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FILED

August 30, 2024

HON. BRUCE J. KAPLAN, J.S.C.

IN RE: ZOSTAVAX LITIGATION

Mercedes Deville v. Merck & Co., Inc. and Merck Sharp & Dohme Corp.,
Docket No.: MID-L-006398-18

Marilyn Meuse v. Merck & Co., Inc. and Merck Sharp & Dohme Corp., Docket No.: MID-L-003561-20

Thomas Szeklinski and Linda Szeklinski v. Merck & Co., Inc. and Merck Sharp & Dohme Corp.,
Docket No.: MID-L-004940-20

Robert Walker v. Merck & Co., Inc. and Merck Sharp & Dohme Corp.,
Docket No.: MID-L-003429-20

SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY

MCL NO. 629

DEFENDANTS' MOTION TO EXCLUDE SPECIFIC CAUSATION OPINIONS OF MARK POZNANSKY, M.D.

ORDER

THIS MATTER having been brought before the Court upon motion by Fox Rothschild LLP, attorney for Defendants, Merck & Co., Inc., and Merck Sharp & Dohme Corp., for an Order to exclude the specific causation opinions of Mark Poznansky, M.D., and the Court having

considered the papers submitted in this matter, opposition filed, reply, arguments of counsel at oral argument on March 21, 2024, and for good cause having been shown;

IT IS on this 30th day of August 2024:

ORDERED that Defendants' motion to exclude the specific causation opinions of Mark Poznansky, M.D., is hereby **GRANTED**; and it is further

ORDERED that the expert opinions of Dr. Poznansky for the Plaintiffs listed in Merck's Motion are **BARRED** and shall be **INADMISSIBLE** at trial; and it is further

ORDERED that service of this Order shall be deemed effectuated upon all parties upon its upload to eCourts. Pursuant to Rule 1:5-1(a), movant shall serve a copy of this Order on all parties not served electronically within seven (7) days of the date of this order.

BY THE COURT:

/S/ Bruce J. Kaplan

OPPOSED

HONORABLE BRUCE J. KAPLAN, J.S.C.

SEE MEMORANDUM OPINION ATTACHED

PURSUANT TO RULES 1:6-2(f) AND 1:7-4(a) THE COURT PROVIDES THE FOLLOWING FINDINGS OF FACT AND CONCLUSIONS OF LAW.

HON. BRUCE J. KAPLAN, J.S.C.

This matter originally came before the Court by way of Defendant, Merck & Co., Inc. and Merck Sharp & Dohme Corp.'s (collectively, "Merck") (hereinafter, "Defendant"), Motion to Bar the Specific Causation Opinions of Plaintiffs' expert Mark C. Poznansky, M.D., Ph.D., (hereinafter, "Dr. Poznansky") as it relates to the four bellwether Plaintiffs selected (Mercedes Deville - MID-L-006398-18; Marilyn Meuse - MID-L-003561-20; Thomas Szeklinski - MID-L-004940-20; Robert Walker - MID-L-003429-20, collectively, "Plaintiffs") who are the subject of this motion. The Court has received and considered Plaintiffs' Opposition, Defendant's Reply and all exhibits attached thereto. Further, the Court offered both Plaintiffs and Defendant the ability to conduct a 104 hearing, which was declined by both parties, on the record, during the March 21, 2024, oral argument.

PROCEDURAL HISTORY

By way of relevant procedural history, this is the second round of motions that seek to bar the expert opinion of Dr. Poznansky. Over two years ago on June 13, 2022, Merck filed their first motion to exclude the specific causation opinions of Dr. Poznansky. Plaintiff filed an opposition to Merck's motion on July 11, 2022. Merck filed a reply in support of its motion on July 25, 2022, and Plaintiff filed a sur reply on September 5, 2022. On December 1, 2022, the Court held oral

argument on Merck's motion. Two months later, on February 16, 2023, the Court held a Rule 104 hearing to obtain testimony from Dr. Poznansky.

This Court, by way of written opinion dated April 17, 2023, barred Dr. Poznansky's differential diagnosis opinion rendered on behalf of the first six bellwether plaintiffs in this litigation. After this Court barred the specific causation opinions of Dr. Poznansky, Merck filed summary judgment motions on May 16, 2023, for all six of the Group A bellwether Plaintiffs (John S. Wesselink - MID-L-005719-20; Alise Plumb - MID-L-005476-20; Sharon Gollakner - MID-L-000561-19; Gorman Swinney - MID-L-007918-18; Rudolph Iannaci - MID-L-003315-20; Barbara Anne Williams - MID-L-008637-18, collectively, "prior Plaintiffs") based on those Plaintiffs' failure to produce admissible expert testimony to prove specific causation. See Order, In re Zostavax, No. 629 (Apr. 17, 2023).

On May 16, 2023, pursuant to the motion to exclude, Defendant moved for summary judgment motions on all six bellwether Plaintiffs. On June 29, 2023, this Court granted Merck's motions for summary judgment finding that the specific causation issues in this case are esoteric, require expert testimony to aid the trier of fact to form a valid conclusion, and the prior Plaintiffs had failed to provide an expert. Following that decision, appeals were timely filed by all prior Plaintiffs on August 14, 2023, however, those appeals were later voluntarily withdrawn by Plaintiffs' counsel.

At the same time, on May 31, 2023, Merck entered a motion seeking a Lone Pine order that would require all of the Group A Bellwether plaintiffs' remaining in the MCL to produce, to the extent they exist, any strain-identification laboratory test results confirming the presence of vaccine-strain shingles, through the use of a polymerase chain reaction assay testing (hereinafter "PCR tests" or "PCR") and permitting Merck to move for dispositive relief in cases where

plaintiffs failed to provide such evidence. Oral argument was held on the Lone Pine motion on July 18, 2023.

Despite the requested relief by Defendants, the Lone Pine order entered on August 16, 2023, struck a more lenient tone and allowed another opportunity for Plaintiffs to present their case on specific causation. CMO No. 34. At that time the Court ruled that while a Lone Pine order was necessary for Plaintiffs to demonstrate a prima facie case, it held short of requiring a PCR test to do so. CMO No. 34 However, the Court expressed weariness of a rehashing of the same arguments at the expense of all parties. Accordingly, the Court entered a more focused discovery schedule focusing on the specific causation of shingles and holding other discovery issues in abeyance until that issue was resolved. The Lone Pine order stayed additional discovery and required Plaintiffs to produce four specific causation expert reports. The Court ultimately ruled if it finds the specific causation opinions of Plaintiffs' expert admissible, then additional fact and expert discovery shall occur for the second bellwether trial pool. CMO No. 34 at 17. However, if the Court does not find said opinions admissible, then Merck shall refile their proposed Lone Pine order and the Court will grant it in its entirety. CMO No. 34 at 17.

