

## Recent Judicial Decisions on Specific Causation

By Lori B. Leskin

It is, of course, black letter law that to prove a claim, a plaintiff in a product liability suit must establish that the product at issue caused the injury suffered by the plaintiff. Causation includes both general and specific: General causation “bears on whether the type of injury at issue can be caused or exacerbated by the defendant’s product,” while specific causation “bears on whether, in the particular instance, the injury actually was caused or exacerbated by the defendant’s product.” *Ruggiero v. Warner-Lambert Co.*, 424 F.2d 249, 251 n. 1 (2nd Cir. 2005). See also *Pick v. Amer. Med. Sys., Inc.*, 958 F. Supp. 1151, 1164 (E.D. La. 1997), aff’d 198 F.3d 241 (5th Cir. 1999). Absent a showing of both types of causation, a plaintiff’s claims necessarily fail. *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950 (D. Minn. 2009).

Plaintiffs have often assumed that if they could overcome the general causation barrier, they could easily create an issue of fact on the issue of specific causation. Recently, however, courts are giving more critical attention to the issue of specific causation, and, with increasing frequency, are excluding unreliable specific causation opinions.

This article highlights three recent court decisions — two involving Viagra® and one involving Seroquel® — rejecting plaintiff’s efforts at establishing specific causation as a matter of law. These decisions confirm that speculative specific causation evidence is inadmissible.

### IN RE VIAGRA PROD. LIAB. LITIG.

In *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 950 (D. Minn. 2009), several plaintiffs in 2006 began filing complaints against Pfizer asserting claims that Viagra®, Pfizer’s prescription medication for the treatment of male erectile dysfunction, caused them to suffer vision loss from a disorder known as non-arteritic ischemic optic neuropathy (“NAION”). Following expert discovery, the court granted Pfizer’s motion excluding three of plaintiffs’ four general

causation experts (*In re Viagra Prod. Liab. Litig.*, 572 F. Supp. 2d 1071 (D. Minn. 2008)), and discovery continued on two of the MDL cases. Pfizer subsequently moved to exclude the remaining general causation expert, as well as the opinions of plaintiffs’ five specific causation experts. The court granted Pfizer’s motion to exclude the general causation expert’s opinion as “not sufficiently reliable” under *Daubert*. *In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 936 (D. Minn. 2009). While the court recognized that the general causation opinion “effectively ended the current litigation,” “for the sake of comprehensiveness,” the court additionally considered, and granted, Pfizer’s motion to exclude the five specific causation experts as well. 658 F. Supp. 2d at 956.

Three of the case specific experts purported to rely on a “differential diagnosis” to reach their conclusion that Viagra caused the plaintiffs’ NAION. As the court explained:

In performing a differential diagnosis, a physician begins by “ruling in” all scientifically plausible causes of the plaintiff’s injury. The physician then “rules out” the least plausible causes of injury until the most likely cause remains. The final result of a differential diagnosis is the expert’s conclusion that a defendant’s product caused (or did not cause) the plaintiff’s injury.

*Id.* at 957, citing *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001). Although under Eighth Circuit precedent a differential diagnosis is “presumptively admissible,” the court recognized that a differential diagnosis that “fails ‘to consider all the possible causes, or to exclude each potential cause until only one remain[s], or to consider which of two or more non-excludable cause [is] the more likely to have caused the condition’ is an inadequate, and inadmissible, methodology. *Id.*, citing *Turner v. Iowa Fire Equipment Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000). The court then examined each expert’s attempts at applying differential diagnosis and found them to be speculative and invalid.

- First, the court held that because he had excluded all of plaintiffs’ general causation experts and because these experts pointed to no additional evidence of general causation, there was no basis to “rule in” Viagra as a

cause of plaintiffs’ NAION, *e.g.*, *Id.* at 958 (“Dr. Williams cannot have an admissible specific causation opinion regarding Viagra without a scientifically valid reason for concluding that Viagra can cause NAION in the first place”), *Id.* at 960 (“without a proper basis for ruling in Viagra as a cause of NAION, Dr. Sher cannot offer an admissible specific causation opinion”).

