



“NOT SCIENCE AT ALL, BUT LITIGATION”: EXCLUDING RESULTS-DRIVEN EXPERT OPINIONS”

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*“Despite the many years the controversy has been brewing, no one in the scientific community—except defendant’s experts—has deemed these studies worthy of verification, refutation or even comment. It’s as if there were a tacit understanding within the scientific community that what’s going on here is not science at all, but litigation.”*⁴

I. INTRODUCTION

Courts are increasingly identifying expert opinions that appear to be “results-driven” rather than science-driven. In this article, the authors describe factors that courts often analyze in determining whether an expert’s opinions are based on sound methodology or are driven solely by a desire to advance one party’s position in litigation.

II. LIPITOR MDL

Beginning in 2012, Pfizer Inc. (“Pfizer”) faced suits nationwide alleging that its cholesterol-lowering drug Lipitor caused Type 2 diabetes.⁵ As thousands of individuals began filing suit, a federal judicial panel consolidated all such claims nationwide before a federal judge in Charleston, South Carolina.⁶

To try to establish that Lipitor caused their diabetes, the plaintiffs offered the expert opinion of a professional statistician.⁷ Based on his analysis of various data, the statistician opined that a statistically significant correlation existed between Lipitor ingestion and an elevated blood glucose level diagnostic of diabetes.⁸ The plaintiffs’ subsequent expert opinions relied upon this statistical correlation in their attempts to establish a causal relationship between Lipitor ingestion and diabetes.⁹

At the close of discovery in 2015, Pfizer moved to exclude the statistician’s expert opinion, contesting that his methodology was unscientific.¹⁰ Simply put, Pfizer argued that the expert “engaged in a results-driven methodology” in reaching his opinions.¹¹ For example, Pfizer claimed that the expert cherry-picked previous studies upon which to rely,¹² conducted multiple alternate tests after initial tests produced unwanted results,¹³ and offered opinions outside the scope of his expertise.¹⁴

⁴ *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995), *remand from* 509 U.S. 579 (1993).

⁵ Jessica Dye, *Pfizer confronts surge of lawsuits over Lipitor*, REUTERS (Aug. 8, 2014, 1:11 AM), <https://www.reuters.com/article/us-pfizer-lipitor-lawsuits-insight-iduskbn0g80e520140808>.

⁶ *Id.*

⁷ *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices and Prods. Liab. Litig.*, 145 F. Supp. 3d 573, 575 (D.S.C. 2015).

⁸ *Id.* at 578.

⁹ *Id.* at 575 (“All of Plaintiffs’ general causation experts have relied on [the expert’s] analysis to some extent in their initial expert reports.”).

¹⁰ *Id.*

¹¹ *In re Lipitor*, 145 F. Supp. 3d at 578.

¹² *Id.* at 576.

¹³ *Id.* at 578.

¹⁴ *Id.* at 579.

The federal judge agreed and excluded much of the statistician’s testimony.¹⁵ He subsequently granted Pfizer summary judgment “across all cases in the MDL.”¹⁶ And in 2018, the Fourth Circuit Court of Appeals affirmed both the exclusion of the expert’s opinion and the grant of summary judgment.¹⁷ Indeed, the Fourth Circuit noted that the statistician’s methodology had cast a “specter of unreliability” over his report.¹⁸

The exclusion of the expert’s results-driven opinion was part of the overall collapse of the plaintiff’s causation claims, which resulted in the grant of summary judgment in all of the cases pending in the MDL. While such a significant effect is not achievable in every case, the methodological problems highlighted in the Lipitor litigation are “classic concerns regarding reliability and relevance.”¹⁹ District courts face them frequently, and the exclusion of unscientific, results-driven opinions can be pivotal—if not dispositive. Significant victories of all sizes are achievable, but they require educated and meticulous scrutiny of an expert’s opinion.

III. “RESULTS-DRIVEN RESEARCH” AND THE LEGAL FRAMEWORK FOR EXCLUSION

A. *What is Results-driven Research?*

Rule 702 of the Federal Rules of Evidence enables experts to provide “scientific” opinions.²⁰ Not all opinions of scientists, however, are necessarily “scientific”²¹—“no matter how imposing their credentials.”²² Indeed, a scientist can offer unscientific opinions even about his own area of expertise.²³

¹⁵ *Id.* at 594 (“The Court finds that [the expert’s] analysis . . . was results driven, that [his] methodology and selection of relevant evidence changed based on the results they produced, and that [he] chose to ignore and exclude from his report his own analyses that did not support his ultimate opinions.”); *see also In re Lipitor* (Atorvastatin Calcium) Mktg., Sales Practices and Prods. Liab. Litig. (NO II) MDL 2502, 892 F.3d 624, 635 (4th Cir. 2018) (“The [district] court here properly discharged its gatekeeping duty by considering—and ultimately excluding—[the expert’s] opinions, and explaining in detail its well-reasoned grounds for doing so.”).