To the credit of all counsel, that Lone Pine order was dutifully followed and led this Court back to the same position less than a year later. Dr. Poznansky was once again retained by the Plaintiffs to author four more expert opinions on behalf of each of the Plaintiffs. Dr. Poznansky subsequently authored four largely identical specific causation reports on October 31, 2023. Dr. Poznansky was then deposed on December 4, 2023. Thereafter, the Court received Defendant's Motion to Bar on December 29, 2023, Plaintiffs filed their opposition on January 19, 2024, and Defendant filed their reply on February 2, 2024.

After reviewing the submissions of the parties in their moving papers, the Court questioned the Plaintiffs' counsel at the February 6, 2024, liaison counsel meeting whether they would be continuing to prosecute the bellwether Plaintiff case of Mercedes Deville. The issue was raised by the Court based on Dr. Poznansky's deposition testimony, which seemed to indicate that he was not confident within a degree of medical certainty that Mercedes Deville's shingles were caused by Zostavax. 12/4/23 Poznansky Dep. at 49:7-11. This was due, in part, according to Dr. Poznansky, because of factors he was not aware of at the time of authoring his report but subsequently became aware of in preparing for his deposition. 12/4/23 Poznansky Dep. at 47:2-8. The Plaintiffs then voluntarily dismissed Mercedes Deville from this litigation on March 12, 2024. Oral argument on the three remaining motions to bar Dr. Poznansky's opinion were then heard on March 21, 2024.

Subsequent, to the oral argument, but prior to the 104 hearing, at the request of both the parties, the Court on May 24, 2024, stayed the litigation until June 19, 2024. On June 19, 2024, the Court continued the stay until November 1, 2024, or further order of the Court. Within the order the Court stated: "[t]he stay order will not prohibit the Court from entering a final order on the motion to bar the opinion of Dr. Poznansky currently pending in this litigation." 6/19/24 Stay Order. Therefore, at this juncture, the Court will exercise its discretion and rule on the pending motion.

In doing so, the Court is aware that it had advised counsel that despite both parties affirmatively waiving the Court's offer for a 104 hearing, the Court did believe it needed to hear additional testimony from Dr. Poznansky in a 104 hearing. After further review of the record, the Court agrees with both parties and has determined a 104 hearing is not necessary, and a decision can be made on the record currently before the Court, this opinion follows.

INTRODUCTION

On July 17, 2018, our New Jersey Supreme Court designated In re Zostavax Litigation, as a multi-county litigation ("MCL") and centralized case management to the Superior Court in Middlesex County. See New Jersey Supreme Court Order, dated July 17, 2018; see also Judge Grant's Notice to the Bar, dated August 15, 2018. The plaintiffs in this MCL all received the Zostavax vaccine for the prevention of shingles. Pursuant to this Court's June 19, 2019, CMO: Bellwether Selection and Scheduling, two groups of plaintiffs were identified for discovery purposes. Group A plaintiffs received the Zostavax vaccine and allege that he or she subsequently developed shingles.

Group B plaintiffs also received the Zostavax vaccine but allege that they subsequently developed a condition other than shingles. Pursuant to that same CMO, the focus of discovery efforts thus far has been on Group A plaintiffs. It is from this pool of plaintiffs that the bellwether plaintiffs were selected, and this motion arises.

In each of these four opinions that the Defendant now seeks to bar, Dr. Poznansky found general and specific causation. Dr. Poznansky opined that within a reasonable degree of medical certainty the cause of shingles for each bellwether plaintiff was more likely than not the Zostavax vaccine. Dr. Poznansky reached this opinion using a differential diagnosis.[1]

The narrow issue in this motion is the admissibility of Dr. Poznansky's expert opinion. Specifically, the ability for Dr. Poznansky to offer a specific causation opinion within a reasonable degree of medical certainty as to the cause of shingles of these four bellwether Plaintiffs.

[1] Dr. Poznansky and Plaintiffs' Counsel interchangeably use differential diagnosis, etiologic diagnosis, differential etiology, Bayesian probabilities, Bayesian reasoning, and Bayesian reasoning process to describe Dr. Poznansky's methodology. The Court notes that despite the name difference, all the forementioned processes involve ruling in and ruling out causes of an injury by way of assigning weight to various factors or data points.

ZOSTAVAX BACKGROUND

Chickenpox (varicella) is caused by the varicella zoster virus (hereinafter "VZV"). Once in the body, that virus remains latent in the dorsal root ganglia and if reactivated, can re-emerge as herpes zoster or zoster (hereinafter, "shingles"). M.N. Oxman et al., *A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults*, 352:22 NEW ENG. J. MED. 2271, 2272 (2005).

In 2005, after completing phase three clinical trials, Merck submitted a license application to the Food and Drug Administration (hereinafter, "FDA") for an attenuated vaccine, labeled Zostavax, for the prevention of shingles. Rafael Harpaz et al., *Prevention of Herpes Zoster Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 57 MORBIDITY & MORTALITY WKLY. REP. (MMWR) 1, 2 (2008). Those trials consisted of more than 58,000 vaccine recipients and included the Shingles Prevention Study (hereinafter, "SPS") and the Zostavax Efficacy and Safety Trial (hereinafter, "ZEST"). English D. Willis et al., *Herpes Zoster Vaccine Live: A 10 Year Review of Post-Marketing Safety Experience*, 35 VACCINE 7231, 7232 (2017). The phase three clinical trials found that Zostavax's efficacy to protect against shingles was 51% for persons sixty-years-old and older; 69.8% in persons fifty to fifty-nine-years-old; additionally, the trials found that Zostavax's efficacy wanes with time—lasting eight years. Id. at 7231. All phase three clinical trials concluded that Zostavax was a safe and effective measure to protect against shingles. Rafael Harpaz et al., at 15-19.