- Second, the experts made no effort — and in fact admitted they were unable — to rule out other potential causes for plaintiffs’ NAION. *Id.* at 957 (Dr. Williams admitted ... that he could not rule out underlying risk factors as the cause of plaintiffs’ NAION”), *Id.* at 959 (“Dr. Lee’s failure to ‘rule out’ all of the other possible causes makes his differential diagnosis scientifically unreliable”).
- Third, the experts did not use “any particular test or methodology for determining that Viagra and not underlying risk factors caused Plaintiffs’ NAION.” *Id.* at 958. Rather, although the clinical findings confirmed the diagnosis of NAION, the experts admitted “nothing in the clinical findings leads to the conclusion that Viagra caused plaintiffs’ NAION.” *Id.* at 960. In other words, there is no examination or test the experts could conduct which would allow them to determine “that Viagra, and not Plaintiffs’ risk factors alone, caused plaintiffs’ NAION” (*Id.* at 960), or for ruling out other medications taken by plaintiffs at the same time (*Id.* at 959).
- Fourth, to the extent the experts relied solely on “temporality” — the fact that plaintiffs’ injuries occurred in temporal proximity with their use of Viagra — the court held that was “insufficient alone to establish causation.” *Id.* at 958. See also *Id.* at 960.
- Fifth, the court also faulted the experts for “employ[ing] a lower standard from what would be used in the medical realm” in reaching their causation conclusions. *Id.*, citing *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 758 (8th Cir. 2006) (affirming exclusion of an expert that

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"admitted that the causation standard she employed ... was a much lower standard than medical causation"). Two of the plaintiffs' experts acknowledged they were applying a less rigorous standard in reaching their opinions in the litigation than they would in their ordinary medical practice.

- Finally, the court rejected one expert's supposed reliance on the "Bradford Hill criteria" for his specific causation opinion because that test is "used to establish general causation from epidemiological studies – they are not used to establish specific causation." *Id.* at 958.

In addition, the court excluded two of the plaintiffs' experts as "unqualified" to render an opinion as to the cause of the plaintiffs' NAION. The court held that the assessment of the cause of the plaintiffs' visual injuries fell "outside the realm" of these experts — one an epidemiologist but not a medical doctor, and the other a treating urologist of one of the plaintiffs — expertise. *Id.* at 960-61.

In excluding the specific causation experts' opinions, the court looked past the rote recitation from the experts that they held their opinions to a "reasonable degree of medical certainty after reviewing all of the evidence." Rather, the court recognized its role as more than a rubber stamp, and its obligation to "exercise its gatekeeper role to ensure that the opinions that [plaintiffs' experts have] offered are sufficiently reliable to make their way to a jury." *Id.* at 959.

#### **GUINN V. ASTRAZENeca PHARMS. LP**

In *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245 (11th Cir. 2010), an expert's questionable use of differential diagnosis was also reviewed by the Eleventh Circuit. *Guinn* was one of the first cases in the Seroquel MDL to reach the *Daubert* motion stage on specific causation. The MDL was formed in the Middle District of Florida in July 2006, and has included claims that AstraZeneca's anti-psychotic medication, Seroquel, caused plaintiffs to develop diabetes.

In *Guinn*, following a *Daubert* hearing, the district court excluded the plaintiff's expert for failing "to articulate any scientific methodology for assessing whether, and to what extent, Seroquel contributed to Guinn's weight gain and diabetes," 598 F. Supp. 2d 1239, 1243 (M.D. Fla. 2009), and granted summary judgment to defendant. On appeal, the Eleventh Circuit affirmed.

Like the district court in the Viagra litigation, the Eleventh Circuit recognized that "[w]hen properly conducted, differential diagnosis can be a reliable methodology under *Daubert*." 602 F.3d at 1253. However, simply claiming that an expert conducted a differential diagnosis, without more, "does not establish the reliability of his techniques or the validity of his conclusions." *Id.*

Looking at the expert at issue in the *Guinn* case, Dr. Marks, the court affirmed the district court's exclusion "because she failed

to adequately consider possible alternative causes of Guinn's weight gain and diabetes." *Id.* A "differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation." *Id.* at 1253, citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999).