¹⁶ *Id.* at 647 (analyzing whether “it was improper for the district court to enter summary judgment across all cases in the MDL after no plaintiff produced adequate evidence of specific causation in response to the court’s show cause orders.”).

¹⁷ *In re Lipitor*, 145 F. Supp. 3d at 638, 649.

¹⁸ *Id.* at 633.

¹⁹ *Id.* at 635.

²⁰ FED. R. EVID. 702(a).

²¹ *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (“[I]n order to qualify as ‘scientific knowledge,’ an inference or assertion must be derived by the scientific method.”).

²² *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 318–19 (7th Cir. 1996).

²³ Notably, “[w]orking scientists can and do readily identify peers whom they regard as having become advocates, no longer capable of reading evidence in an even-handed way.” Eliot Marshall, *When does Intellectual Passion Become Conflict of Interest?*, SCIENCE, July 31, 1992, at 620, *quoted in* Mark R. Patterson, *Conflicts of Interest in Scientific Expert Testimony*, 40 WM. & MARY L. REV. 1313, 1329 (1999). Moreover, even if not “results-driven,” any expert’s opinion which does not “adhere to the same standards of intellectual rigor that are demanded in [his or her] professional work” is unscientific. *See Rosen*, 78 F.3d at 318 (analogizing that, because a professor “would not accept from his students or those who submit papers to his journal an essay containing neither facts nor reasons,” the court should not accept his mere “exposition”); *Wessmann v. Gittens*, 160 F.3d 790, 805 (1st Cir. 1998) (“The only excuse that Dr. Trent proffered for his failure to follow proper protocols was that a thorough study would have required more time than he had available. That is unacceptable. An expert witness can only deviate from accepted methods of scientific inquiry in ways that are consistent with the practices and usages of the scientific community.”).

A common form of such an unscientific opinion is the so-called “results-driven opinion.”²⁴ An expert’s opinion is results-driven if he or she came to a firm conclusion first and then did research to support it.²⁵ Thus, “results-driven” research can be defined as research “undertaken for the purpose of finding evidence favoring one side in litigation, and explaining away or otherwise playing down evidence favoring the other side.”²⁶ Importantly, a “[r]esults-oriented methodology is not consistent with general principles of scientific research, and an expert’s testimony may be excluded if an expert reaches a conclusion before conducting an[y] research or examination and simply states facts to support his pre-determined opinion.”²⁷ Of course, while a scientist’s adoption of “initial tentative hypotheses” is perfectly scientific, a subjective “conviction” adopted “prior to performing the necessary validating tests” is not.²⁸

For example, an expert’s report in the Rezulin litigation suggested that Warner-Lambert had “failed to provide the FDA with all necessary information regarding the risk of liver injury [posed by Rezulin] and that the FDA would not have approved [it] had it received different information.”²⁹ However, the expert wrote this report before even considering the evidence; he admitted that he “wrote a lot of the declaration without having the raw information in hand under the assumption that it would be provided to [him], so . . . [he] wasn’t able to reference it when [he] wrote the declaration.”³⁰

In response to that admission, the court reiterated the settled principle that “an expert may not reach his conclusion first and do the research later.”³¹ Because the expert “wrote his report before having the supporting data, his opinions [were] not ‘based upon sufficient facts or data’ and d[id] not proceed from ‘reliable principles and methods,’ as required by Rule 702.”³²

B. The Legal Framework for Exclusion

Under Rule 702 of the Federal Rules of Evidence, district court judges must ensure that all admitted expert testimony is “the product of reliable principles and methods”—i.e., that it is truly scientific.³³ The term reliable “‘applies to all aspects of an expert’s testimony: the methodology,

²⁴ *In re Lipitor*, 145 F. Supp. 3d at 587 (“[The expert’s] opinion . . . is . . . results driven. . . . [R]ather than conducting statistical analyses of the data and then drawing a conclusion from these various analyses, [the expert] formed an opinion first, sought statistical evidence that support his opinion and chose to exclude *his own* contrary analyses from this report.”). Experts espousing results-driven opinions are sometimes deemed a “hired gun” or an expert “available to the highest bidder.” See Patterson, *supra* note 22, at 1329 (explaining the example of Peter Duesberg, a scientist who maintained that “the HIV retrovirus does not cause AIDS”).

²⁵ *Claar v. Burlington N.R. Co.*, 29 F.3d 499, 502–03 (9th Cir. 1994) (“In order to qualify as ‘scientific knowledge’ [as required by Rule 702], an inference must be derived by the scientific method. Coming to a firm conclusion first and then doing research to support it is the antithesis of this method.”).