In 2006, the FDA granted Merck's application and officially licensed Zostavax as a single dose, live-attenuated vaccine for persons fifty-years-old and older. English D. Willis et al., at 7231; Rafael Harpaz et al., at 1. However, Zostavax was contraindicated for immunocompromised persons. Rafael Harpaz et al., at 20. The Kaiser Permanente Northern California (hereinafter

"KPNC") and Centers for Disease Control and Prevention (hereinafter "CDC") performed extensive post-licensure studies which confirmed the findings of phase three clinical trials—Zostavax "is generally safe and well tolerated in routine conditions of use." Id. at 7232. Ten years later, after the administration of more than thirty-four million vaccines, Zostavax's safety record "remains favorable and consistent with that observed in clinical trials and post-licensure studies." English D. Willis et al., at 7231, 7237 (explaining that adverse experiences caused by Zostavax were rarely reported and primarily occurred in individuals who should not have received the vaccine).

The allegation in this case involves the development of shingles after receiving the Zostavax vaccine. There are essentially five ways in which these Plaintiffs could have contracted shingles, naturally, and then the four mechanisms opined by Dr. Poznansky (1) Zostavax virus (pure); (2) Combined wild strain and Zostavax rash (mixed); (3) Recombination; and (4) mutation back to wild strain, reversion to wild strain from Zostavax, or variant trending towards wild strain derived from Zostavax. See Order, In re Zostavax, No. 629 (Apr. 17, 2023). Dr. Poznansky later clarified his opinions to only include mechanisms one and two as more likely than not the cause of all bellwether plaintiffs' shingles. See Order, In re Zostavax, No. 629 (Apr. 17, 2023).

There are two potential ways that these Plaintiffs could have developed shingles. First, that their shingles were caused from a reactivation of the wild strain virus that remained latent in their nervous system, a risk that exists in anyone who had contracted chickenpox previously. M.N. Oxman et al., *A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults*, 352:22 NEW ENG. J. MED. 2271, 2272 (2005). The second possible cause would be caused from Defendant's live attenuated vaccine, which according to Dr. Poznansky either causes its own shingles reaction or wakes up the wild strain and creates a "mixed" shingles reaction. The only

definitive methodology for testing between these two causes, wild strain, and vaccine strain, is through a PCR test.

APPLICABLE LAW

In New Jersey, an expert's differential diagnosis is admissible provided compliance with those procedures as set forth by our New Jersey Supreme Court in Creanga v. Jardal, 185 N.J. 345, 357 (2005). A differential diagnosis allows an expert to make medical conclusions in situations, like ours, when essential facts are missing. Id. at 361. In said situations, a differential diagnosis does not need to prove a single theory of causation, but rather allows an expert to disprove all other causational theories. See ibid. However, "simply uttering the phrase 'differential diagnosis'" does not render and expert's opinion admissible. Ibid. An expert must follow a two-step procedure. Id. at 358. First, an expert must rule in alternative causes for the plaintiff's condition. Id. at 356. Second, an expert must rule out alternative causes that did not cause plaintiff's condition "so as to reach a conclusion as to the most likely cause of the findings in that particular case." Ibid.

An expert does not need to rule out all possible causes of a plaintiff's condition, as long as the expert performs "sufficient techniques to have good grounds" for their conclusion. Ibid. Stated differently, an expert must use "scientific methods and procedures" rather than "subjective beliefs or unsupported speculation" to rule out alternative causes. Id. at 358. If an expert "'utterly fails . . . to offer an explanation for why the proffered alternative cause' was ruled out," then a court is justified in barring the differential diagnosis. Ibid. While a differential diagnosis opinion does not require absolute certainty, the opinion must be reached within a reasonable degree of medical certainty. Id. at 362; State v. Freeman, 223 N.J. Super. 92, 116 (App. Div. 1988) (explaining that "medical expert testimony 'must be couched in terms of reasonable medical certainty or probability; opinions as to possibility are inadmissible.'").

The admission or exclusion of expert testimony lies within the sound discretion of the trial court. State v. Berry, 140 N.J. 280, 293 (1995). The Supreme Court of the United States has "reinforced that trial courts are the 'gatekeeper' tasked with screening [expert] testimony." In re Accutane Litigation, 234 N.J. 340, 400 (2018) (citing General Electric Co. v. Joiner, 522 U.S. 136, 138-39 (1997)). In doing so, our Supreme Court "stated that, in its gatekeeper role, a trial court is free to exclude expert testimony where the expert's conclusions are not sufficiently tethered to the facts or drawn from the applicable data." Id. (citing General Electric Co., 522 U.S. at 146-47).

"[New Jersey's] Rules have fixed, clear guidelines that govern the admissibility of expert opinions and against which trial courts must make their evaluations." Pomerantz Paper Corp. v. New Community Corp., 207 N.J. 344, 372 (2011).

N.J.R.E. 702 first provides that expert testimony must be offered by one who is "qualified as an expert by knowledge, skill, experience, training, or education and may testify thereto in the form of an opinion or otherwise" to "assist the trier of fact to understand the evidence or to determine a fact in issue."

N.J.R.E. 703, on the other hand, sets forth the criteria for a trial court to assess the foundation of the expert's opinion. Expert opinions must be grounded in "facts or data derived from (1) the expert's personal observations, or (2) evidence admitted at trial, or (3) data relied upon by the expert which is not necessarily admissible in evidence, but which is the type of data normally relied upon by experts." Townsend v. Pierre, 221 N.J. 36, 53 (2015) (quoting Polzo v. Cnty of Essex, 196 N.J. 569, 583 (2008)).

Of particular importance to the within motion, "a [trial] court must ensure that the proffered expert does not offer a mere net opinion." Pomerantz Paper Corp., 207 N.J. at 372. "The net opinion rule is a 'corollary of [N.J.R.E. 703] . . . which forbids the admission into evidence of an

expert's conclusions that are not supported by factual evidence or other data.'" Townsend, 221 N.J. at 53-54 (alteration in original) (quoting Polzo, 196 N.J. at 583). An expert is required to "give the why and wherefore' that supports the opinion 'rather than a mere conclusion.'" Id. at 54 (citation omitted). To do so, an expert witness must "identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and the methodology are reliable." Id. at 55 (quoting Landrigan v. Celotex Corp., 127 N.J. 404, 417 (1992)). "The net opinion rule is succinctly defined as "a prohibition against speculative testimony." Harte v. Hand, 433 N.J. Super. 457, 465 (App. Div. 2013) (quoting Grzanka v. Pfeifer, 301 N.J. Super. 563, 580 (App. Div.), certif. denied, 154 N.J. 607 (1997)).

