

579 F.Supp.3d 675

United States District Court, E.D. Pennsylvania.

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION

This Document Relates to:

John Michael Bush and Johnny Mitchell v. Merck & Co., Inc., et al.

Richard Doman and Maureen M. Doman v. Merck & Co., Inc., et al.

David R. Elmegreen as Trustee of the Sue A. Elmegreen Trust v. Merck & Co., Inc., et al.

John Niedzialowski and Katherine Niedzialowski v. Merck & Co., Inc., et al.

Emily Sansone v. Merck & Co., Inc., et al.

MDL NO. 2848

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CIVIL ACTION NO. 18-md-2848, Civil Action No. 19-1117, Civil Action No. 18-20118,

Civil Action No. 17-2044, Civil Action No. 19-20025, Civil Action No. 18-20114

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Signed December 1, 2021

Synopsis

Background: Patients brought actions against pharmaceutical companies, asserting claims for strict liability and negligence arising from personal injuries as a result of inoculation with companies' shingles vaccine. Companies moved to exclude specific causation opinions of patients' expert

Holdings: The District Court, [Harvey Bartle, J.](#), held that:

doctor qualified as expert, but

doctor's opinion about specific causation of injuries was not reliable, as required to be admissible.

Motion granted.

Procedural Posture(s): Motion to Exclude Expert Report or Testimony.

***676** MEMORANDUM IN SUPPORT OF PRETRIAL ORDER NO. 409

[Bartle](#), District Judge

The court has before it five bellwether strict liability and negligence actions in this Multidistrict Litigation involving Zostavax,

***677** a vaccine developed by defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. to prevent shingles.¹ The defendants have moved to exclude the specific causation opinions of plaintiffs' expert Mark Poznansky, M.D. on the ground that he has not met the standards required under [Rule 702 of the Federal Rules of Evidence](#) and [Daubert v. Merrell Dow Pharm., Inc.](#), 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993).

It is well known that the varicella-zoster virus (VZV) causes both [chicken pox](#) which typically occurs in childhood and shingles, or [herpes zoster](#), which occurs in adulthood after a person has experienced [chickenpox](#). The VZV remains in the body for life. It

travels up nerve fibers from the skin and becomes dormant in nerve cells, called ganglia, near the spinal cord until it reactivates. When it reactivates, it travels down the nerve fibers and results in shingles. Virtually all persons over 30 in the United States have had [chickenpox](#) and carry the so-called wild-type virus in their systems. Shingles manifests itself in a painful rash on various parts of the body. It is estimated that one out of three adults will experience shingles during his or her lifetime.

[Zostavax](#) was developed to prevent shingles in adults 50 years or older and was licensed by the Food & Drug Administration (FDA) in 2006. It includes the Oka strain of the VZV, a live-attenuated virus that is a weakened form of the natural or wild-type virus found in the body of someone who has had [chickenpox](#). [Zostavax](#) is not designed to produce immunity by causing a mild case of shingles but rather to prevent shingles by effecting immunity before an outbreak of shingles takes place. [Zostavax's](#) effective rate is around 50% and wanes over time. The effectiveness also declines with the age of the patient. Merck concedes that an immunocompetent adult who receives [Zostavax](#) can develop shingles from the live-attenuated virus but contends that such an occurrence is extremely rare. It maintains there is only one known case of this happening. The plaintiffs reference evidence which in their view establishes that [Zostavax](#) causes shingles in 15% or more of those inoculated.

Each plaintiff has alleged that he or she contracted shingles as a result of being inoculated with [Zostavax](#). None has undergone a [polymerase chain reaction](#) assay, known as a PCR test, which can reliably discern between the live-attenuated and wild-type strains. Rather, each plaintiff relies on the specific causation opinion to be offered at trial by Dr. Poznansky. He has prepared an initial report as well as two rebuttal reports on each plaintiff and has been deposed. Each report predominates with a discussion of the nature of [Zostavax](#) and its general capacity to cause shingles. Each then turns to the specific circumstances of the subject plaintiff.²

[Rule 702 of the Federal Rules of Evidence](#) provides that:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- *678 (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Our Court of Appeals has described [Rule 702](#) as requiring expert testimony to meet three standards: (1) qualification, (2) reliability, and (3) fit. See, e.g., [Schneider ex rel. Estate of Schneider v. Fried](#), 320 F.3d 396, 404 (3d Cir. 2003).