²⁶ See Susan Haack, *What’s Wrong with Litigation-Driven Science? An Essay in Legal Epistemology*, 38 SETON HALL L. REV. 1053, 1075 (2008) (describing such research as a subset of “litigation-driven” research, but applying the term “litigation-driven in the strong sense” rather than the term “results-driven” adopted here).

²⁷ *T.G. v. Remington Arms Co., Inc.*, No. 13–CV–0033–CVE–PJC, 2014 WL 1310285, at *5 (N.D. Okla. Mar. 28, 2014).

²⁸ *Claar*, 29 F.3d at 503.

²⁹ *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 550 (S.D.N.Y. 2004).

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ FED. R. EVID. 702(c); *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1232 (9th Cir. 2017).

the facts underlying the expert’s opinion, [and] the link between the facts and the conclusion.”³⁴ Importantly, however, “the test under *Daubert* is not the correctness of the expert’s conclusions but the soundness of his [or her] methodology.”³⁵

The proponent of expert testimony bears the burden of demonstrating that the principles and methods behind an expert’s opinion are scientific and reliable.³⁶ The proponent can meet this burden in multiple ways. Ideally, the proponent can satisfy at least some of the four nonexclusive *Daubert* factors—establishing that the expert’s method has gained general acceptance in the relevant scientific community, has been peer-reviewed, can be (and has been) tested, and has a known and acceptable rate of error.³⁷ In listing these factors, the *Daubert* court identified two potential arbiters of methodological soundness: the scientific community and the judge.³⁸ If the expert has subjected his litigation-driven research to peer review, he has exposed his “readiness to publish and be damned.”³⁹ In such cases, some courts may be more receptive to the methodological soundness of the expert’s opinion with less scrutiny.

Where an expert has *not* subjected his methodology to his peers’ scrutiny, on the other hand, he must “explain precisely how [he] went about reaching [his] conclusions and point to some objective source—a learned treatise, the policy statement of a professional association, a published article in a reputable scientific journal or the like—to show that [he] ha[s] followed the scientific method, as it is practiced by (at least) a recognized minority of scientists in [his] field.”⁴⁰

Failure to do so, however, can be damning.⁴¹ And as the Fifth Circuit Court of Appeals has noted,

³⁴ *In re Zolofit (Sertraline Hydrochloride) Prods. Liab. Litig.*, MDL No. 2342, 2015 WL 7776911, at *16 (E.D. Penn. Dec. 2, 2015) (citing *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012)).

³⁵ *Daubert*, 43 F.3d at 1318.

³⁶ *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 n.4 (10th Cir. 2001); *P.S. ex rel. Nelson v. The Farm, Inc.*, 658 F. Supp. 2d 1281, 1288 (D. Kans. 2009) (“[The proponent] bears the burden of establishing the necessary reliability and scientific validity of its experts’ opinions, which necessarily entails the identification of particular studies or literature supporting those opinions.”); *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 526 (W.D. Penn. 2003) (“Plaintiff bears the burden of demonstrating that each of her proffered experts is qualified to render an expert opinion, that the opinion is reliable, and that the opinion would assist the trier of fact in resolving a disputed issue of material fact—here, causation.”) (citation omitted); *Wynacht v. Beckman Instruments, Inc.*, 113 F. Supp. 2d 1205, 1207 (E.D. Tenn. 2000) (“The party offering the opinion evidence bears the burden of demonstrating that it comports with and is undergirded by the dictates and procedures of ‘sound science.’”) (citation omitted).

³⁷ *Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1420–21 (9th Cir. 1998) (quoting *Daubert*, 509 U.S. at 580).

³⁸ *See Daubert*, 43 F.3d at 1318 (“One means of showing this is by proof that the research and analysis supporting the proffered conclusions have been subjected to normal scientific scrutiny through peer review and publication. . . . Where such evidence is unavailable, the proponent of expert scientific testimony may attempt to satisfy its burden through the testimony of its own experts.”).

³⁹ *Id.*

⁴⁰ *Id.* at 1319; *Cabrera*, 134 F.3d at 1420–21 (quoting *Daubert*, 509 U.S. at 580). While not dispositive, the designation of research as “litigation-driven” nonetheless creates “[a]nother significant fact weighing against admitting the testimony” *Wehling v. Sandoz Pharm. Corp.*, No. 97-2212, 1998 WL 546097, at *3 (4th Cir. Aug. 20, 1998) (citation omitted).