"[I]f an expert cannot offer objective support for his or her opinions but testifies only to a view about a standard that is 'personal,' it fails because it is a mere net opinion.'" Pomerantz Paper Corp., 207 N.J. at 373. Expert opinions must relate to generally accepted standards in that individual's field of expertise. Buckelew, 87 N.J. at 528-29; see also Taylor v. DeLosso, 319 N.J. Super. 174, 180 (App. Div. 1999) (quoting Fernandez v. Baruch, 52 N.J. 127, 131 (1968) ("The expert testimony must relate to generally accepted . . . standards, not merely to standards personal to the witness."); Kaplan v. Skoloff & Wolfe, P.C., 339 N.J. Super. 97, 103 (App. Div. 2001) (discussing that the Taylor Court was "concerned by 'the total absence in [plaintiff's expert's] testimony of reference to any textbook, treatise, standard, custom or recognized practice, other than his personal view."); Grzanka, 301 N.J. Super. at 581 (excluding an expert opinion where the expert was unaware of applicable specifications, did not consult with any other experts, and relied on his personal observations as sole basis for his conclusion). In sum, "a standard which is personal to the expert is equivalent to a net opinion." Taylor, 319 N.J. Super. at 180.

"A trial court may determine in a given case that 'there is simply too great an analytical gap between the data and the opinion proffered' for the expert testimony to be considered reliable. In re Accutane Litigation, 234 N.J. at 400 (quoting General Electric Co., 522 U.S. at 146-47) (explaining that an expert's conclusions and methodology "are not entirely distinct from one another."). "When a proponent does not demonstrate the soundness of a methodology, both in terms of its approach to reasoning and to its use of data, from the perspective of others within the relevant scientific community, the gatekeeper should exclude the proposed expert testimony on the basis that it is unreliable." In re Accutane Litigation, 234 N.J. 340, 400 (2018). "An opinion lacking in foundation is worthless and ceases to aid the trier of fact to understand the evidence and determine the issue." Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 526 (App. Div. 2007).

The Rubanick Court instructed courts to "consider whether others in the field use similar methodologies," and explained that the proper inquiry is whether comparable "experts in the field would actually rely on that information," Rubanick v. Witco Chem. Corp., 125 N.J. 421, 449-52 (1991). In Landrigan v. Celotex Corp., the Court elaborated: when relying on epidemiological studies, the trial court should review them and "then determine whether the expert's opinion is derived from a sound and well-founded methodology that is supported by some expert consensus in the appropriate field." Landrigan, 127 N.J. 404, 417 (1992).

Moreover, Landrigan suggested tools for trial courts to use in rendering gatekeeping determinations about the reliability of an expert's methodology when the ultimate scientific opinion is not itself generally accepted, including "reference to professional journals, texts, conferences, symposia, or judicial opinions accepting the methodology." Ibid.

A witness qualified pursuant to Rule 19 as an expert by knowledge, skill, experience, training, or education may testify in the form of opinion or otherwise as to matters requiring

scientific, technical or other specialized knowledge if such testimony will assist the trier of fact to understand the evidence or determine a fact in issue. State v. Kelly, 97 N.J. 178, 208 (1984).

The Rule imposes three basic requirements: (1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony. Ibid.

This need for supporting data and a factual basis for the expert's opinion is especially important when the opinion is seeking to establish a cause-and-effect relationship. Tabatchnick v. G.D. Searle & Co., 67 F.R.D. 49, 55 (D.N.J.1975). However, the rule frequently focuses, as in Parker v. Goldstein, 78 N.J. Super. 472, 483-484 (App. Div. 1963), certif. den. 40 N.J. 225 (1963), on the failure of the expert to explain a causal connection between the act or incident complained of and the injury or damage allegedly resulting therefrom. See Rempfer v. Deerfield Packing Corp., 4 N.J. 135, 144-145 (1950); Castroll v. Franklin Tp., 161 N.J. Super. 190, 193 (App. Div. 1978); See also Sabloff v. Yamaha Motor Co., Inc., Ltd., 113 N.J. Super. 279, 280 (App. Div. 1971), aff'd 59 N.J. 365 (1971).

While a novel opinion is not barred per se by the New Jersey Court rules, the standard experts offering an opinion must abide by is in toxic-tort litigation, a scientific theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field. Landrigan, 125 N.J. at 449. The evidence of such scientific knowledge must be proffered by an expert who is sufficiently qualified by education, knowledge, training, and experience in the specific field of science. **The expert must possess a demonstrated professional capability to assess the scientific significance of the**

underlying data and information, to apply the scientific methodology, and to explain the bases for the opinion reached. Ibid. (emphasis added).

PRIOR OPINION

The Court's April 17, 2023 Order was the culmination of a years-long process through which a fundamental threshold question for the majority of the cases remaining in this MCL has emerged: whether plaintiffs who allege that Zostavax caused them to develop shingles-related injuries can produce specific causation evidence necessary to overcome (1) the overwhelming statistical likelihood that wild-type VZV (hereinafter "wild strain"), not Zostavax (hereinafter "vaccine strain"), caused their shingles, and (2) the scientific consensus that strain-identification testing alone can identify vaccine-strain shingles. See Order, In re Zostavax, No. 629 (Apr. 17, 2023).

More specifically, the Court found that Plaintiffs had not demonstrated the soundness of Dr. Poznansky's methodology, in both terms of his approach to reasoning and to his use of data, from the perspective of others within the relevant scientific community. See Carl v. Johnson & Johnson, 464 N.J. Super. 446, 454 (App. Div. 2020). Additionally, the Court found that Dr. Poznansky's differential diagnosis failed the Daubert considerations as outlined in Accutane. The non-exhaustive list of general factors provided by the Accutane Court include:

> 1. Whether the scientific theory can be, or at any time has been, tested;
> 2. Whether the scientific theory has been subjected to peer review and publication, noting that publication is one form of peer review but is not a "sine qua non"
> 3. Whether there is any known or potential rate of error and whether there exists any standards for maintaining or controlling the technique's operation; and
> 4. Whether there does exist a general acceptance in the scientific community about the scientific theory.
>
> In re Accutane Litigation, 234 N.J. at 400.