The court operates in a “gatekeeping role” that ensures that the testimony “both rests on a reliable foundation and is relevant to the task at hand.” [Daubert](#), 509 U.S. at 597, 113 S.Ct. 2786. This gatekeeping prevents opinion testimony that does not meet these requirements from reaching the jury. [Schneider](#), 320 F.3d at 404. The party presenting the expert need not show that the opinions of the expert are correct but rather that by a preponderance of the evidence the opinions of the expert are reliable. [In re Paoli R.R. Yard PCB Litig.](#), 35 F.3d 717, 744 (3d Cir. 1994). This inquiry under [Rule 702](#) is a “flexible one” that is focused “solely on principles and methodology, not on the conclusions that they generate.” [Daubert](#), 509 U.S. at 594-95, 113 S.Ct. 2786. Instead “[t]he analysis of the conclusions themselves is for the trier of fact.” [Kannankeril v. Terminix Int'l, Inc.](#), 128 F.3d 802, 807 (3d Cir. 1997).

First, defendants challenge in passing the qualifications of Dr. Poznansky. He is a professor at Harvard Medical School and has practiced in the field of infections, diseases, and immunology for almost four decades. For more than a decade, he has served as the Director of the Vaccine and Immunotherapy Center at Massachusetts General Hospital. While he has no experience with

patients who have been inoculated with Zostavax, his experience and formal qualifications are sufficient to meet the less than stringent standards to qualify as an expert here. See [Paoli](#), 35 F.3d at 741. Moving on from Dr. Poznansky's qualifications, defendants do not challenge the “fit” of his opinions.

Defendants focus their challenge on the reliability of Dr. Poznansky's methods. The judge as the gatekeeper may find flaws in an expert's methodology, disagree with the conclusions of the expert, and believe there are better grounds for a different conclusion but still permit the expert to testify because there are “good grounds to hold the opinion that he or she does even though the judge thinks that the opinion is incorrect.” [Paoli](#), 35 F.3d at 744. Nonetheless, as stated in [Paoli](#),

[Daubert](#)’s requirement that the expert testify to scientific knowledge--conclusions supported by good grounds for each step in the analysis--means that any step that renders the analysis unreliable under the [Daubert](#) factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.

[Id.](#) at 745.

The defendants’ central argument is that Dr. Poznansky did not perform a proper differential diagnosis necessary to offer reliable opinions that [Zostavax](#) caused the outbreak of shingles experienced by the five plaintiffs. In other words, defendants maintain his methodology was flawed in that he did not have good grounds for each step in his analysis. Plaintiffs do not dispute that the use of a differential diagnosis by their expert is necessary. They argue he has done so and can meet their burden of proof.

As explained by our Court of Appeals in [Kannankeril](#),

***679** We have recognized ‘differential diagnosis’ as a technique that involves assessing causation with respect to a particular individual. Differential diagnosis is defined for physicians as ‘the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings.’

128 F.3d at 807 (citations omitted).

A differential diagnosis is the hallmark of internal medicine and is used to rule in or out alternative causes. [Paoli](#), 35 F.3d at 756. However, the expert must rule out, not all other possible causes, but only obvious alternative causes. [Heller v. Shaw Indus., Inc.](#), 167 F.3d 146, 156 (3d Cir. 1999). In excluding an alternative cause, the expert must provide “good grounds” for doing so. [Paoli](#), 35 F.3d at 743.

The expert may rely on various types of relevant medical information such as a physical examination, medical records, tests, medical literature, and experience. See [Heller v. Shaw Indus., Inc.](#), 167 F.3d 146, 155-56. The expert need not make use of all of these techniques to render a reliable diagnosis. [Kannankeril](#), 128 F.3d at 807.

