety of allowing industry litigants to define the contours of admissibility); Stagl v. Delta Air Lines, Inc., 117 F.3d 76, 81 n.2 (2d Cir. 1997) (noting the impropriety of allowing industry litigants to define reasonableness); Patterson, *supra* note 95, at 1366–93 (suggesting methods of scrutinizing industry influence as a question of admissibility).

should guide this inquiry.[215] A court should exclude the evidence if the opposing party clearly and convincingly shows that the admission of the evidence would improperly interfere with the impartial adjudication of the case or unfairly obstruct the presentation of an opposing claim or defense.[216] Unlike prototypical evidentiary fraud, the attempted introduction of industry-influenced evidence might not be so unconscionable as to warrant dismissal of the case.[217] Instead, this inquiry is more moderate: industry influence is more than a matter of weight but less than a matter of dismissal.[218] Still, an important question remains: how will a court know when to conduct this inquiry?[219]

C. Mandatory Disclosure: Flagging Industry-Influenced Evidence for Meaningful Admissibility Reviews

Mandatory disclosure of industry influence would trigger an admissibility review without creating a presumption about the outcome of the review.[220] A system analogous to mandatory disclosure in litigation already exists in the scientific community.[221] The federal government forbids financial conflicts of interest in research funded by or produced through cooperative agreements with the federal Public Health Service (PHS).[222] Federal law requires each institution seeking PHS support to maintain a written conflict of interest policy.[223] Every researcher must be aware of the policy and their responsibilities under it.[224] Enforcement of this policy is internal, led by a designated reviewer who ensures that each researcher discloses all personal and familial financial interests that could impact the research, including salary, consulting fees, hon-

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[215] *See Hazel-Atlas Glass Co.*, 322 U.S. at 246 (summarizing and applying the evidentiary fraud doctrine).

[216] *See Aoude*, 892 F.2d at 1118–19 (explaining the standard for the involuntary dismissal of a case in which a litigant has committed evidentiary fraud).

[217] *See supra* note 9 and accompanying text (recognizing that not all industry-influenced evidence threatens judicial integrity).

[218] *See supra* notes 192–208 and accompanying text (arguing that industry influence is too insidious to be handled by jurors).

[219] *See* Patterson, *supra* note 95, at 1361 ("[A]t a minimum, courts should require expert witnesses to disclose conflicts of interest of the scientists who conducted the research about which they testify . . . . Only then will courts be able to assess the significance of the conflicts.").

[220] *See id.* at 1376–77 (proposing that courts order litigants to disclose all relevant research efforts); *see also* Boden & Ozonoff, *supra* note 7, at 119 (arguing that because most studies are industry-funded, automatic exclusion of these studies or a "rebuttable presumption" against their admissibility "would have a disproportionately negative impact on plaintiffs by excluding much of the available evidence," at least some of which plaintiffs would need to prevail at trial).

[221] *See* Patterson, *supra* note 95, at 1340–45 (summarizing efforts to combat industry influence in scientific journalism).

[222] 42 C.F.R. § 50.602 (2019); *see* 42 U.S.C. § 289b-1 (2018) (requiring the identification, management, and elimination of financial conflicts of interest in public-private pharmaceutical research).

[223] 42 C.F.R. § 50.604(a).

[224] *Id.* § 50.604(b).

oraria, stocks, stock options, and intellectual property rights.[225] The institution must maintain records of these disclosures for three years following the date of publication, during which time PHS and the federal Department of Health and Human Services may conduct discretionary inspections.[226] Though the institution must report the existence of a conflict to PHS and must manage, reduce, or eliminate such conflicts within sixty days of their discovery, the institution retains discretion over the sanctions (if any) to impose.[227] The law further suggests seven methods of managing conflicts.[228] A special provision applies to institutions engaged in medical or pharmaceutical research: in that context, any conflicted researcher must attach a written disclosure to the research and acknowledge the conflict in every public presentation.[229]

Many scientific journals impose even stricter conflict of interest rules.[230] In the *New England Journal of Medicine* (NEJM), for example, every published study must list the study's sponsor, and no author may have a "significant" financial conflict of interest.[231] The *Journal of the American Medical Association* (JAMA) goes further, requiring authors to disclose all "relevant" financial ties.[232] NEJM and JAMA, along with the weekly scientific journals *Nature* and *Science*, consider the provision of expert testimony to be a conflict of interest.[233]

In light of these regulatory and journalistic measures, similar requirements in litigation are reasonable.[234] Federal Rule of Civil Procedure

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[225] *Id.* §§ 50.603–.604.