Significantly, the court rejected the expert's reliance on temporal proximity to explain why Seroquel would be the most likely cause of the plaintiff's diabetes. The expert tried to explain why the plaintiff's "numerous other risk factors for diabetes" were not the sole cause because "they remained constant" while the plaintiff took Seroquel, but did "not explain why having a stable risk profile makes it unlikely that preexisting risk factors caused" the plaintiff's illness, particularly where it was not disputed that those risk factors "put her at an extremely high risk for diabetes." *Id.* at 1254:

An expert, however, cannot merely conclude that all risk factors for a disease are substantial contributing factors in its development. The fact that exposure to a substance may be a risk factor for a disease does not make it an actual cause simply because the disease developed ... . While multiple factors can work together to cause diabetes, Dr. Marks was still required to provide some analysis of why she concluded that, more likely than not, Seroquel substantially contributed to Guinn's weight gain and such weight gain was among the factors that substantially contributed to her diabetes.

*Id.* (citations omitted). Having failed to explain properly the bases for ruling out other potential causes of the plaintiff's injury, Dr. Marks' opinion was held inadmissible. Moreover, the court found that Dr. Marks did not "conduct standard diagnostic techniques she normally used to rule out potential alternative causes." *Id.* Thus, as with the Viagra litigation, the expert failed to "employ[ ] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.*, citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Given the failings of Dr. Marks' opinion, ultimately the Eleventh Circuit affirmed the decision to exclude her opinion as "mere speculation." *Id.* at 1257.

#### **RIDGEWAY V. PFIZER INC.**

Finally, in another decision involving Viagra, *Ridgeway v. Pfizer Inc.*, 2010 WL 1729187 (E.D.La. April 27, 2010), the court reaffirmed the need for admissible expert medical evidence to support specific causation. In *Ridgeway*, the plaintiff suffered a hemorrhagic stroke following use of Viagra. During the course of discovery, none of the plaintiff's treating physicians attributed the plaintiff's stroke to his use of Viagra. To the contrary, at least one of the doctors considered such a causal relationship to be "totally ridiculous." 2010 WL 1729187, at \*2. None of the doctors could even identify any medical literature that would establish a causal link. *Id.*

In the face of this testimony, the plaintiff

identified no affirmative evidence of causation and designated no experts. Rather, the plaintiff simply asserted that the claimed injury was "so new there has not been sufficient scientific testing to establish the causality of the use of [Viagra] and a hemorrhage." *Id.* at 3. In response to Pfizer's motion for summary judgment, the plaintiff turned to the doctrine of *res ipsa loquitur*.

This doctrine allows a plaintiff to assume negligence where an injury occurred under circumstances that would not normally occur in the absence of negligence. *Id.* However, as the court recognized, "the mere mention of *res ipsa loquitur* ... does not relieve a plaintiff of the burden imposed by the law." *Id.* As with an expert's invocation of "differential diagnosis," under *res ipsa loquitur*, a plaintiff "bear[s] the burden of excluding reasonable explanations for the accident other than defendant's negligence." *Id.* Applying these principles to Mr. Ridgeway's claims, the court rejected the plaintiff's efforts to invoke the theory.

The court recognized that *res ipsa loquitur* only applies where the circumstances are "so unusual" that they would "not typically occur in the absence of negligence." *Id.* at \*4. Mr. Ridgeway's use of Viagra for over 10 years followed "on one occasion" by a "relatively common medical injury with no clear association with Viagra" was not such a circumstance. *Id.* The plaintiff's admission that his theory of causation was "speculative" further "undercuts the argument that *res ipsa loquitur* should apply." *Id.*

Moreover, the plaintiff failed to exclude other possible causes for the plaintiff's stroke, including the plaintiff's history of hypertension, the "leading cause of hemorrhagic stroke." *Id.* Thus, the court refused to presume fault "when plaintiffs themselves admit that their theory of causation is so novel that no one has yet had a chance to study it." *Id.*

#### **CONCLUSION**

In sum, challenges to the reliability and sufficiency of plaintiffs' specific causation evidence are as important as challenges to general causation. Where general causation is established — or at least considered sufficiently reliable for *Daubert* purposes — a specific causation challenge may be the only avenue for winning on causation as a matter of law. Courts have closely analyzed experts' invocation of differential diagnosis, and have rejected opinions where the application lacks reliable scientific methodology or factual bases. The recent Viagra and Seroquel opinions discussed herein underscore the importance of closely questioning the plaintiffs' specific causation evidence.