A medical expert, however, must do more than simply pronounce an opinion that Zostavax caused a plaintiff's injuries. As the Supreme Court has declared on several occasions, the ipse dixit of the expert as the only connection to the underlying data is insufficient to establish reliability. [Kumho Tire Co. v. Carmichael](#), 526 U.S. 137, 157, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999); [Gen. Elec. Co. v. Joiner](#), 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997).

It is undisputed that all five plaintiffs here had had [chickenpox](#) and that all received the [Zostavax](#) vaccine at some point prior to developing shingles. There is no doubt that defendants have presented an obvious alternative cause of the plaintiffs’ shingles, that is, the activation of the natural wild-type virus latent in their bodies.

The court now turns to the specific causation opinions Dr. Poznansky has rendered as to each of the five plaintiffs, beginning with John Michael Bush. Dr. Poznansky has not examined or spoken to Mr. Bush and never saw a visual image of his rash or the condition of his eye where the rash manifested itself. He has read Mr. Bush's deposition and the deposition of a treating physician and reviewed his medical records. He is also familiar with [Zostavax](#) and the relevant literature.

Mr. Bush was aged 60 at the time of his vaccine and has [Type 2 diabetes](#) and other medical issues. His shingles developed some four months after he was inoculated with [Zostavax](#) and manifested itself in the inner corner of his eye and the left side of his scalp. He continues to have vision problems.

Dr. Poznansky opined that the [Zostavax](#) was the cause of his injuries. In his expert reports, Dr. Poznansky first goes into great detail about [Zostavax](#) containing a live-attenuated virus and its ability to cause shingles. In the causation section of his initial report, he concludes that there is “a clear temporal link” between Mr. Bush's [vaccination](#) and the occurrence of shingles based on the four-month interval between the two events. In support of causation as a result of this temporal link, he writes:

Simply stated, the administration of a live virus that had only been attenuated on epithelial cell lines in vitro was capable of establishing an infection in the vaccinated infection that subsequently *680 established latency and then reactivation in the patient's eye.

He then adds:

It is more than likely scientifically and medically than not that [Zostavax](#) induced more risk and harm than benefit in this patient after [vaccination](#) on the 7th of July, 2017 resulting in further prolonged VZV reactivation and OD requiring treatment with courses of [ValAcyclovir](#).

Dr. Poznansky concludes in support of his opinion that Mr. Bush's rash was “proximal” to the [vaccination](#), had no stress or condition which made him vulnerable to the wild-type virus, and had not been exposed to children with active [chicken pox](#).

In his expert reports, Dr. Poznansky records that Mr. Bush and all the other plaintiffs were immunocompetent when they were inoculated with [Zostavax](#). To the extent that he relies on this fact to support his specific causation opinions, he never explains why it means that [Zostavax](#) was the cause of their shingles rather than the wild-type virus latent in their systems. Zostavax is designed only for immunocompetent individuals. If immunocompetent individuals could not contract shingles, there would be no reason for [Zostavax](#). He cites no literature, personal experience, or other reliable source to support his opinion on this issue.

Plaintiffs also assert that Dr. Poznansky's causation opinion relies on the physical appearance of the rash of Mr. Bush and the other plaintiffs which in his view differs from that of the rash caused by the wild-type virus. Again, he never states his reasoning for this conclusion. He cites no supporting scientific or medical studies.³ Merck references relevant literature to the contrary. Further, he never saw images of the rashes of any of the plaintiffs and has never seen or diagnosed a patient with Zostavax-caused shingles. Thus he cannot rely on his experience. Again, the court has before it nothing more than an ipse dixit pronouncement.

When asked at his deposition for the basis of his opinion that Zostavax caused the onset of Mr. Bush's shingles, Dr. Poznansky replied:

Simply that that's a live virus vaccine that when injected into the arm has this potential to spread either by local transmission or by systemic transmission to the eye and thereby induce the VZV.

Poznansky Dep. 347:5–9.

There followed this additional question and answer:

***681** Q. How did you rule out reactivation of the -- of Mr. Bush's wild-type VZV coincidentally four months after he was vaccinated with [Zostavax](#)?