[226] *Id.* §§ 50.604–.607.

[227] *Id.* § 50.605.

[228] *See id.* § 50.605(a)(1) (suggesting disclosure to the general public, targeted disclosures, appointment of an independent monitor, modifications of the research plan, changes to personnel, reduction or elimination of the conflicted interests, and severance of the relationships underlying the conflict).

[229] *Id.* § 50.606(c).

[230] *See* Ransom, *supra* note 6, at 583 (stating that conflict of interest rules in scientific journalism differ greatly from the less restrictive federal regulatory standards).

[231] *See Editorial Policies*, NEW ENG. J. MED., https://www.nejm.org/about-nejm/editorial-policies [https://perma.cc/MFS6-59RH] ("The *Journal* expects that authors of such articles have no significant financial interests in any biomedical company relevant to topics and products discussed in the subject they are reviewing or the article on which they are commenting."); *see also* Jeffrey M. Drazen et al., Editorial, *Financial Associations of Authors*, 346 NEW ENG. J. MED. 1901, 1901–02 (2002) (defining "significant" financial conflicts of interest).

[232] *See* Howard Bauchner et al., *Conflicts of Interests, Authors, and Journals*, 320 JAMA 2315, 2315 (2018) ("Authors are expected to provide detailed information about all relevant financial interests, activities, relationships, and affiliations . . . .").

[233] Bauchner et al., *supra* note 232, at 2315; *Competing Interests*, NATURE RES., https://www.nature.com/authors/policies/competing.html [https://perma.cc/Q2N8-RQX4]; *Editorial Policies*, *supra* note 231; Science *Journals: Editorial Policies*, SCI., https://www.sciencemag.org/authors/science-journals-editorial-policies [https://perma.cc/D8ET-GEQG].

[234] *See* Patterson, *supra* note 95, at 1375 ("At a minimum, scientific institutions require disclosure of potential conflicts, and a similar requirement would be reasonable in litigation." (footnote omitted)); *see also* FED. R. EVID. 702 advisory committee's notes to 2000 amendments (recognizing that

26(a)(2)(B) already requires litigants to exchange expert witness reports, which must describe the expert's reasons and conclusions, bases in fact and data, and any supporting exhibits.[235] One additional mandatory disclosure could be the extent of industry influence on the expert's bases in fact and data.[236] The following factors are illustrative but not exhaustive.[237] For each study upon which an expert will rely, the proffering party would be obliged to disclose the following: the title of the study and its intended use at trial; the amount of financial assets (such as consulting fees, honoraria, intellectual property, salary, stock, and stock options) paid by the proffering party to the study's authors, editors, or publisher; the nature of donations (such as capital, labor, and real estate) paid by the proffering party to the study's authors, editors, or publisher; the existence of contracts (such as agreements, arrangements, and consulting retainers) between the proffering party and the study's authors, editors, or publisher; and the study's funding sources.[238]

This new burden would likely involve a review of the study's acknowledgements, attributions, and conflicts of interests sections, as well as some communication with the study's authors, editors, or publisher.[239] When a proffering party is unable to supply this information, the party must describe its efforts to obtain it and explain why those efforts fell short—just as some scien-

courts have already "shown considerable ingenuity and flexibility in considering challenges to expert testimony under *Daubert* [*I*]").

[235] FED. R. CIV. P. 26(a)(2)(B).