The Court found there was simply too great an analytical gap between Dr. Poznansky's differential diagnosis and his specific causation opinions. See Order, In re Zostavax, No. 629 (Apr. 17, 2023). Instead of explaining the whys and wherefores for his opinions and providing objective support, Dr. Poznansky only offered conclusions and citations to his previous conclusions. See Ibid. Accordingly, the Court found that Dr. Poznansky had not made the required differential diagnosis and that his opinions would not "aid the trier of fact to understand the evidence and determine the issue" because they were completely devoid of any scientific foundation. Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 526 (App. Div. 2007).

The fundamental challenge that shingles-injury plaintiffs have repeatedly sought and failed to overcome is twofold. First, the universally acknowledged cause of most shingles cases is wildtype VZV – which one-third of U.S. adults will develop in their lifetimes. It is uniformly recognized in the medical literature that cases of vaccine-strain shingles are rare, and that, in the words of VZV experts from the CDC, the "overwhelming majority" of shingles cases following Zostavax administration are caused by natural reactivation of wild-type VZV, not the vaccine. See Tseng, et al., Herpes Zoster Caused by Vaccine-Strain Varicella Zoster Virus in an Immunocompetent Recipient of Zoster Vaccine, 58 CLIN. INFECT. DIS. 1125, 1127 (2014) (noting that laboratory testing of 634 vaccinees by the CDC and Merck detected only a single case of vaccine-strain shingles (.16%)).

At most, Plaintiffs experts allege that Zostavax caused 15% of shingles rashes in vaccine recipients, meaning that even under plaintiffs' scientifically unsupported theory, 85% of vaccine recipients who develop shingles do so because of reactivation of wild type virus. As the Court observed, "Dr. Poznansky fails to account for and rule out the 85% of [vaccine recipients] who did not contract shingles from Zostavax." Order, In re Zostavax, No. 629 at 46-47 (Apr. 17, 2023).

Judge Bartle similarly recognized that this 15% figure "doesn't advance the ball for proof" absent other credible evidence. See 11/17/21 MDL Hr'g Tr. at 55:20-24; 56:2-3.

Second, cases of vaccine-strain shingles do not present differently from wild-type shingles. As a result, it is uniformly recognized within the scientific community that laboratory testing is necessary to prove that a given case of shingles is one of the extremely rare cases caused by the vaccine. See CDC Surveillance Manual, https://www.cdc.gov/ vaccines/pubs/survmanual/chpt17-varicella.html at 17-3 (stating that vaccine-strain shingles "can only be confirmed" through laboratory testing).

The Court found that, when confronted with the threshold question of specific causation, plaintiffs in both this litigation and in the Zostavax MDL have failed to explain, let alone demonstrate, how they could evade established science by proving specific causation in the absence of laboratory results confirming the presence of vaccine-strain shingles. Order, In re Zostavax, No. 629 (Apr. 17, 2023).

The Court found that the Plaintiffs have repeatedly failed to explain how they can prove their cases without strain-identification testing. They failed to do so in opposition to Merck's motion to exclude Dr. Poznansky in the Zostavax MDL. They failed to do so in opposition to Merck's motion for a Lone Pine order in the MDL. They failed to do so in opposition to Merck's motion to dismiss approximately 1,200 shingles injury cases in the MDL (instead telling Judge Bartle that the theory on which they intend to rely has "been introduced in the New Jersey consolidated litigation...before the Honorable Judge Bruce J. Kaplan."). See In re Zostavax, 2:18-md-02848, (E.D. Pa. Oct. 3, 2022). And they failed to do so in opposition to Merck's motion to exclude Dr. Poznansky in this litigation. Judge Bartle, put it most succinctly, "common sense dictates that it would have surfaced by now." In re Zostavax (Zoster Vaccine Live) Prods. Liab.

Litig, 2022 WL 17477553, at *5. To the contrary, Plaintiffs have provided no reason for this Court to believe that they can overcome the obstacles to establishing specific causation in any given case without laboratory test results in hand.

Critically, the Group A Bellwether Plaintiffs could not meet their burden of proof on specific causation due to the same weakness that likely permeates other shingles injury claims – only laboratory testing can rule out wild-type shingles, the most statistically likely cause of shingles infection in any given plaintiff. Like virtually all U.S. adults, the Group A Bellwether Plaintiffs had chickenpox as children. They therefore harbored wild-type VZV, which will reactivate as wild-type shingles in one-third of U.S. adults. While each of the Group A Bellwether Plaintiffs also received Zostavax to protect against a shingles outbreak, its 51% efficacy does not guarantee protection. Against this backdrop, the Group A Bellwether Plaintiffs tried, and failed, to provide other credible evidence of specific causation through Dr. Poznansky without the benefit of PCR testing.

While Dr. Poznansky purported to conduct a differential diagnosis ruling out wild type VZV as the cause of Plaintiffs' shingles, the Court found that there was "simply too great an analytical gap between [his] differential diagnosis and his specific causation opinions, and that "[i]nstead of explaining the whys and wherefores for his opinions and providing objective support, Dr. Poznansky only offers conclusions and citations to his previous conclusions." Order, In re Zostavax, No. 629 at 47 (Apr. 17, 2023). The Court found that Dr. Poznansky thus failed to proffer objective criteria capable of ruling out wild-type shingles through a differential diagnosis, despite multiple opportunities to do so in two expert reports for each of the six Group A Bellwether Plaintiffs, deposition testimony, and Kemp hearing testimony. He likewise failed to do so in any of the three reports for each of the bellwether Plaintiffs in the Zostavax MDL.

In excluding his specific causation opinions in six different cases involving Plaintiffs with six different medical histories, the Court noted that Dr. Poznansky abandoned "opinions comparing risk percentages and assigned specific risk percentages based on age." Order, In re Zostavax, No. 629 at 45 (Apr. 17, 2023). The Court recognized that Dr. Poznansky relied on five factors as having the potential to reactivate dormant VZV—age; psychological stress; physical trauma or surgery; gender and race; and inflammatory disease, chronic disease, and use of immunosuppressant agents. See Order, In re Zostavax, No. 629 at 45 (Apr. 17, 2023). This left temporality as "the only remaining factor" and his opinion was "a one size fits all conclusion. If anyone age 60 and above receives the live attenuated Zostavax vaccine and subsequently develop shingles—then Zostavax was more likely than not the cause of their shingles. This conclusion is purely temporal and will not help the trier of fact determine the root cause." Id. at 45; see also, 12/1/22 MCL Hr'g Tr. at 155:18-22 ("The Court: I'm just having a hard time imagining any patient who is over 60 years old who receives the vaccine who ultimately gets shingles where Dr. Poznansky would not conclude it was more likely than not that it was the vOka.").