⁴¹ *Arias v. Dyncorp*, 928 F. Supp. 2d 10, 25 (D.D.C. 2013) (“[N]either the plaintiffs nor Dr. Wolfson offer any explanation or evidence regarding the reliability of Dr. Wolfson’s methodology. Because the plaintiffs have not met their burden to show that Dr. Wolfson is qualified and that his testimony is reliable, Dr. Wolfson’s medical monitoring testimony is inadmissible.”); *Wynacht*, 113 F. Supp. 2d at 1210 (“Dr. Ziem does not offer any informed assessment of how the chemicals interacted with Wynacht’s body systems (other than describing them as having initial

“[c]ourts should particularly pay close attention when expert witnesses depart from generally accepted scientific methodologies If, therefore, an expert proposes to depart from the generally accepted methodology of his field and embark upon a sea of scientific uncertainty, the court may appropriately insist that he ground his departure in demonstrable and scrupulous adherence to the scientist’s creed of meticulous and objective inquiry.”⁴²

Indeed, “[t]o forsake the accepted methods without even inquiring *why* they are the accepted methods . . . and without even knowing *what* the accepted methods are” is “irresponsible.”⁴³

IV. IDENTIFYING RESULTS-DRIVEN EXPERT OPINIONS

As noted above, where an expert has not satisfied the four *Daubert* factors, the proponent of his testimony must “explain precisely” the methodology and sources he employed to reach his conclusions. Based on this explanation, the court must determine whether his opinion is scientific—including whether it is results-driven.

As detailed below, courts often examine one or more factors that signal “results-driven” opinions: (1) whether and why the expert ignored contrary data, opinions, or dominant methodologies; (2) whether the expert modified or changed study results by changing the definitions or criteria; (3) whether he or she failed to follow his or her stated research principles; (4) whether he or she opines beyond the scope of his or her expertise; and (5) whether his or her presently proffered opinion harmonizes with his or her past opinions. While problems with any one of these considerations may or may not be dispositive, a court may also look at whether the expert’s opinion had multiple methodological issues.⁴⁴

‘irritant’ effects) and how they led to Wynchach’s myriad diseases and conditions. Although Rule 702 does not require Dr. Ziem to undertake massive toxicological research in developing her causation opinion, the fact that such principles are well-known and regularly employed bolsters the Court’s conclusion that her reasoning does not display the intellectual rigor required of experts testifying [in] the federal courts.”); *Wills v. Amerada Hess Corp.*, No. 98 Civ. 7126 (RPP), 2002 WL 140542, at *9–10 (S.D.N.Y. Jan. 31, 2002) (“The paucity of support for his opinion in his First Report demonstrates that Dr. Bidanset was ready to form a conclusion first, without any basis, and then try to justify it. He appears to be claiming that he is using the dose-response theory to conclude Decedent was ‘intensely exposed to these carcinogenic hydrocarbons’ and yet he makes no attempt to quantify Decedent’s level of exposure, the essential step in using the dose-response theory. . . . Dr. Bidanset’s willingness to draw such a conclusion without a scientific basis in his first report is troubling.”); *Claar*, 29 F.3d at 502 (“Fundamentally, the district court was concerned that the experts, Drs. Hines and Nelson, failed to explain the basis for their conclusions . . . [T]he district court repeatedly ordered the experts to explain the reasoning and methods underlying their conclusions. Despite those orders, the affidavits are devoid of any such explanation. Consequently, the district court could not make the findings required by Rule 702, and therefore properly refused to admit the affidavits into evidence.”).

⁴² *Allen v. Pa. Eng’g Corp.*, 102 F.3d 194, 197 n.4 (5th Cir. 1996) (quoting *Braun v. Lorillard Inc.*, 84 F.3d 230 (7th Cir. 1996), *cert. denied*, 519 U.S. 992 (1996)). Indeed, “the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.” *Rosen*, 78 F.3d at 319. Thus, a court “may well cast a jaundiced eye upon a technique which is not supported by any evidence of general acceptance absent other indicia of reliable methodology.” *In re TMI Litig.*, 193 F.3d 613, 669 (3d Cir. 1999).

⁴³ *Braun*, 84 F.3d at 235.

⁴⁴ *In re Zolof*, 2015 WL 7776911, at *16 (“[T]he Court concludes that . . . [the expert], *inter alia*, has failed to consistently apply the scientific methods he articulates, has deviated from or downplayed certain well-established principles of his field, and has inconsistently applied methods and standards to the data so as to support his *a priori*

The following sections provide examples and explanations from cases in which courts were troubled by experts' explanations of their research.

A. Ignoring Contrary Data, Opinions, or Dominant Methodologies

In reaching their opinions, scientists should account for the full “scientific landscape.”⁴⁵ They cannot “pick and choose”⁴⁶ or “cherry-pick”⁴⁷ facts, methodologies, or previous studies. For example, in the Lipitor litigation, the expert statistician had the data regarding two randomized controlled clinical trials before his initial report but did not address one such study that was contrary to his opinion; rather, he testified that he “chose not to study [that] data.”⁴⁸ This type of selectively ignoring contrary data is one key hallmark of a “results-driven” opinion.