A. Because, again, in order of likelihood, it was much more likely than not, having received an injection of the live virus, that that was the cause of his shingles, rather than reactivation of a virus that we don't actually have definitive evidence for that he had prior to his [Zostavax](#) injection, although we have definitive evidence that he was injected with a live [herpes zoster](#) virus Oka strain.

Id. at 348:8–18.

Dr. Poznansky has stated and repeated in great detail that Zostavax can cause shingles and then leaps to his unsupported bare-bones conclusion that it is more likely than not that it caused shingles experienced by Mr. Bush. As noted, Dr. Poznansky primarily relies on the temporal relationship of four months between inoculation and the appearance of shingles to support his opinion. A strong temporal relationship between the receipt of the Zostavax vaccine and the onset of shingles can support a reliable medical opinion that [Zostavax](#) was the cause of the shingles. However, there is a significant caveat. The Court of Appeals in [Heller](#) cautioned that such a conclusion is reliable only if it is “part of a standard differential diagnosis.” 167 F.3d at 158. As illustrated above, Dr. Poznansky provides no basis that a four-month timeframe supports a strong temporal relationship. As explained later, reliance on a temporal link by itself is fallacious. In essence, Dr. Poznansky's opinion as to causation rests simply on the fact that Mr. Bush was inoculated with Zostavax.

Furthermore, Dr. Poznansky has not provided any grounds to rule out the reactivation of the wild-type virus as the cause of Mr. Bush's shingles, admittedly an obvious alternative cause advanced by Merck. Even if he properly ruled in [Zostavax](#) as the cause, Dr. Poznansky has at best reached second base without advancing to home plate. His opinion that Zostavax was the culprit without making any attempt to rule out the wild-type virus is simply an *ipse dixit* frowned upon by the Supreme Court. [Kumho Tire](#), 526 U.S. at 157, 119 S.Ct. 1167; [Joiner](#), 522 U.S. at 146, 118 S.Ct. 512. In a word, Dr. Poznansky has not conducted a valid differential diagnosis for Mr. Bush, and his opinion about specific causation of Mr. Bush's injuries is not reliable. His opinion will not be received into evidence.

The court next turns to plaintiff Richard Doman. At the time he received the [Zostavax vaccination](#) in December 2015, he was in his mid-60s. He did not experience symptoms of shingles until January 3, 2017, over a year later and then on the right side of his neck and behind his right ear. Several weeks later the lesions had resolved.

Dr. Poznansky reviewed the deposition of Mr. Doman and a treating physician as well as plaintiff's medical records. He never examined or spoke to Mr. Doman and never saw a visual image of his rash. Dr. Poznansky opined that the [Zostavax](#) vaccine caused the onset of his shingles.

There was evidence that Mr. Doman had stress in his life. Dr. Poznansky, however, conceded that stress can cause the wild-type virus to reactivate. He also opined, “significant stress is certainly associated with that. And it can equivalently reactivate OKA [live-attenuated] strain, as it can reactivate wild-type virus.” Poznansky Dep. 285:4–7. Thus, since stress can activate shingles whether or not a person has received the vaccine, any reliance on stress as causing shingles from the live-attenuated virus as opposed to the wild-type virus cannot stand.

***682** Dr. Poznansky, as with Mr. Bush, relies on the immunocompetence of Mr. Doman and the appearance of his shingles rash in formulating his opinion. He again states no reliable methodology as to these points. Dr. Poznansky strongly focuses on the twelve-month period between Mr. Doman's injection with [Zostavax](#) and the appearance of his shingles as the crucial temporal link from which he draws the conclusion that the live-attenuated virus was more likely to have caused his shingles than the reactivation wild-type already in his body. He merely writes in the causation section of his initial report:

It is more likely scientifically and medically than not that [Zostavax](#) induced more risk and harm than benefit in this patient after [vaccination](#) on the 24th of December 2015 resulting in further prolonged VZV latency and then reactivation one year later.

