Legal Backgrounder

Vol. 31 No. 13 May 13, 2016

Washington Legal Foundation
Advocate for Freedom and Justice®
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Washington, DC 20036
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In re Zoloft MDL Judge's Rejection of Causation Testimony Provides Helpful Lessons for Bench and Bar

by Victor E. Schwartz

One of the most challenging areas of modern tort litigation is whether scientific and medical experts should be permitted to provide testimony to a jury about causation in pharmaceutical cases. A plaintiff's counsel's presentation of scientific evidence of causation comes down to an assumption in many cases that if an adverse medical event followed a patient's use of a prescription drug, that drug must have caused that adverse event. This type of "*post hoc*" argument, however, can lead courts to draw false conclusions.

Over 75 years ago, Judge V.A. Griffith of the Mississippi Supreme Court observed this persistent problem, stating:

> There is one heresy in the judicial forum which appears to be Hydra-headed, and although cut off again and again, has the characteristic of an endless renewal. That heresy is that proof that a past event possibly happened, or that a certain result was possibly caused by a past event, is sufficient in probative force to take the question to a jury … . '*Post hoc ergo propter hoc*' is not sound as evidence or argument.[1]

As experienced judges and litigators know, the *post hoc* fallacy lingers in the present judicial system.[2] Thus, when a judge recognizes the concerns expressed by Judge Griffith in a modern litigation, involving far more complex causation evidence, it is an occurrence about which both the bench and bar should know and from which they should learn. In that regard, Judge Cynthia M. Rufe's ruling in *In re Zoloft Products Liability Litigation*[3]—multi-district litigation (MDL) in the U.S. District Court for the Eastern District of Pennsylvania—exemplifies how expert evidence of general and specific causation should be scrutinized in a pharmaceutical case. The decision provides a number of helpful takeaways and lessons for both judges and lawyers.

Background on *In re Zoloft Products Liability Litigation*

In 2012, the U.S. Judicial Panel on Multi-District Litigation established the Zoloft® MDL, consolidating in Judge Rufe's court all pending cases claiming that Zoloft® caused birth defects. At the initial MDL hearings, the plaintiffs' counsel sought to offer testimony by multiple experts opining that the use of Zoloft® during pregnancy was capable of causing a range of birth defects.[4] Judge Rufe rejected these early attempts at

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[1] *Kramer Service Inc. v. Wilkins*, 186 So. 625, 627 (Miss. 1939) (citation omitted).
[2] *See* Victor E. Schwartz & Cary Silverman, *The Draining of* Daubert *and the Recidivism of Junk Science in Federal and State Courts*, 37 Hofstra L. Rev. 215, 234-257 (2006).
[3] 2016 WL 1320799 (E.D. Pa. Apr. 5, 2016).
[4] *See id.* at *1.

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showing general causation, finding they relied on flawed methodology or failed to "address adequately epidemiological studies that did not support [their] opinion."[5]

Over the next several years, the plaintiffs' counsel sought to introduce additional testimony and additional experts to satisfy a threshold showing that Zoloft® was capable of causing birth defects, and also that taking Zoloft® caused a specific plaintiff's injury.[6] Pfizer, the maker of Zoloft®, and several other companies named as defendants in the litigation filed *Daubert* motions seeking to exclude each expert's testimony as unsupported by sound scientific evidence. Judge Rufe painstakingly reviewed the plaintiffs' counsel's proposed expert testimony, each time recognizing that the evidence could not overcome the hurdle of showing that ingesting Zoloft® caused birth defects, and was therefore inadmissible.[7] After over three years of complex pharmaceutical litigation, Judge Rufe dismissed *all* MDL claims against Pfizer alleging that the prescription antidepressant caused birth defects.[8]

This LEGAL BACKGROUNDER examines five key lessons from Judge Rufe's decision.