Likewise, experts cannot employ “selectivity in defining the universe of relevant evidence.”⁴⁹ Indeed, “experts asserting causation opinions must thoroughly analyze the strengths and weaknesses of [other inconsistent research] and explain why that body of research does not contradict or undermine their opinion.”⁵⁰ In short, “[s]cientists are expected to address and reconcile data that does not support their opinions”; they cannot “simply rely upon data which does.”⁵¹

For example, in the Rezulin litigation discussed above, the District Court for the Southern District of New York deemed an expert's opinion unreliable and inadmissible because, among other things, he glaringly omitted other studies from his report.⁵² The expert planned to opine that “the risk of Rezulin outweighed its benefits.”⁵³ To support this claim, the expert cited a biostatistician's report that “the chance of Rezulin-induced liver failure [was] 1 in 1000.”⁵⁴ However, the expert had not considered and failed to account for “two epidemiological studies (one published, the other available to him through plaintiff's counsel) that addressed this very

opinion. It is improper for an expert to take a results-driven approach to a question, molding his methodology and selectively relying upon data so as to confirm his preconceived opinion. Because the Court finds that [the expert's] opinion is based upon his failure to faithfully apply reliable scientific and statistical methods . . . the Court will exclude his testimony . . .”).

⁴⁵ *Lust By and Through Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 596 (9th Cir. 1996).

⁴⁶ *Id.*

⁴⁷ *In re Lipitor*, 145 F. Supp. 3d at 587; *Barber v. United Airlines, Inc.*, 17 Fed. Appx. 433, 437 (7th Cir. 2001) (“Because in formulating his opinion Dr. Hynes cherry-picked the facts he considered to render an expert opinion, the district court correctly barred his testimony because such a selective use of facts fails to satisfy the scientific method . . .”); *Fail-Safe, L.L.C. v. A.O. Smith Corp.*, 744 F. Supp. 2d 870, 889 (E.D. Wis. 2010) (“[I]t is readily apparent that Dr. Keegan all but ‘cherry picked’ the data he wanted to use, providing the court with another strong reason to conclude that the witness utilized an unreliable methodology.”); *In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007) (“[The expert] reaches his opinion by first identify his conclusion—causation at 200 mg/d—and then cherry-picking observational studies that support his conclusion and rejecting or ignoring the great weight of the evidence that contradicts his conclusion.”).

⁴⁸ *In re Lipitor*, 145 F. Supp. 3d at 575.

⁴⁹ *In re Rezulin*, 309 F. Supp. 2d at 563.

⁵⁰ *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 475 (E.D. Penn. 2014).

⁵¹ *In re Zoloft*, 2015 WL 7776911, at *7.

⁵² *In re Rezulin*, 309 F. Supp. 2d at 564.

⁵³ *Id.* at 561.

⁵⁴ *Id.*

subject but reached drastically different conclusions”⁵⁵ The neglected studies suggested that the chance of Rezulin-induced liver failure was 1 in 10,000—“less than one-fourth” of the risk the expert provided.⁵⁶ Ultimately, the plaintiffs’ expert’s failure to account for other studies which “addressed [his] very subject but reached drastically different conclusions” rendered his opinion unreliable.⁵⁷

Similarly, the District Court for the District of Columbia deemed an expert’s general causation opinion inadmissible where he dismissed without explanation other research conflicting with his conclusion.⁵⁸ In *Arias v. DynCorp*, the plaintiffs’ general causation expert reported that exposure to an herbicide manufactured by the defendant placed individuals “at a significant increased risk for the development of cancers in the future.”⁵⁹

In describing his methodology to the court, the expert identified “a few peer-reviewed studies to support his conclusion”⁶⁰ However, the court’s “brief review of the cited studies” revealed that many of them came to conclusions directly contrary to the expert’s opinion.⁶¹ The expert’s failure to account for these studies was damning; the expert failed to “explain why he decided to credit [an agreeing study’s] results and dismiss [a contrary study’s] results”⁶² What’s more, his application of the study upon which he relied was inconsistent with its own findings.⁶³ Accordingly, the court found that the explanation had “shortcomings,” and that his testimony was not “reliable.”⁶⁴

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ *Id.* at 563–64.

⁵⁸ *Arias*, 928 F. Supp. 2d at 25.

⁵⁹ *Id.*

⁶⁰ *Id.* at 24.

⁶¹ *Id.* at 24–25.

⁶² *Id.* at 25.