Dr. Poznansky thus failed to proffer objective criteria capable of ruling out wild-type shingles through a differential diagnosis, despite multiple opportunities to do so in two expert reports for each of the six Group A Bellwether Plaintiffs, deposition testimony, and Kemp hearing testimony. He likewise failed to do so in any of the three reports for each of the bellwether Plaintiffs in the Zostavax MDL.

Following a rejection of the opinion offered on the first set of Group A bellwethers, Dr. Poznansky presents to us a new opinion, which allegedly focuses on the deficiencies of the prior opinion, specific causation. Fast forward to today we are left with largely the same questions. The opinion of Dr. Poznansky with respect to general causation remains admissible. The ultimate

failure of Dr. Poznansky's first opinion and the issue which still plagues us today is whether he is utilizing an acceptable methodology to conclude that the Plaintiffs' individual use of the Defendants' vaccine caused them to develop shingles, this expert methodology must be sound and rely on data utilized by similar experts in this field. "An expert opinion is unreliable unless its proponent can 'demonstrate the soundness of a methodology, both in terms of its approach to reasoning and to its use of data, from the perspective of others within the relevant scientific community.'" Carl, 464 N.J. Super. 446, 454 (App. Div. 2020)

In order to better understand the opinion currently before the Court, it is important to fully review the prior, unsatisfactory opinion and note whether the deficiencies, as noted by the Court in its first opinion were adequately addressed.

The prior opinion of this Court concluded that Dr. Poznansky's differential diagnosis failed the Daubert considerations as outlined in Accutane. The Court found there was simply too great an analytical gap between Dr. Poznansky's differential diagnosis and his specific causation opinions. In re Accutane Litigation, 234 N.J. at 400. The Court found that instead of explaining the whys and wherefores for his opinions and providing objective support, Dr. Poznansky only offered conclusions and citations to his previous conclusions. See Townsend v. Pierre, 221 N.J. 36, 54-55 (2015); Pomerantz Paper Corp. v. New Community Corp., 207 N.J. 344, 373 (2011). The Court found that Dr. Poznansky's unshared theories and opinions offered in this litigation would not "aid the trier of fact to understand the evidence and determine the issue" because it was completely devoid of any scientific foundation. Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 526 (App. Div. 2007). Accordingly, the Court barred the six expert opinions offered. Therefore, critical to this Court's current opinion is a bridging of this analytical gap between the differential diagnosis and Dr. Poznansky's specific causation opinion.

ARGUMENTS OF COUNSEL

In moving to bar Dr. Poznansky's opinion, the Defendant stated Dr. Poznansky's CMI theory has already been rejected by this Court and has not changed. That the risk factors cited to by Dr. Poznansky do not move it in favor or against and therefore cannot be labeled a differential diagnosis, that Dr. Poznansky still continues to improperly use general population statistics to prove specific causation. Finally, that Dr. Poznansky's opinion on temporality, but the only basis of temporality is the vaccine occurred more recently than shingles and the temporality of the Plaintiffs' reaction from the time the vaccine is received has no impact in Dr. Poznansky's opinion. For these reasons, the Defendants state this second round of bellwethers is simply a rehashing of Dr. Poznansky's prior opinions and do not serve to add anything new to this litigation and do not provide sufficient grounds for the Court to not follow its prior opinion barring Dr. Poznansky.

In opposition, the Plaintiffs put forth several arguments in favor of their expert's testimony. First, Plaintiffs reiterate the general causation points that the vaccine can cause shingles and the studies show a low natural occurrence of shingles. Second, the Plaintiffs argue that the PCR protocol in the SPS was flawed. Third, Plaintiffs argue that a mixed reaction can occur combining both wild strain and vaccine strain shingles. Plaintiffs point to Dr. Poznansky's analysis of the specific risk factors for these Plaintiffs as further proof of Dr. Poznansky's credence in his specific causation opinion. Plaintiffs argue that latency bolsters Dr. Poznansky's specific causation opinion with latency times ranging from days to 8 years and 11 months.

In reply, Defendants reject all of these points stating that the opinion of Dr. Poznansky is nothing more than unsupported conjecture. The Defendants reiterate the Court's prior finding that the opinion of Dr. Poznansky is not shared in the scientific literature. Instead, Zostavax is routinely held to be a safe and effective way of treating shingles. Defendants state that the occurrence of

vaccine-induced shingles is extraordinarily rare and that taking even Plaintiffs' best argument, cannot prove specific causation for these Plaintiffs.

DISCUSSION

It is not in dispute that the "gold standard" for the determination of a Zostavax-induced shingles outbreak would be the utilization of a PCR test. It is also not in dispute that PCR assay testing is the only way to differentiate between these two potential causes of shingles and that no PCR assay testing was performed in this litigation. However, utilizing a differential diagnosis, Dr. Poznansky opined that within a reasonable degree of medical certainty, the cause of shingles for each bellwether Plaintiff was more likely than not the Zostavax vaccine. The operative question, therefore, is if the methodology utilized by Dr. Poznansky explains the whys and wherefores of his opinion or if, as the Defendants allege, his opinion is an impermissible net opinion that does not stand up to the standards set forth by the New Jersey Supreme Court in Accutane. While no PCR assay testing was performed for any of our bellwether Plaintiffs, assay testing is not routinely performed because the cause of a patient's shingles is not relevant for a medical professional's treatment plan. See Order, In re Zostavax, No. 629, *19 (Apr. 17, 2023).

As the Supreme Court of the United States has recognized, "[w]ithin the medical discipline, the traditional standard for 'factfinding' is a 'reasonable medical certainty.'" Addington v. Texas, 441 U.S. 418, 430 (1979). Dr. Poznansky opines that three of the four bellwether Plaintiffs satisfy this standard. The Court's role now is whether testimony is acceptable to present before a New Jersey jury. On one hand we have a Defendant who created a shingles vaccine that certainly has the capability to cause the injury that Plaintiff alleges. On the other hand, we have a Plaintiffs' expert that seems incapable of applying this generally accepted proposition to a more specific

causation with respect to the four bellwether Plaintiffs in this case. In the seminal Supreme Court case Joiner v. General Electric, Chief Justice Rehnquist stated:

> [C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the Federal Rules of Evidence require a district court to admit opinion evidence which is connected to existing data only be the *ipse dxit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.