At his deposition, he testified in a conclusory manner as to why he ranked Zostavax as the cause:

I'm talking about how I ranked [Zostavax](#) as a cause of the patient's rash, as the more-likely-than-not cause of his shingles. So -- in both of these cases. So while, as I said, wild-type reactivation is on the differential, it's much less likely than the fact that he had actually received the [Zostavax](#) that we know can cause shingles, and we know that it -- you know, that patients who have had the [Zostavax](#) developed rashes and so forth as a result of it. And therefore, given that, it's more likely than not --

You know, if -- that's the point: We're not -- we have a differential. We're not saying that wild-type is impossible; it's just much less possible than the Zostavax, which is a live virus and we know can cause shingles and we know that it can go latent and reactivate and disseminate and all the rest of it. We know that.

Poznansky Dep. 290:7–25.

Dr. Poznansky has simply jumped to his conclusion that Zostavax is more likely than not to have caused Mr. Doman's illness merely because Mr. Doman received the vaccine. He never outlined any basis, let alone a reasonable basis, to rule out the wild-type virus as the cause. This ipse dixit formulation is not a reliable differential diagnosis. His testimony will be excluded.

The third plaintiff is Sue A. Elmegreen who is now deceased. She received the [Zostavax vaccination](#) on May 21, 2015 when she was 60 years old. Seven days later she experienced a rash on her labia and her lower back. Pain and other symptoms continued in that area in 2016 through January 2019. According to Dr. Poznansky she also suffered from worsening vision and insomnia. Dr. Poznansky reviewed her deposition and those of two of her physicians as well as her medical records. He never examined or spoke to her and never saw a visual image of any rash. She had also suffered from significant stress and anxiety for which she was taking medication. She was alienated from her mother and other members of her family and had been the subject of sexual harassment in the workplace. In addition, she had cold sores and she had suffered injuries due to a fall.

Dr. Poznansky pursued the same type of analysis here as he did with Mr. Bush and Mr. Doman. It is particularly problematic for him to assert she was immunocompetent when her undisputed medical and personal history established the contrary. His conclusion about the image of her rash which he never saw is likewise unreliable as discussed above. These factors, however, appear to be asides to his emphasis on the temporal link. He opined in the causation part of his initial report:

This patient demonstrates a clear temporal relationship between inoculation *683 and therefore infection with the [Zostavax](#) containing Oka strain VZV and disease resulting from it 7 days later and then extending for years beyond this with chronic manifestations entirely concordant with post Herpetic [neuropathy](#).

He then explains:

Furthermore, the Oka strain virus is capable of undergoing latency and entering into a dormant infection of nerve cells that supply the right buttock and labia of the vaccinated individual. When the Oka virus reactivates in this setting it can generate both localized and systemic infection in the skin and nerve supply to the patient's perineum and buttock.

He opines to a reasonable degree of medical certainty that [Zostavax](#) caused her shingles condition. His opinion is merely conclusory. Again at no point in his diagnosis of Ms. Elmegreen does he ever attempt to rule out the wild-type virus as the cause of her condition. Of course, the temporal link of seven days between her receipt of [Zostavax](#) and the appearance of shingles is much closer than in the cases of Mr. Bush and Mr. Doman. One might easily but wrongly assume a causal connection as a result. Reliable expert medical testimony, not lay assumptions or guesswork, is required under [Daubert](#). Here, Merck has presented an obvious alternative cause. The court cannot admit expert testimony based solely on the *post hoc ergo propter hoc* fallacy, that is, the fallacy that the mere happening of an event such as a [vaccination](#) injection must be the cause of a later happening such as an illness or injury. See [McClain v. Metabolife Int'l, Inc.](#), 401 F.3d 1233, 1243 (11th Cir. 2005); [Ohio v. U.S. Dep't of Interior](#), 880 F.2d 432, 473 (D.C. Cir. 1989). As previously explained, our Court of Appeals in [Heller](#) has made clear that any reliance on a temporal link alone is insufficient unless it is part of a differential diagnosis. 167 F.3d at 158. The recurring problem is that Dr. Poznansky does little more than rely on the temporal link. He cites no medical literature or data and does not rely on his own experience as a treating physician since he has never treated or seen a person with [Zostavax](#) related shingles. He never makes a differential diagnosis and never states any good grounds for ruling in the live-attenuated virus or ruling out the wild-type virus. His opinion is simply *ipse dixit*. Thus, he may not testify as a causation expert for the late Ms. Elmegreen.