⁶³ *Id.* (“Also, the Eriksson study found that there is a dose-response effect between glyphosate and lymphoma but Dr. Wolfson does not opine as to the plaintiffs’ exposure. Thus, the plaintiffs have not demonstrated that the results of the Eriksson study apply to the faces of this case.”).

⁶⁴ *Arias*, 928 F. Supp. 2d at 24–25.

The examples provided above are but a few cases in which a court has excluded an expert opinion for failure to account for contrary opinions or dominant methodologies. Examples abound,⁶⁵ even outside the context of hard sciences.⁶⁶

B. Changing Results of Studies by Selecting Different Definitions or Criteria

Another hallmark of a results-driven opinion is changing data from a study, especially published and peer-reviewed data, to reach a different conclusion. In the Lipitor litigation, one of the published studies reported no significant association between diabetes and Lipitor.⁶⁷ After originally choosing not to address the study that reported a contrary finding, the plaintiff's expert statistician later reported a contrary result by changing the definition of diabetes used in the study.⁶⁸ Rather than using the adjudicated data as determined by the blinded study investigators, the plaintiff's expert changed the definition of new-onset diabetes before running statistical analyses.⁶⁹ The court explained: "Despite the fact that he didn't quite know what new-onset diabetes mean[t], he decided that, instead of using the data adjudicated by a blinded committee of clinicians that did understand the term, he would use unadjudicated raw data . . . that conveniently resulted in a significant finding."⁷⁰

This presumptuous conduct concerned the court; the expert—"someone with no clinical expertise"—chose to "replace [the study's] adjudicated data with particular lab values that he assumed were equivalent with new-onset diabetes and conveniently resulted in a statistically significant finding."⁷¹ The court found that this conduct "raise[d] serious questions as to the

⁶⁵ See, e.g., *In re Zolofit*, 2015 WL 7776911, at *7 ("Scientists are expected to address and reconcile data that does not support their opinions, and not simply rely upon data which does. Was [a contrary study] better designed, addressing design flaws, biases, and confounders which inflated associations reported in earlier studies, or was it poorly designed and thus unable to detect a true association? Dr. Jewell fails to explain his reasoning, leaving the Court to speculate as to why Dr. Jewell continues to rely upon the earlier Danish studies notwithstanding the very different results of [the contrary study]."); *Lennon v. Norfolk and Western Ry. Co.*, 123 F. Supp. 2d 1143, 1151–52 (N.D. In. 2000) ("His opinion that head injury may precipitate MS is based in part upon his review of medical literature. That review, however, has been very select. Indeed, the epidemiological study from the University of Arizona and that from the records of the Mayo clinic—two studies which have received a great deal of attention[—]were not reviewed by Dr. Romain. Nor is there evidence that Dr. Romain reviewed the report from the American Academy of Neurology. Other studies discounting any association were also not reviewed. In fact, it would appear that the only study referenced by Dr. Romain was the McAlpine study of 1952, a study, which as previously indicated has since been undermined by its own author because of a lack of a sufficient statistical proof . . . Dr Romain's review of what may be labeled a lop-sided perspective of the literature on the causality ([or] lack thereof) between trauma and MS is, in this court's view the antithesis of the scientific method . . .").

⁶⁶ See, e.g., *MTX Communic. Corp. v. LDDS/WorldCom, Inc.*, 132 F. Supp. 2d 289, 292–93 (S.D.N.Y. 2001) (excluding a financial valuation expert's opinion where "[h]e ignored financials and quality of management" because "[c]ommon sense and experience, as well as the flexibility afforded [the court] by *Daubert* and its progeny, dictate that financials and quality of management—particularly of a start-up company—must be considered in valuing a company and its probability of success. It makes little sense, if no sense at all, to consider a company's lifeline in a vacuum. . . . [The expert's] failure to include these factors . . . renders his valuation unreliable and unfit for the jury's consideration.").

⁶⁷ *In re Lipitor*, 145 F. Supp. 3d at 589.

⁶⁸ *Id.* at 576.

⁶⁹ *Id.* at 590–92.

⁷⁰ *Id.* at 592 (formatting and citations omitted).

⁷¹ *Id.* at 591–92.

reliability of [the expert's] determinations.”⁷² “This is the very definition of cherry picking data to reach a pre-determined conclusion and is unacceptable under *Daubert*.”⁷³

C. Failure to Follow Stated Principles

Like an expert's failure to account for contrary opinions and methodologies, an expert's failure to follow his or her own stated principles arouses great suspicion in judges. Indeed, an expert's condemnation of an undesirable study utilizing certain methodologies but simultaneous celebration of a desirable study utilizing the same methodologies suggests his or her opinion is improperly results-driven.