Our Courts have found that a speculating expert "ceases to be an aid to the trier of fact and becomes nothing more than an additional juror." Jimenez v. GNOC Corp., 286 N.J. Super. 533, 540 (App. Div.) certif. denied, 145 N.J. 374 (1996). In New Jersey, an expert's differential diagnosis is admissible provided compliance with those procedures as set forth by our New Jersey Supreme Court in Creanga v. Jardal, 185 N.J. 345, 357 (2005). A differential diagnosis allows an expert to make medical conclusions in situations, like ours, when essential facts are missing. Id. at 361. In these cases, a differential diagnosis does not need to prove a single theory of causation, but rather allows an expert to disprove all other causational theories. See Ibid.

However, "simply uttering the phrase 'differential diagnosis'" does not render an expert's opinion admissible. Ibid. An expert must follow a two-step procedure. Id. at 358. First, an expert must rule in alternative causes for the plaintiff's condition. Id. at 356. Second, an expert must rule out alternative causes that did not cause plaintiff's condition "so as to reach a conclusion as to the most likely cause of the findings in that particular case." Ibid.

An expert does not need to rule out all possible causes of a plaintiff's condition, as long as the expert performs "sufficient techniques to have good grounds" for their conclusion. Ibid. Stated differently, an expert must use "scientific methods and procedures" rather than "subjective beliefs or unsupported speculation" to rule out alternative causes. Id. at 358. If an expert "'utterly fails . . . to offer an explanation for why the proffered alternative cause' was ruled out," then a court is

justified in barring the differential diagnosis. Ibid. While a differential diagnosis opinion does not require absolute certainty, the opinion must be reached within a reasonable degree of medical certainty. Id. at 362; State v. Freeman, 223 N.J. Super. 92, 116 (App. Div. 1988) (explaining that "medical expert testimony 'must be couched in terms of reasonable medical certainty or probability; opinions as to possibility are inadmissible.'").

In light of these requirements and the gatekeeping function placed upon this Court, it is imperative to take inventory on Dr. Poznansky's testimony and where it brings us today. The unfortunate reality of this case is the underlying facts of this litigation itself. Unlike many traditional toxic torts, where a diagnosis such as cancer is given and the role of the expert is to pin the cause of this cancer on a corporation releasing PCB's as was the case in Rubanick, this litigation involves the same manifestation of symptoms for all Plaintiffs and the causes have occurred likewise in each Plaintiff. See Rubanick, 125 N.J. 421 (1991). All three bellwether Plaintiffs in this case have a history of chickenpox, which means latent wild strain shingles exist in their system. Second, all Plaintiffs have received the Zostavax vaccine, which means latent vaccine strain shingles also exists in their system. The Zostavax vaccine which, like VZV, remains latent indefinitely and can reactivate at any time to cause shingles. Hung Fu Tseng et al., *Herpes Zoster Caused by Vaccine Strain Varicella Zoster Virus in an Immunocompetent Recipient of Zoster Vaccine*, 58 CLINICAL INFECTIOUS DISEASES 1125 (2014).

GENERAL POPULATION STATISTICS TO SPECIFIC CAUSATION

Plaintiffs again reiterate the ability for Zostavax to cause shingles. This is an uncontested point and supported by the documented case of Zostavax-induced shingles in an immunocompetent adult. Hung Fu Tseng et al., 1127 (2014); See In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig., Memorandum in Support of Pretrial Order No. 458 at *5. (E.D. Pa. 2022).

However, this is once again a general causation point which has been conceded. The Plaintiffs once again attempt to go beyond these general causation points in applying them to specific causation.

Initially, Dr. Poznansky attempts to draw a difference between this population who run the risk of contracting shingles either through the wild strain which has laid dormant within them or the vaccine strain which was recently introduced. "A trial court may determine in each case that 'there is simply too great an analytical gap between the data and the opinion proffered' for the expert testimony to be considered reliable." In re Accutane Litigation, 234 N.J. at 400 (quoting General Electric Co., 522 U.S. at 146-47) (explaining that an expert's conclusions and methodology "are not entirely distinct from one another.").

The Plaintiffs also argue that epidemiological studies demonstrate a low incidence rate of shingles caused by wild type. Dr. Poznansky moves on to the most critical part of his differential etiology analysis: "The most important factor in ruling out VZV wild type are the numerous published epidemiological studies cited herein demonstrating a low incident rate per 1,000 when stratified by age. The incident rates ranged from less than 1% up to 2 to 3%. See Bellwether Pl. Reports.

Plaintiffs state that numerous population studies spanning decades of data on incidence rate of HZ when stratified by age show that spontaneous reactivation for those 60 and older is an unlikely event— less than 1 per 1,000 person or less than 1% chance of the event occurring. Defense would have us accept coincidence as the most likely explanation of the plaintiffs' Harpaz et al, "The Epidemiology of Herpes Zoster in the United States During the Era of Varicella and Herpes Zoster Vaccines: Changing Patterns Among Older Adults" Clinical Infectious Diseases 2019. However, while this does give us the basic incidence rate for shingles in a population group,

there is no indication that this number is exclusive of vaccine strain shingles. Moreover, Dr. Poznansky attempts to use this unlikely general statistic to inform causation in these specific Plaintiffs, as the Court has found in its prior opinions, this type of testimony is impermissible to prove specific causation.

Further, a broader view of shingles infections paints a significantly more commonplace picture. While the incidence rate per one thousand seems relatively low, in the United States alone, 99.5% of the population above the age of 40 has the potential to develop shingles because of a previous chickenpox infection. Rafael Harpaz et al., *Prevention of Herpes Zoster Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, at 6. Moreover, one out of three people in the United States, approximately one million people annually, will develop shingles in their lifetime. Id. at 1, 9. Dr. Poznansky's opinion seems to have an undertone of "this cannot just be a coincidence" but the occurrence of shingles was common enough for a vaccine to be developed against it. Subsequent to Zostavax, a second and more effective vaccine was brought to market called Shingrix. So, while the Court recognizes the low occurrence of shingles, it is by no means unheard of.