The next bellwether plaintiff is John Niedzialowski, who was aged 77 at the time of his [Zostavax vaccination](#) on March 28, 2012 and who had various underlying conditions at the time. It was not until June 27, 2016, over four years later, that he experienced a red rash to his lower rib cage area. Dr. Poznansky reviewed the depositions of Mr. Niedzialowski and of his physician as well as his medical records used at his physician's deposition. He never examined or spoke to Mr. Niedzialowski, and he has never seen an image of his rash.

After repeating the language in the other reports of his conclusory opinion that [Zostavax](#) can cause shingles, he opines in the causation section of his report as to John Niedzialowski:

It is more than likely scientifically and medically that [Zostavax](#) induced more risk than benefit after [vaccination](#) on the 28th of March, 2012 disseminating through the body of the recipient and then resulting in it entering a latent phase of infection in the nerve cells supplying the patient's rib cage. This latent virus infection then reactivated in June 2016. This timeline between [Zostavax](#) administration and reactivation of its infection 4 years later is well within our *684 understanding of the capacity of a VZV strain, namely the Oka strain contained within [Zostavax](#) to establish a replicating infection first and then a [latent infection](#) subsequently that reactivates years later.

He opines to a reasonable degree of medical certainty that [Zostavax](#) caused the shingles outbreak to Mr. Niedzialowski. Dr. Poznansky's approach here is no different than in the other bellwether cases. His conclusions about immunocompetence of Mr. Niedzialowski and the image of his rash fail to advance his opinion beyond the gatekeeper. The temporal link here is over four years, much longer than in the above cases. Again, even if somehow Dr. Poznansky properly ruled [Zostavax](#) in, he never ruled the wild-type virus out. In essence, all he does is conclude that the injection of the vaccine is “a smoking gun” of causation.

Poznansky Dep. 270:19–22. He is correct only about the smoke. He does not make a reliable differential diagnosis. His ipse dixit opinion does not meet the standard of reliability to be admitted.

Finally, there is the case of Emily Sansone who has a series of underlying conditions. She received a [Zostavax](#) inoculation on September 17, 2007 and is 77 years old. Dr. Poznansky reviewed her deposition and those of two of her physicians. He also reviewed her medical and pharmacy records. Like the other plaintiffs, he has not examined or spoken to her or any of her treating physicians and does not recall seeing any visual image of her rash. On September 27, 2007, ten days after her inoculation, she experienced eye pain and a rash on the right side of her face surrounding her eye with continued complications for almost twelve years. She is now blind in her right eye.

Again, Dr. Poznansky merely relies on the same fallacious criteria as with the other plaintiffs and the short timeframe between receipt of the vaccine and the onset of her symptoms for shingles. He then immediately vaults to his opinion to a reasonable degree of medical certainty that [Zostavax](#) caused her injuries. As with the other four bellwether plaintiffs, Dr. Poznansky has failed to make a reliable differential diagnosis. Reliance on the temporal link without it being a part of a reliable differential diagnosis is of no avail. Again, plaintiffs cannot rely on the post hoc ergo propter hoc fallacy to save the day. Dr. Poznansky does not properly rule Zostavax in and does not provide any grounds, let alone good grounds, to exclude the reactivation of the wild-type virus latent in Ms. Sansone's body. The court will not permit him to offer his ipse dixit opinion testimony of causation as to Ms. Sansone.

In summary, the five plaintiffs like virtually all adults have had [chickenpox](#). As a result the five plaintiffs and virtually all adults carry in their bodies the varicella-zoster virus, that is the wild-type virus. That wild-type virus can reactivate and cause shingles. This is not an uncommon occurrence. Approximately one third of adults will experience shingles in their lifetimes. The [Zostavax](#) vaccine is designed to prevent shingles in immunocompetent adults although it has only a 50% effective rate. Thus individuals who receive the vaccine, like those who have not received the vaccine, can suffer from shingles as a result of the wild-type virus. Individuals can also suffer from shingles as a result of the vaccine which contains the live-attenuated virus.

