Legal Backgrounder

Vol. 32 No. 29 November 17, 2017

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

Ninth Circuit Improperly Lowers Admissibility Bar for Expert Causation Testimony

by David R. Geiger and Richard G. Baldwin

In *Wendell v. GlaxoSmithKline LLC*,[1] the U.S. Court of Appeals for the Ninth Circuit reversed a trial court order[2] that excluded expert testimony concerning the cause of a profoundly rare and deadly disease. The decision contravened multiple aspects of the U.S. Supreme Court's opinions on the admissibility of expert testimony and sets up a split among the federal circuits on the issue.

Background

Plaintiffs' son Maxx died in 2007 at age 21 from hepatosplenic T-cell lymphoma (HSTCL), an "exceedingly rare and aggressive" form of non-Hodgkin's lymphoma. In 1999, following a diagnosis of inflammatory bowel disease (IBD), Maxx was prescribed six-mercaptopurine (6-MP), an immunosuppressant of the thiopurine class that was not specifically approved for IBD but was widely used for that purpose. In 2002, doctors added to his drug regimen infliximab, marketed as Remicade® and one of a class of anti-TNF drugs approved for treatment of autoimmune disorders such as Crohn's disease (a form of IBD).

When Maxx's IBD went into remission in 2006, he discontinued Remicade but remained on 6-MP. Two months later, the Food and Drug Administration approved a labeling change for Remicade that reported cases of HSTCL in young males with Crohn's disease treated with Remicade and a thiopurine. Accordingly, when Maxx's IBD symptoms returned he was prescribed a different anti-TNF drug whose label did not include this risk. He then stopped taking 6-MP in April 2007 after reading in a magazine article that young men taking both Remicade and an immunosuppressant had developed HSTCL. He also discontinued his anti-TNF drug in June. In July 2007, Maxx was diagnosed with HSTCL, and he succumbed to the disease five months later.

Following Maxx's death, his parents brought negligence and strict-liability claims under California law against six manufacturers and distributors of his various medications, alleging they had not adequately warned of the drugs' risks. Five years into the litigation, the remaining defendants moved for summary judgment arguing, among other things, that plaintiffs' causation experts' testimony was not scientifically reliable and was therefore inadmissible under Federal Rule of Evidence 702.

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[1] 858 F.3d 1227 (9th Cir. 2017).

[2] *Wendell v. Johnson & Johnson*, No. C 09-4124 CW, 2014 U.S. Dist. LEXIS 89576, 2014 WL 2943572 (N.D. Cal. June 30, 2014).

David R. Geiger and **Richard G. Baldwin** are Partners with Foley Hoag LLP in the firm's Boston, MA office. They are members of the firm's Litigation Department and Product Liability and Complex Torts Practice Group, for which Mr. Geiger serves as Chair.

District Court Ruling

The U.S. District Court for the Northern District of California granted the motion, finding the opinions of plaintiffs' two causation experts—both medical doctors—not based on sufficiently reliable scientific data. The court first noted that a plaintiff claiming injury from a pharmaceutical must "establish that the substance at issue was capable of causing the injury alleged (general causation), and that the substance caused, or was a substantial factor in causing, the specific plaintiff's injury (specific causation)."

The court then recited the reliability standard and illustrative factors established by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals*,[3] including "whether the theory or technique in question can be (and has been) tested, whether it has been subjected to peer review and publication, its known or potential error rate and the existence and maintenance of standards controlling its operation, and whether it has attracted widespread acceptance within a relevant scientific community."

In *Wendell*, plaintiffs' experts (1) had never conducted any independent research or published any studies on the relationship between the drugs at issue and HSTCL, and indeed conceded their opinions would not satisfy the standard for peer-reviewed publication, and (2) failed to identify any animal or epidemiologic studies showing a causal link between HSTCL and the drugs. The absence of studies was of particular concern for HSTCL since more than 70 percent of cases were idiopathic, *i.e.*, had no known cause.

As to the "handful" of studies and individual case reports plaintiffs' experts claimed to rely on (some of which were not even cited in their expert reports), they did not purport to show that the drugs caused HSTCL, only the incidence of that condition among different patient populations, including IBD patients. Nor did plaintiffs' experts opine that any increased incidence of HSTCL among IBD patients was statistically significant, or rule out alternative causes such as IBD itself either in the cited studies or in Maxx's individual case.

Problematic Ninth Circuit Ruling

On plaintiffs' appeal, the Ninth Circuit reversed. While calling it "a close question," the circuit court concluded the trial court had "looked too narrowly at each individual consideration, without taking into account the broader picture of the experts' overall methodology," and had "improperly ignored the experts' experience, reliance on a variety of literature and studies, and review of Maxx's medical records and history, as well as the fundamental importance of differential diagnosis by experienced doctors treating troubled patients." The Ninth Circuit also asserted the trial court had "overemphasized the facts that (1) the experts did not develop their opinions based on independent research and (2) the experts did not cite epidemiological studies."

The Ninth Circuit's opinion is problematic in multiple respects. First, although the court noted at the outset the abuse of discretion standard it was required to apply under the Supreme Court's decision in *General Electric v. Joiner,*[4] in its actual analysis the court only referred back to this standard once. And its suggestion that the trial court had erred in viewing each missing indicium of reliability as somehow fatal by itself, rather than looking at total effect of all the experts' methodologic flaws, was simply not an accurate characterization of the trial court's ruling.

[3] 509 U.S. 579, 593–94 (1993).
[4] 522 U.S. 136 (1997).

