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Plaintiffs' General Causation Expert Is Excluded: Now What?

By Robin Shah

In product liability cases involving complex medical and scientific issues, plaintiffs are typically required to offer expert testimony to establish general causation because the issue of causation is beyond the knowledge of a lay jury.

If defendants are successful in excluding plaintiffs' general causation expert under *Daubert* or similar standards, courts commonly grant summary judgment for the manufacturer because without the requisite expert testimony, there is no genuine issue of material fact pertaining to causation. *See, e.g., C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 838 (7th Cir. 2015) ("With no experts to prove causation…summary judgment in this case was proper."); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 956 (D. Minn. 2009) ("[A]bsent an admissible general causation [expert] opinion, Plaintiffs' claims necessarily fail and… summary judgment must be granted."); *In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567, 579 (S.D.N.Y. 2006) (same).

However, in recent years, plaintiffs have tried to circumvent *Daubert* rulings by arguing that there is enough non-expert evidence to establish general causation and deny summary judgment for defendants. Courts are reluctant to allow such an end-run around the need for scientific expert testimony in complex cases and have rejected such attempts by finding that the following categories of information are not adequate substitutes for expert testimony.

Adverse Event Reports

Some plaintiffs have argued that adverse event reports are enough to establish a causal relationship between the product and the injury reported. For instance, in *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, the plaintiffs cited reports in which doctors or patients suggested that incidents of birth defects occurred after using Zoloft. 176 F. Supp. 3d 483, 494 (E.D. Pa. 2016), *aff'd sub nom. In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017). In granting summary judgment for Pfizer, the court noted that "[a]lthough a court may rely on anecdotal evidence such as case reports, courts must consider that case reports are merely accounts of medical events. They reflect only reported data, not scientific methodology" that can point to causation. *Id.* at 497. Similarly, in *Vallejo v. Amgen, Inc.*, the court rejected the plaintiffs' argument that a MedWatch report established a causal connection that obviated the need for an expert. 274 F. Supp. 3d 922, 926 (D. Neb. 2017), *aff'd*, 903 F.3d 733 (8th Cir. 2018). The court found that "[a]t most, the report suggests a 'temporal association' between the pharmaceutical product and the reported medical event of an individual who has no relation to the present dispute." But that association was not "scientifically valid proof of causation" and did not constitute a proper substitute for expert testimony. *Id.* (citation omitted).

Product Labels

Courts have similarly refused to accept plaintiffs' arguments that product labels, either of the product at issue or related products, amount to party admissions that can prove general causation. For example, in *Coleson v. Janssen Pharm., Inc.*, the court granted summary judgment for Janssen and found that Risperdal's warning label discussing the injury at issue could not defeat summary judgment because "[p]roduct warning labels can have over-inclusive information on them," and warning about a potential event does not equate to causation. 251 F. Supp. 3d 716, 723 (S.D.N.Y. 2017). Similarly, in *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II),* the court found that the label on another contraceptive product indicating that the applicable injury had been reported in rare occasions did not support a finding of causation. Instead, the court held that the warning merely revealed the existence of historical case reports and a decision to err on the side of caution by warning about a rare event. 387 F. Supp. 3d 323, 356 (S.D.N.Y. 2019).

Medical Literature

Courts have also drawn distinctions between studies finding correlation versus causation, finding that providing a jury with evidence of the former in lieu of expert testimony would be improper. In *In re Mirena*, the plaintiffs argued that a study evidenced a statistically significant association between Mirena and the alleged injury that would allow the jury to find general causation. 387 F. Supp. 3d at 344.

The court disagreed and held that "the Valenzuela study showed nothing more than a correlation, subject to identifiable confounders, between Mirena and IIH [idiopathic intracranial hypertension]." *Id.* Accordingly, the court concluded that the study "could not be relied on as proof of general causation[.]" *Id.* *See also In re Zoloft*, 858 F.3d at 497 (finding that internal communications about epidemiological studies only demonstrated that Pfizer employees were raising questions about the "association" between Zoloft and birth defects as opposed to proving causation).

Previously Excluded Testimony

Finally, some plaintiffs have essentially ignored *Daubert* rulings altogether and tried to resurrect pieces of the previously excluded expert testimony that they consider to be non-controversial. In *In re Mirena*, the court responded with incredulity and held that the "end-run around Rule 702—and th[e] Court's Daubert ruling—is unsustainable." 387 F. Supp. 3d at 344. In that case, the court rejected the plaintiffs' argument that a lay person could draw on aspects of the previously excluded testimony to conclude that Mirena is a cause of idiopathic intracranial hypertension. The court held that "even assuming *arguendo* that various scientific propositions nestled within plaintiffs' experts' reports were, largely, scientifically uncontested," they could not be "revived as fodder from which a lay jury could speculate about and derive a theory of general causation." *Id.* The court specifically admonished the plaintiffs for their "backdoor means" to revive the excluded expert analyses.

Conclusion

In sum, defendants should be vigilant for an attempt by plaintiffs to defeat summary judgment after favorable *Daubert* rulings by arguing that non-expert evidence can demonstrate general causation. Fortunately, courts have been hesitant to accept the various types of evidence advanced by plaintiffs, and plaintiffs certainly face a steep uphill battle in identifying non-expert evidence that can pass muster in lieu of traditional expert testimony.

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