For example, in the Bextra litigation, a judge deemed the foundation of an expert's opinion “not a scientifically valid methodology” where he dismissed meta-analyses in one breath, but endorsed them in another.⁷⁴ The plaintiffs claimed that their use of the arthritis pain medications Celebrex and Bextra caused cardiovascular injury.⁷⁵ The plaintiffs' cardiology expert asserted that a 200 mg dose of Celebrex could increase the risk of heart attacks.⁷⁶

In reaching this conclusion, however, the expert failed to follow his own stated principles.⁷⁷ Indeed, in one breath, the expert “testified that he prefer[red] the Oxford Centre for Evidence Based Medicine ranking of the levels of evidence that a scientist should consider,” which identified “systematic review, including meta-analysis, as the highest level for each category of evidence.”⁷⁸ Yet in another breath, he “wholly reject[ed] [an undesirable] meta-analysis and [] other observational studies that d[id] not support his opinion” on the “blanket ground that meta-analysis is inappropriate for observational studies.”⁷⁹

Additionally, he claimed that his “heavy reliance” upon a certain study from the United Kingdom was based on its status as a “prospective, rather than retrospective” study.⁸⁰ Yet, as the court noted, “many of the other studies he reject[ed] out of hand [were] also prospective, and he [did] not cite anything in the medical literature that suggest[ed] that it is a valid scientific method to prefer one study over many that have contradictory results simply because the study that supports the expert's conclusion utilized [a more complete database].”⁸¹

Thus, his own testimony was internally inconsistent, suggesting to the court its results-driven status. Moreover, the plaintiffs' other experts had in fact characterized the same meta-

⁷² *Id.* at 592.

⁷³ *In re Lipitor*, 145 F. Supp. 3d at 593; *see also In re Zolofit*, 2015 WL 7776911, at *15 (“The Court also has concerns about the methodology used in a two-study meta-analysis [the expert] performed, which combined data from [one study on] paused SSRI users . . . with data from women in [another study] that [the expert] categorized as “paused” using different criteria . . .”).

⁷⁴ *In re Bextra*, 524 F. Supp. 2d at 1176–77.

⁷⁵ *Id.* at 1169.

⁷⁶ *Id.* at 1176.

⁷⁷ *Id.* at 1177.

⁷⁸ *Id.*

⁷⁹ *Id.* at 1176.

⁸⁰ *In re Bextra*, 524 F. Supp. 2d at 1176.

⁸¹ *Id.*

analysis as a “good study” and thereupon relied.⁸² Thus, the expert’s opinion not only contradicted his own opinions, but the opinions of his co-experts.⁸³ The court ultimately found that he “reach[ed] his opinion by . . . cherry-picking observational studies that support[ed] his conclusion and rejecting or ignoring the great weight of the evidence that contradict[ed] his conclusion.”⁸⁴ Accordingly, the court excluded his testimony because it was not “good science.”⁸⁵

Similarly, in the Rezulin litigation described above, the plaintiffs’ expert’s “selectivity in defining the universe of relevant evidence” had “violated his own standard of proper methodology that ‘[a]ll evidence should be taken into account.’”⁸⁶ The court was troubled by the expert’s failure to follow his stated principles.⁸⁷ It found that this failure “suggest[ed] that he d[id] not apply the same rigor in the courtroom that he would apply to his medical endeavors.”⁸⁸

Additionally, the court also noted the expert’s deviation from his previous declaration “that death is a side effect of other medications on the market and that diabetes medications that he prescribe[d] . . . also carr[ied] serious risks.”⁸⁹ Despite this acknowledgment, the expert nonetheless testified that “Rezulin is special”; he claimed “there [was] no acceptable risk for Rezulin”⁹⁰ This “extreme” departure from his acknowledged scientific principles troubled the court and suggested that he was “not employing in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field, or at the very least [that] particular expert.”⁹¹

As the above examples illustrate, experts’ failure to follow their stated principles is common.⁹² Paired with the other issues discussed here, it can be damning.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.* at 1184.

⁸⁶ *In re Rezulin*, 309 F. Supp. 2d at 563.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.* at 564.

⁹⁰ *Id.* (formatting omitted).