Lesson One: General Causation Must Be Established Before Specific Causation

As Judge Rufe understood, causation has two levels: general and specific causation. Plaintiffs' counsel must prove both. As Judge Rufe stated, "General causation is whether a substance is capable of causing a particular injury or condition in the general population…"[9] This explanation has been provided by countless courts, but the judge's warning that "sequence matters" is helpful.[10] A plaintiff must first establish general causation before moving to specific causation. Plaintiffs' counsel often do not follow the sequence, and instead rush to try to show that a particular plaintiff was harmed by a particular drug. They take this step without ever establishing that the drug generally caused a type of condition in the general population.

Plaintiffs' counsel in the instant case tried to use experts whose opinions assumed general causation and then focused on specific causation.[11] The court, however, recognized that such testimony was not reliable in proving that Zoloft® had generally caused birth defects in the children of mothers who took the drug while pregnant. Judge Rufe made clear that general causation needed to be established by a preponderance of evidence before proceeding with a specific-causation analysis.

Lesson Two: When Epidemiological Evidence Is Available, It Cannot Be Circumvented

There has been controversy about how and whether a complex pharmaceutical or medical causation case can proceed if no epidemiological evidence is available. Some commentators believe a plaintiff's case should proceed even though the science has not developed to the point of having epidemiological support.[12] Others call for a "wait and see" approach, and would not entertain verdicts based on speculation. In this case, however, epidemiological evidence was available. The problem for the plaintiffs' counsel was that the "many large epidemiological studies" examining the use of Zoloft® by pregnant women did *not* show that taking the drug caused birth defects.[13]

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[5] *Ibid.*
[6] *See ibid.*
[7] *See id.* at *3-4.
[8] *See id.* at *11.
[9] *Id.* at *4.
[10] *Ibid* (quoting *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375 (5th Cir. 2010)).
[11] *See id.* at *10 ("Plaintiffs … have cobbled together evidence of … specific causation opinions based on an assumption that general causation has been established.").
[12] *See* RESTATEMENT (THIRD) OF TORTS: LIABILITY FOR PHYSICAL AND EMOTIONAL HARM § 28 comment c (2010).
[13] *In re Zoloft Prods. Liab. Litig.*, 2016 WL 1320799, at *2.

Judge Rufe explained that when epidemiological evidence is available, and demonstrates a lack of general causation, it cannot be circumvented by other less persuasive evidence.[14] Experts must account for and distinguish epidemiological evidence that does not support their opinions, and must not, as Judge Rufe said, "ignor[e] the full universe of epidemiological evidence."[15] For example, Judge Rufe pointed out that an expert cannot sidestep sound epidemiological evidence conducted on a drug's effect on humans by substituting less reliable studies that have been conducted on animals.[16]

In addition, testimony by doctors or patients about "adverse events" that were perceived to occur after patients used Zoloft® were deemed by Judge Rufe "certainly relevant to the generalization of study hypotheses, but … insufficient to create a material question of fact on general causation."[17] While the words the court used were more extensive than those of Judge Griffith in 1939, the conclusion was the same: *post hoc, ergo propter hoc* does not hold up as sound science.

Judge Rufe further explained that evidence of differential diagnosis may not circumvent epidemiological evidence simply by "ruling out" other potential causes of a condition.[18] She appreciated that this is particularly true with respect to birth defects, which can have a multiplicity of causes, many unknown. By merely ruling out *some* potential causes, the plaintiffs' counsel could not meet the threshold of proving general causation.

Lesson Three: The Quality, Not Quantity, of Evidence Should Drive Evidentiary Decisions

As explained previously, the plaintiffs' counsel put forth numerous experts over a three-year period in this MDL litigation. They also produced hundreds of documents in support of their argument that Zoloft® caused birth defects. Specifically, the plaintiffs' counsel produced 405 asserted statements of material facts and nearly 200 exhibits.[19] Some judges might have been overwhelmed and persuaded by the sheer quantity of this purported proof, but Judge Rufe remained focused on whether proof had actually been demonstrated.

Judge Rufe recognized that "the quantity of the evidence is not … coterminous with the quality of evidence with regard to the issues now before the Court."[20] She weeded through the reams of evidence, finding much of it "irrelevant to the question of whether Zoloft® can cause birth defects."[21] Moreover, Judge Rufe refused to be baited into allowing the MDL to continue by plaintiffs' counsel's presentation of voluminous materials that did not directly address the causation issues at hand.