[236] *See* Patterson, *supra* note 95, at 1376–77 ("The solution most likely to produce full information would be to require that the sources of the in-house research disclose all of the research that they perform."). In other contexts, scholars have suggested that industry influence could be tracked in a database. *See* Barday, *supra* note 21, at 732 (suggesting a database to track industry influence in legal scholarship). Scholars contemplate a database in which a user could search the name of an author or the title of an article to ascertain funding connections. *Id.* It is worth noting that the National Institutes of Health maintain RePORT, a funding source database for studies that receive federal funds. *Research Portfolio Online Reporting Tools (RePORT)*, NAT'L INSTS. HEALTH, https://report.nih.gov/index.aspx [https://perma.cc/M4EW-BC79].

[237] *See infra* note 238 and accompanying text. If adopted verbatim, this list would not flag research conducted by industry members other than the member making the disclosure; such research may remain just as likely to be proffered—and just as likely to be unreliable. *See* Patterson, *supra* note 95, at 1377 ("If a party to litigation were to offer research sponsored by others—e.g., others in the same industry—some other approach would be necessary, because discovery would not necessarily reach non-parties.").

[238] *See* Patterson, *supra* note 95, at 1375 ("[W]hen witnesses testify about research done by others, courts should require them to disclose any conflicts of the scientists who performed the research."). In *In re Silicone Gel Breast Implant Products Liability Litigation*, the U.S. District Court for the Northern District of Alabama required the litigants routinely to disclose current research efforts relevant to the litigation. *See id.* at 1377 (discussing the court's order in *In re Silicone Gel Breast Implant Products Liability Litigation*).

[239] *See supra* notes 155–165 and accompanying text (describing three allegedly ghostwritten studies that acknowledged industry influence).

tists must certify the same under federal law.[240] A party seeking to preclude expert testimony based on a disclosed study would bear the burden of proving that the study is unreliable.[241]

Although mandatory disclosure may have the potential for discouraging industry-led research, that concern is based on two questionable assumptions about scientists' hesitancy to disclose the extent of industry influence on their work.[242] The first is that scientists fear damaging their reputations in the scientific community.[243] Although scientists are rightly concerned about their professional reputations, the scientific community knows—even if the lay and legal communities largely do not—that most research involves industry influence to some extent.[244] Mandatory disclosure would merely acknowledge that reality.[245] The second assumption is that scientists do not want the disclosure of their industry connections to jeopardize the likelihood of being asked to give lucrative in-court testimony.[246] This is a feature and not a bug of mandatory disclosure.[247] No one expects experts to testify without remuneration, so

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[240] *See* Patterson, *supra* note 95, at 1375 ("[I]nstances may exist in which witnesses will not have access to information about the conflicts of those about whose research they testify. In such cases, presumably the best a court could do is require . . . that the litigant provide a certification that it has acted with due diligence to obtain the information but was unable to do so and stating the reason." (internal quotation marks omitted)); *see also* 21 C.F.R. § 54.4(a), (c) (2019) (providing that the U.S. Food and Drug Administration "may refuse to file any marketing application" that "relies in whole or in part on clinical studies" if the applicant does not disclose the prescribed information and does not certify that the applicant "acted with due diligence to obtain the information but was unable to do so and stating the reason").

[241] *See supra* notes 209–219 and accompanying text (setting forth a proposed standard for evaluating industry-influenced evidence as a matter of admissibility).

[242] *See infra* notes 243–255 and accompanying text (discussing arguments against mandatory disclosure of industry influence).

[243] *See generally* Alexander Michael Petersen et al., *Reputation and Impact in Academic Careers*, 111 PROC. NAT'L ACAD. SCI. 15,316 (2014) (analyzing the import of a scientist's reputation on their career prospects).

[244] *See* Mervis, *supra* note 3 (describing the trend toward industry funding and away from government funding).

[245] *See* Patterson, *supra* note 95, at 1324 ("Editors select writers according to their reputation, academic performance, and independence. In truth, such criteria are vague and entirely subjective—the skill, or bias, of the editor in making these selections is critical. Yet editors find it increasingly difficult to identify academic experts who have not crossed over to the commercial world in some way . . . . So, should the opinions of researchers who have collaborated with industry be disqualified from the pages of journals?" (quoting *The Politics of Disclosure*, 348 THE LANCET 627, 627 (1996))).

