

## Beyond the Obvious: Does the Failure to Rule Out Idiopathic Causes Survive a Rule 702 Challenge?

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In forming an admissible opinion about whether exposure to or use of a defendant's product caused a plaintiff's disease or condition, the plaintiff's expert must factor into their differential diagnosis the role played by potential alternative causes. Yet in many instances, plaintiffs' experts do not rule out unknown or unexplained causes—also known as idiopathic causes—even when idiopathy is the most likely explanation for the disease or condition. In the Zostavax MDL in the Eastern District of Pennsylvania, the court in two cases addressed whether a proper differential diagnosis must include idiopathic causes and excluded the plaintiffs' specific causation experts under Federal Rule of Evidence 702 based in part on their failure to rule out idiopathy as a potential cause of the plaintiffs' alleged injury.

In the first of two cases, the plaintiff alleged that he developed Guillain-Barré syndrome (GBS) as a result of being inoculated with the defendant's vaccine.<sup>[1]</sup> GBS is a rare autoimmune disorder that causes the body's immune system to attack its own nerves.<sup>[2]</sup> As noted by the court, "[t]he cause of GBS is not well understood," and the "National Institute for Neurological Disorders and Stroke reports that GBS tends to appear days or weeks following a respiratory or gastrointestinal infection."<sup>[3]</sup> The court also observed that it is "undisputed that the cause is unknown in approximately one-third of the cases of GBS."<sup>[4]</sup>

The plaintiff offered a specific causation opinion from only one expert, who concluded that the defendant's vaccine caused the plaintiff to develop GBS.<sup>[5]</sup> The expert asserted that he performed a differential diagnosis to reach this conclusion, which the court noted is "the hallmark of internal medicine and is used to reach a diagnosis by ruling in conditions and ruling out alternative explanations for symptoms."<sup>[6]</sup> As part of a "sufficiently reliable differential diagnosis," the court stated that an expert "must rule out not all other possible causes, but only obvious alternative causes."<sup>[7]</sup> The court also explained that an expert "may consider medical records, peer-reviewed literature and scientific studies as well as their own clinical experience in making this determination."<sup>[8]</sup>

Here, in performing his differential diagnosis, the plaintiff's expert relied primarily on the short temporal span between when the plaintiff was inoculated with the defendant's vaccine and when his GBS symptoms began.<sup>[9]</sup> The expert also claimed that the plaintiff was "experiencing immunosenescence"—a weakened immune system due to age—that made the plaintiff more vulnerable to developing GBS.<sup>[10]</sup> Lastly, the plaintiff's expert also relied on his own clinical experience "of over 25 years working as a specialist in diagnosing and managing GBS."<sup>[11]</sup> However, the plaintiff's expert admitted that "approximately one-third of cases of GBS result from unknown or unexplained

causes,” and that “[h]is own clinical experience demonstrates that one-half of the cases of GBS he has seen have idiopathic causes.”<sup>[12]</sup>

In considering the defendant’s Rule 702 challenge to the expert’s opinions, the court found that while the expert ruled out obvious known alternative causes of the plaintiff’s GBS, he did not “rule out idiopathic” or “unknown or unexplained causes.”<sup>[13]</sup> Notably, the court explained that “[w]hen unexplained causes are common, a differential diagnosis is insufficient when it does not eliminate these causes.”<sup>[14]</sup> The court observed that when “such a significant portion of cases are idiopathic, the expert must exclude idiopathic causes to have a reliable opinion of a known cause.”<sup>[15]</sup> And, critically, the plaintiff’s expert “conceded at his deposition that he did not rule out idiopathic causes of [the plaintiff’s] GBS.”<sup>[16]</sup> Thus, the court ruled that the expert did not “have good grounds for his specific causation opinion that [the defendant’s vaccine] caused [the plaintiff’s] GBS,” and his opinion did not “meet the reliability standards of Rule 702 and *Daubert*.”<sup>[17]</sup>

In the second case from the Zostavax MDL, the plaintiff alleged that she developed persistent daily headache (PDH) as a result of being inoculated with the defendant’s vaccine.<sup>[18]</sup> The plaintiff presented a single expert to opine on both general and specific causation.<sup>[19]</sup> As for the expert’s general causation opinion, the court found the expert relied on irrelevant scientific literature and did not have “any relevant clinical experience with which to support his conclusion about how patients contract PDH.”<sup>[20]</sup> In other words, his opinion was “merely an ipse dixit analysis, that is his bare say-so.”<sup>[21]</sup>

The court found that the plaintiff’s expert’s specific causation opinions “misse[d] the mark” as well.<sup>[22]</sup> Along with identifying a litany of errors with the expert’s specific causation opinions, the court also found that the plaintiff’s expert’s differential diagnosis was methodologically flawed under Rule 702, as it did not “reliably connect” the plaintiff’s PDH to the administered vaccine.<sup>[23]</sup> While the expert had ruled out a prior injury from horseback riding as the cause of the plaintiff’s PDH, he did not rule out idiopathic causes, even though the scientific literature that the expert relied on for his opinions provided that “53% of PDH cases do not have a known precipitating factor.”<sup>[24]</sup> As the court stated, “[w]hen unexplained causes are common, a differential diagnosis is lacking unless those unexplained causes are eliminated.”<sup>[25]</sup> Thus, the court ruled that the expert’s differential diagnosis and specific causation opinions were not sufficiently reliable under Rule 702, as “he does not exclude idiopathic causes of [the plaintiff’s] PDH,” leaving him with “a conclusion based solely on post hoc ergo propter hoc reasoning.”<sup>[26]</sup>

## STRATEGIC TAKEAWAYS

In many cases, plaintiffs’ experts fail to rule out idiopathy as the cause of an alleged injury. These two decisions from the Zostavax MDL emphasize the importance of considering a Rule 702 motion when a plaintiff’s expert has not thoroughly considered the role of idiopathic causes, especially when scientific publications highlight the absence of a known cause for the alleged disease or condition.

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<sup>[1]</sup> *In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig.*, No. CV 18-20020, 2023 WL 6626581, at \*1 (E.D. Pa. Oct. 11, 2023).

<sup>[2]</sup> *Id.* at \*2.

<sup>[3]</sup> *Id.* (internal quotations omitted).

<sup>[4]</sup> *Id.*

<sup>[5]</sup> *Id.* at \*5. The defendant also unsuccessfully challenged the admissibility of the plaintiff’s expert testimony on general causation issues.

<sup>[6]</sup> *Id.*

<sup>[7]</sup> *Id.*

<sup>[8]</sup> *Id.*

<sup>[9]</sup> *Id.* at \*6.

<sup>[10]</sup> *Id.*

<sup>[11]</sup> *Id.*

<sup>[12]</sup> *Id.*

<sup>[13]</sup> *Id.*

<sup>[14]</sup> *Id.*

<sup>[15]</sup> *Id.*

<sup>[16]</sup> *Id.*

<sup>[17]</sup> *Id.*

<sup>[18]</sup> *In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig.*, No. CV 18-MD-2848, 2023 WL 6465837, at \*1 (E.D. Pa. Oct. 4, 2023).

<sup>[19]</sup> *Id.* at \*2.

<sup>[20]</sup> *Id.* at \*4.

<sup>[21]</sup> *Id.*

<sup>[22]</sup> *Id.* at \*5.

<sup>[23]</sup> *Id.* at \*6.

<sup>[24]</sup> *Id.* at \*7.

<sup>[25]</sup> *Id.*

<sup>[26]</sup> *Id.*  
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[Sandra Edwards](#)

[Rand Brothers](#)

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Sandra Edwards



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