Lesson Four: Courts Must Look Beyond What an Expert Says to What that Expert Is Relying Upon to Draw Conclusions

Plaintiffs' counsel in the MDL produced many experts with good reputations, but perhaps the pinnacle of prestige was achieved with former Food and Drug Administration Commissioner Dr. David A. Kessler. He submitted an expert report and opined on causation, but his testimony was rejected by Judge Rufe because it failed to create any material issue as to general causation.[22] In particular, Dr. Kessler opined that he would "leave it to other epidemiologists to discuss the strengths and limitations of each [epidemiological] study" showing a lack of causation between taking Zoloft® and experiencing a birth defect.[23]

[14] *See id.* at *5-6.
[15] *Id.* at *10.
[16] *See id.* at *7.
[17] *Id.* at *9.
[18] *Id.* at *7.
[19] *See id.* at *5.
[20] *Ibid.*
[21] *Ibid.*
[22] *See id.* at *9.
[23] *Ibid.*

ISBN 1056 3059

Judge Rufe pointed out that "in this litigation there is no admissible testimony from 'other epidemiologists,' and Dr. Kessler's own statement demonstrates that he has not conducted the analysis that the Court ... requires in this litigation."[24] Hence, despite the prestigious reputation of this causation expert, Judge Rufe was not swayed by "style over substance" and made certain to look beneath the surface at what evidence the expert relied upon in drawing his conclusions.

In addition, the plaintiffs' counsel attempted another form of a "look who said it" means of persuasion by seeking to use internal statements made by Pfizer to prove general causation.[25] Judge Rufe appreciated that the company's internal statements merely raised questions about a possible *association* between Zoloft® and birth defects, and about epidemiological evidence that ultimately failed to show causation. She concluded that none of the statements raised a genuine issue of material fact as to causation.

Judge Rufe's ruling on this point also furthers sound public policy. The tactic of trying to use defendants' statements to prove causation where plaintiffs' counsel cannot produce credible witnesses under *Daubert* standards for the admissibility of scientific evidence appears to be increasing. As a matter of public policy, the law should encourage drug company employees to question potential side effects and have open discussions about the potential risks of a drug without having their statements used in hindsight as proof that a drug caused a general type of injury.

Lesson Five: At Some Point "Enough Is Enough"—When Plaintiffs' Counsel Consistently Fail to Provide Reliable Expert Evidence on Causation, the Case Should Be Dismissed

As indicated, the Zoloft® MDL has gone on since 2012 and plaintiffs had made numerous attempts to demonstrate general causation. Nevertheless, with all of the evidence and approaches used by plaintiffs' counsel, they could not overcome clear epidemiological evidence indicating no causation between women taking Zoloft® while pregnant and their children's experiencing birth defects. At some point, a court must determine that "enough is enough" and that plaintiffs' counsel cannot keep pursuing injury claims indefinitely.

In this case, Judge Rufe decided that the "MDL has been extensively litigated for more than three years through substantial discovery from Pfizer and two rounds of *Daubert* hearings on five experts, at what must have been considerable expense."[26] She also determined that the precise issue of general causation had been "exhaustively litigated" such that there was no longer a valid reason to "keep the litigation gates open" on the chance that general causation—the issue already exhaustively litigated—might one day be established.[27] In effect, Judge Rufe concluded that "enough was enough" for the entire MDL to be dismissed.

Conclusion

Judges and lawyers, who perhaps more often study the opinions of the U.S. Supreme Court or other appellate courts, would be wise to study Federal District Court Judge Rufe's opinion in *In re Zoloft Products Liability Litigation.* It delves into the practical and high-stakes world of pharmaceutical litigation, and it shows exactly how a court should comprehensively analyze expert evidence and separate the wheat from the chaff on causation issues.

[24] *Ibid.*
[25] *See ibid.*
[26] *Id.* at *11.
[27] *Ibid.*

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