Second, the circuit court ultimately grounded its view that the district court had erred on the experts' qualifications and their purported use of a generally accepted "differential diagnosis" methodology in reaching their causation opinions. Regarding qualifications, the circuit court both began[5] and ended[6] its analysis with an emphasis on the experts' impeccable medical qualifications, including those specifically related to T-cell lymphoma. But *Daubert* and its progeny, and the current Federal Rule of Evidence 702, are unmistakably clear that the reliability of an expert's testimony is completely distinct from his qualifications. *See* F.R.E. 702 ("A witness who *is* qualified as an expert ... may testify in the form of an opinion or otherwise *if* ....").

As to a purported "differential diagnosis" methodology, the mere invocation of that term should not be a talisman sufficient to render reliable all expert testimony so labeled. Indeed, the use of the term here was actually a misnomer: the experts were not purporting to consider all the medically established conditions that might explain Maxx's symptoms so as to perform further testing and analysis to ultimately reach a *diagnosis* as to which of those diseases he suffered from. Rather, having already diagnosed him as suffering from HSTCL, they were purporting to opine as to the *cause* of that disease. Accordingly, they were actually applying a technique of differential causation or etiology.

Nor is this distinction merely semantic. As recognized by the district court, causation requires proof of both general and specific causation. Thus a proper differential-causation analysis requires the expert *first* to demonstrate what factors have been reliably established to cause the disease at issue in humans generally, and *then* to perform sufficient analysis reliably to exclude all but one of those factors for the individual in question (or at least to conclude that that factor among all those not excluded is more likely than not to be the specific cause).

In *Wendell,* the circuit court ignored general causation entirely and misunderstood the district court's concern about the lack of evidence showing a causal relationship in humans between HSTCL and the drugs at issue. Plaintiffs' experts could not rule out alternative causes such as IBD itself as explaining any increased incidence of HTSCL in the studies they cited. Regarding specific causation, neither the experts nor the circuit court explained how they could rule out idiopathic HSTCL in Maxx's case (in fact, the experts conceded they could not), or at least conclude the drugs were more likely the cause, when 70% of HSTCL cases are idiopathic.

At bottom, the Ninth Circuit's opinion appears driven by the concern that plaintiffs should not be disadvantaged by the fact that their son died from a disease that was quite rare, as a result of which the scientific community had developed very little relevant causation data.[7] As the court stated, "The first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victims' condition and the toxic substance, has not yet been completed."[8]

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[5] 858 F.3d at 1233 ("To begin, the experts were highly qualified doctors.").

[6] *Id.* at 1237 ("Where, as here, two doctors who stand at or near the top of their field and have extensive clinical experience with the rare disease or class of disease at issue, are prepared to give expert opinions supporting causation, we conclude that *Daubert* poses no bar based on their principles and methodology.").

[7] The circuit court repeatedly referred to the rarity of HSTCL to excuse the experts' lack of support for their opinions. *See id.* at 1235 (expert opinion may be reliable without peer review and publication "especially ... when dealing with rare diseases); *id.* at 1236 (lack of animal or epidemiological studies "not surprising" because HSTCL is an "exceedingly rare cancer").

[8] 858 F.3d at 1237 (quoting *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1060 (9th Cir. 2003) (quoting *Turner v. Iowa Fire Equip Co.*, 229 F.3d 1202, 1209 (8th Cir. 2000))) (internal quotations omitted).

ISBN 1056 3059

Of course, the court's suggestion that the medical literature "will eventually show the connection" assumes the very conclusion that was at issue in the case. In any event, the Ninth Circuit's view is squarely at odds with the approach taken by at least five other federal circuits, and indeed the Supreme Court. Among the circuits, the Seventh was the first to note that the requirement of a scientifically reliable basis for expert testimony necessarily means that "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it."[9] The Fifth,[10] Sixth,[11] Tenth[12] and Eleventh[13] Circuits have subsequently recognized this principle. And in *Daubert* itself, the Supreme Court noted: "We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by the Rules of Evidence."

Conclusion

In *Wendell*, the Ninth Circuit has recognized a new, lower bar for the admissibility of expert causation testimony in cases of new or rare diseases, under which judges may largely abdicate their gatekeeper role in deference to qualified experts who offer their professional judgment but lack true scientific support. The decision contradicts the commands of *Daubert* and Federal Rule of Evidence 702, invades the discretion afforded trial judges under *Joiner*, is contrary to the conclusion of five other circuit courts, and increases legal risk for the manufacturers of drugs and other substances that could conceivably have toxic effects.

[9] *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996).

[10] *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 381 & n.33 (5th Cir. 2010) ("Perhaps [defendant's drug] is a cause of problem gambling, but the scientific knowledge is not yet there. [Plaintiff] urges the law to lead science—a sequence not countenanced by *Daubert*.").

[11] *Tamaraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677 (6th Cir. 2010) ("Both sides agree that [plaintiff] is a good man who suffers from a terrible disease; we now force him to take the chance of prevailing at trial a second time, with less evidence than before. If he does not, yet it turns out ten years from now that [defendant's drug] causes his disease, that result will seem unfair. But the alternative route—allowing the law to get ahead of science—would be just as unfair.").

[12] *Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1217 (10th Cir. 2002).

[13] *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1202 (11th Cir. 2002) ("Given time, information, and resources, courts may only admit the state of science as it is. Courts are cautioned not to admit speculation, conjecture or inference that cannot be supported by sound scientific principles.").

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