[246] *See, e.g.*, Douglas Starr, *Expert Witness David Egilman Wins Billions—and Makes Enemies—as He Fights Companies over Public Health*, SCI. MAG. (Jan. 24, 2019), https://www.sciencemag.org/news/2019/01/expert-witness-david-egilman-wins-billions-and-makes-enemies-he-fights-companies-over [https://perma.cc/M489-AR53] (reporting on the positive financial consequences of one scientist's fight against industry influence).

[247] *See* Patterson, *supra* note 95, at 1327–33 (discussing the risks of "professional" and "hired gun" witnesses).

mandatory disclosure would simply flag some individuals and studies for a more sensitive review.[248]

There are two other noteworthy drawbacks to mandatory disclosure.[249] First, an expert could be less than forthright about the extent of industry influence on their testimony.[250] Second, mandatory disclosure of industry influence would lengthen the already arduous discovery process.[251] These are not reasons to abandon mandatory disclosure entirely.[252] With respect to the first drawback, concealing industry influence already violates principles of scientific integrity and risks lasting reputational damage.[253] With respect to the second, the purpose of the Federal Rules of Civil Procedure is not solely to facilitate speedy disposition but also to ensure just determination.[254] Because litigants already evaluate potential experts in myriad other ways, the benefits of mandatory disclosure outweigh its burdens.[255]

CONCLUSION

The problem of industry-influenced evidence arises at the intersection of scientific and legal epistemology. Despite the U.S. Supreme Court's rejection of such evidence, many courts have failed even to recognize its dangers. The courts that have recognized industry influence have treated it as a matter of weight rather than admissibility. This has allowed industry-influenced evidence to evade meaningful applications of the *Frye*, *Daubert I*, and *Daubert II* standards. This practice ignores the risks posed by the admission of indus-

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[248] *See Daubert II*, 43 F.3d at 1317 ("[F]ew experts appear in court merely as an eleemosynary gesture."); Patterson, *supra* note 95, at 1329 ("One cannot use the mere fact that an expert is paid by his client as a basis for inferring that his testimony is biased; one must look more carefully at the expert's testimony to determine if it is biased, and once one makes that further inquiry, one is not relying on the premise that the expert is a 'hired gun.'").

[249] *See infra* notes 250–255 and accompanying text.

[250] *See* Patterson, *supra* note 95, at 1375–76 (proposing court-ordered disclosure of industry influence). The likelihood of incomplete disclosure might decrease with a uniform adoption of mandatory disclosure through the Federal Rules of Civil Procedure rather than through a court-by-court or case-by-case approach. *See id.* at 1375 (recognizing the reasonableness of adopting a practice of disclosure based on existing regulatory and journalistic standards).

[251] *See* 28 U.S.C. § 471 (2018) (recognizing the burdens of discovery and requiring each U.S. District Court to develop a plan to alleviate them); Patterson, *supra* note 95, at 1378 ("Requiring disclosure of all research results, as suggested above for parties, however, might be thought too intrusive.").

[252] *See infra* notes 253–255 and accompanying text.

[253] *See, e.g.*, *Basic Information About Scientific Integrity*, U.S. ENVTL. PROTECTION AGENCY, https://www.epa.gov/osa/basic-information-about-scientific-integrity [https://perma.cc/ANM6-BQ8Y] (explaining the importance of scientific integrity).

[254] *See* FED. R. CIV. P. 1 (providing that the Federal Rules of Civil Procedure are to be "construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding").

[255] *See* Peter L. Winik, *Strategies in Expert Depositions*, 24 LITIG. 14, 16–17 (1998) (explaining the process of "sizing up" expert witnesses before trial).

try-influenced evidence, which in rare cases could amount to evidentiary fraud warranting dismissal. In most cases, however, only meaningful admissibility reviews are necessary. These reviews should entertain arguments regarding the effect of the industry influence on the fair resolution of the case. Without mandatory disclosure to flag such influence, however, courts may very well turn a blind eye to the admission of potentially unreliable evidence.

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