⁹¹ *Id.*

⁹² *See, e.g., In re Zolofit*, 2015 WL 7776911, at *10 (“[A]lthough Dr. Jewell’s report describes this mathematical approach to determine whether associations are true or the result of chance, Dr. Jewell does not then apply this mathematical approach to the p-values that can be calculated from results reported in independent studies of Zolofit and cardiac birth defects. Instead, he generalizes The Court finds Dr. Jewell’s failure to apply the methodology he outlined to the studies he reviewed problematic.”); *Allen*, 102 F.3d at 197 (“[The experts] rely on certain studies as ‘suggestive’ of a link between EtO exposure and brain cancer. ‘Suggestiveness’ is not by the experts’ own admission statistical significance . . . this basis for their scientific opinion must be rejected.”); *Baker v. Smith & Nephew Richards, Inc.*, No. 95–58737, 1999 WL 811334, at *36 (D. Tex. June 7, 1999) (“[The expert’s] willingness to offer a causation opinion without the benefit of a physical examination is not necessarily determinative that the opinion is unreliable, but it is a factor that suggests unreliability. . . . [The expert] presents no evidence that in his medical practice he gives opinions without a medical examination, particularly without request for a consultation or second opinion from another physician and without having any conversations with a treating doctor. He does not state that he gives medical opinions to patients under these conditions or that it is an accepted part of medical practice to do so under any circumstances, let alone under the circumstances here (no request from another physician).”).

D. Opining Beyond the Scope of Expertise

An expert may not opine on material beyond the scope of his or her expertise—nor should he or she.⁹³ Indeed, expert opinion beyond the scope of expertise is not only inadmissible as unqualified,⁹⁴ but it can also be suggestive of a results-driven opinion. As *Daubert* declared, “[o]ne 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.”⁹⁵ An expert’s willingness to opine on subjects beyond the scope of his expertise is necessarily *not* based upon that expertise; thus, courts are left speculating as to *why* an expert would choose to do so. Frequently, the most logical conclusion is that the expert’s opinion is improperly results-driven.

For example, in the Bextra litigation described above, the plaintiff’s expert—a clinical cardiologist—offered opinions on the merits of specific observational studies.⁹⁶ The cardiologist lacked “any specialized epidemiology training,” and “ha[d] not published any research since 1992.”⁹⁷ Moreover, his previous research was “unrelated to the subject matter” of his opinions in the Bextra litigation.⁹⁸ The court thus found his willingness to offer such opinions troubling; after all, “he only became interested in Celebrex . . . *after* he was retained by plaintiffs in th[e] litigation.”⁹⁹

Thus, opinions beyond the scope of an expert’s expertise can be not only inadmissible as unqualified but also suggestive of a results-driven opinion.

E. Inconsistencies with Previous Opinions

Finally, an expert’s opinion should be relatively consistent across time; it should not change from litigation to litigation. An opinion’s inconsistency with the expert’s previous opinions in prior litigation suggests its results-driven status.

For example, in the Zoloft litigation referenced above, the court disapproved of an expert’s “situational science” as an invalid methodology where he had taken contrary opinions in previous litigation.¹⁰⁰ In previous litigation regarding Prozac, the expert had “relied heavily on two meta-analyses” which “did not report statistically significant associations between Zoloft and the outcomes of interest.” In the Zoloft litigation, however, he conspicuously “d[id] not rely upon those same studies.”¹⁰¹

⁹³ FED. R. EVID. 702.

⁹⁴ *In re Bextra*, 524 F. Supp. 2d at 1176 (“[The expert] is a clinical cardiologist who sees patients 95 percent of his physician time. He does not have any specialized epidemiology training. . . . He is therefore not qualified to opine that one or two observational studies are correct while all the other studies . . . are wrong.”).

⁹⁵ *Daubert*, 43 F.3d at 1317, quoted in *In re Bextra*, 524 F. Supp. 2d at 1176.

⁹⁶ *In re Bextra*, 524 F. Supp. 2d at 1176.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *In re Zoloft*, 2015 WL 7776911, at *10–11.

¹⁰¹ *Id.* at *11.

While the expert “set forth a scientific rationale for his variable reliance on relevant meta-analyses in the Prozac MDL and the Zoloft MDL,” the court was nonetheless “concerned that [he] selectively relie[d] upon the principle [espoused in the studies] in a results-driven manner.”¹⁰² Thus, the court would not consider his methodology “valid.”¹⁰³

Accordingly, an expert’s inconsistent opinions from litigation to litigation can suggest a results-driven approach to research.

V. CONCLUSION

Courts must be vigilant in guarding against results-driven research in accordance with their *Daubert* obligations. As detailed above, they frequently deem the characteristics identified in this article suggestive of a results-driven approach, especially when appearing together. While the problems articulated here are not the exclusive considerations courts undertake,¹⁰⁴ they are widespread and relatively uniform across litigation in all areas of science and beyond.

The exclusion of an expert opinion can be significant for any case, and in some cases it can even be dispositive. As such, educated and meticulous scrutiny of an expert’s methodology is essential for any substantial litigation.

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ Among others, for example, courts also consider unjustified extremism as suggestive of a results-driven opinion. See *In re Rezulin*, 309 F. Supp. 2d at 564 (“[The expert’s] view that there is no acceptable risk for Rezulin therefore is so extreme that it appears to be shared by no other expert inside or outside this litigation.”).