Plaintiffs' expert Dr. Poznansky simply opines that it was the vaccine that caused their injuries without any reliable methodology. He fallaciously and indiscriminately relies on a temporal link no matter what its length — four months (Mr. Bush), one year (Mr. Doman), seven days (Ms. Elmegreen), *685 four years (Mr. Niedzialowski), and ten days (Ms. Sansone). His opinion also fails because he has not come forward with any grounds that rule out the wild-type virus as the cause. In short, he has not made the required differential diagnosis. The jury would be left with nothing but speculation as to what caused plaintiffs' shingles — the wild-type virus or the live-attenuated virus. The law however does not countenance speculation. It requires sufficient evidence to enable plaintiffs to sustain their burden of proof. From the parts of the record to which plaintiffs refer in their briefs, such evidence complying with [Daubert](#) is lacking.

Our Court of Appeals has stated that “judges are not like pigs, hunting for truffles in the record.” [United States v. Morton](#), 993 F.3d 198, 204 n.10 (3d Cir. 2021) (quoting [Doebler's Pa. Hybrids, Inc. v. Doeblor](#), 442 F.3d 812, 820 n.8 (3d Cir. 2006)). The record here is sizeable. During the lengthy oral argument on the pending motion, the court asked plaintiffs' counsel to guide the court to the place or places in the expert reports or the deposition of Dr. Poznansky where he ruled out the reactivation of wild-type virus as the cause of shingles suffered by the plaintiffs. Counsel, with appreciated candor, conceded that there is nothing to this effect as to any plaintiff in Dr. Poznansky's initial and third reports and nothing explicit in his second report. Likewise, counsel could not cite anything on point in Dr. Poznansky's deposition. At best, according to counsel, any ruling out of the wild-type virus is implicit or must be inferred. Unfortunately for plaintiffs, no straining or stretching of the words of Dr. Poznansky can satisfy [Daubert](#) or [Rule 702 of the Federal Rules of Evidence](#).

Accordingly, the motion of Merck to exclude the specific causation opinion testimony of Mark Poznansky, M.D. as to each of the five bellwether plaintiffs will be granted.

PRETRIAL ORDER NO. 409

AND NOW, this 1st day of December, 2021, for the reasons stated in the foregoing Memorandum, it is hereby ORDERED that the motion of defendants Merck & Co., and Merck Sharpe & Dohme Corp. to exclude the specific causation opinions of Mark Poznansky, M.D. in the above five actions is GRANTED.

All Citations

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Footnotes

- 1 The spouses of several of the lead plaintiffs assert loss of consortium claims.
- 2 In another motion, Merck challenges Dr. Poznansky's general causation opinions as they relate to Zostavax. That issue is not relevant for the present motion.
- 3 Plaintiffs rely solely on an internal Merck documents which states in relevant part:

The protocol anticipates that the vaccine may modify the clinical findings of [herpes zoster] from the classic vesicular pattern to a maculopapular rash. The vaccine may also modify the associated viral burden, such that individual lesions may be associated with fewer virus particles that are present for a shorter period of time. How the laboratory assays perform in the context of vaccine-modified [herpes zoster] represents the most important scientific issue facing this trial. It is possible that the laboratory assays will be more likely to miss virus present in HZ cases occurring among vaccine recipients as compared with placebo recipients. This could result in an overestimate of vaccine efficacy.

This document simply notes that the shingles rash of persons who have previously received the Zostavax vaccine may have a different appearance from the rash of persons who experience shingles but who did not receive the vaccine. It does not conclude that the rash of someone who contracts shingles because of the vaccine is different from the rash of someone who received the vaccine but develops shingles from the wild-type virus. Again, Zostavax, which is designed to prevent shingles, is only 50% effective. It is undisputed that persons inoculated with the vaccine can still experience shingles from the wild-type virus in their systems.