Moving further into Dr. Poznansky methodology, he explains how he uses the 1% in his differential etiology stating, "It weighed, but there were other components in addition to it." 12/4/23 Poznansky Dep. at 75:22-25. Dr. Poznansky claims he "absolutely [did] not" compare this 1% statistic to the 15% SPS statistic. 12/4/23 Poznansky Dep. at 33:1-5; 74:22-24; 32:10-24. However, it is unclear how this statistic moves the ball forward on the specific issue of specific causation for these bellwethers. According to Dr. Poznansky's own opinion, the chance of a Zostavax recipient contracting shingles is "extremely low, but it's not zero." 12/4/23 Poznansky Dep. at 114:4-115:22.

Combining this with the fact that Zostavax is at best only 51% effective at preventing shingles, which means even once vaccinated, there is still a 49% chance of contracting naturally occurring shingles. M.N. Oxman et al., *A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults*, 352:22 NEW ENG. J. MED. 2271, 2280 (2005).

Moreover, both parties in this litigaiton also agree that Zostavax's efficacy significantly declines with time. Hung Fu Tseng et al., *Declining Effectiveness of Herpes Zoster Vaccine in Adults Ages ≥60 Years*, 213 J. INFECTIOUS DISEASES 1872, 1874 (2016) (noting a " relatively rapid decline in the effectiveness of [Zostavax]"); Hector S. Izurieta et al., *Effectiveness and Duration of Protection Provided by the Live-Attenuated Herpes Zoster Vaccine in the Medicare Population Ages 65 Years and Older*, 64 CLINICAL INFECTIOUS DISEASES 785, 793 (2017) ("the duration of protection [for Zostavax]. . .wanes over time"); Roger Baxter et al., *Long-Term Effectiveness of the Live Zoster Vaccine in Preventing Shingles: A Cohort Study*, 187 AM. J. EPIDEMIOLOGY 161, 168 (2018) ("[Zostavax effectiveness] decreased to 47% in the second year, and then waned more gradually over the next six years."). This immunity then wanes completely over the next six years necessitating a Plaintiff to receive another vaccine in order to stay safe.

Dr. Poznansky's states his differential etiology is directly in compliance with the methodology for a differential etiology described in the Reference Manual on Scientific Evidence, 3rd edition: "In a differential etiology, an expert first determines other known causes of the disease in question and then attempts to ascertain whether those competing causes can be "ruled out" as a cause of plaintiff's disease." The Federal Judicial Center's Reference Manual on Scientific Evidence, 617. "The common statement that "alternative causes of disease must be ruled out" before causation is attributed can be more accurately refined to say that "the role of other causes must be adequately considered." Id. at 476. Even so, this statistical analysis, while not explicitly

stated by Dr. Poznansky, does not weigh towards specific causation for any of these Plaintiffs. Put differently, Dr. Poznansky's use of these statistics does not apply to these Plaintiffs any differently then it applies to anyone else who had chickenpox and subsequently received Zostavax. All Dr. Poznansky's opinion on this point provides is a statistical estimate, even in its most beneficial light, that provides a 15% chance of Zostavax causing Shingles **generally**. The Court finds once again that these general population statistics do not bridge the analytical gap between a differential diagnosis and specific causation.

PCR AND SPS TESTING FLAWS & MIXED REACTION RASH

Dr. Poznansky testifies that "In combination with the indeterminate and the PCR debate about the mixed infection," the scientific studies that he cites support the opinion that mixed infections can occur. Dupledge, et al., 2018, for example, is a study Dr. Poznansky cites for support of mixed infection, that wild-type VZV strains are detected in patients with encephalitis. It's unclear, however, how the existence of mixed reactions is anything more than a general causation point dressed up in specific causation clothing. While Dr. Poznansky cites to studies where mixed rashes have been detected and sequenced, the implication of this to specific causation in these Plaintiffs is unclear.

Dr. Poznansky further emphasizes the PCR testing flaws in the Merck SPS study stating that because the study was designed to be a qualitative PCR, the results were only a simple binary: yes or no. Therefore, Dr. Poznansky contends that mixed infections were simply designated as "indeterminant" and ignored. Dr. Poznansky additionally relies on Merck's own PCR data showing "mixed rashes." See Merck PCR Test, MRK-ZOSMCL-03116060. He further states that the presence of mixed rash reactions, if the dynamics of the studies were changed, would have outweighed the presence of the wild strain shingles. It seems that because of this determination,

Dr. Poznansky goes on to conclude that these general causation statistics weigh in favor of reactions being more likely than not either vaccine induced or mixed reactions. He cites other factors that Plaintiffs suffered weighing "equally" in favor of wild strain and vaccine strain, concluding that this evidence weighs on the side of the differential diagnosis that weighs in favor of vaccine-induced shingles being more likely than not.

This testimony, however, belies all of the testimony that has been elicited in this case up until this point, however, including that of Dr. Poznansky himself. Dr. Poznansky's ultimate statistical opinion remains unchanged between this round of Plaintiffs that between 0.16 and 15% of shingles rashes in Zostavax recipients are caused by the vaccine—meaning that according to Dr. Poznansky, wild-type VZV causes 85-99.84% of shingles rashes in Zostavax recipients. 12/4/23 Poznansky Dep. at 15:6-11; 82:12-18; 165:8-14. Therefore, even accepting this 15% figure, the Defendant argues that mixed rash infection possibility, combined with risk factors that weigh neutrally, weigh in favor of vaccine-induced shingles. This cannot possibly be matched with the prior testimony of Dr. Poznansky, where 15% of infections was at the upper range of the possibility of the infections.

Moreover, Defendant takes issue with this 15% number, stating Dr. Poznansky was "informed" by the scientifically unsupported opinion of Plaintiffs' retained expert, Dr. Pinghui Feng, which stated that "Merck under-detected the presence of vOka strain virus" during its clinical trials. Pl. Opp. at 6. Defendants argue however that Plaintiffs never disclosed Dr. Feng's opinions in this litigation, but that Dr. Poznansky continues relies on Dr. Feng's litigation driven reinvention of Merck's data to opine that up to 15% of rashes tested in the Zostavax clinical trials contained trace amounts of vaccine-strain shingles (1-5%) and therefore constituted "mixed" reactions.

As the Court has found previously, Dr. Feng never offered the opinion that the risk of vaccine-induced shingles is 15%. That opinion was derived by Dr. Poznansky, who testified that after review of Dr. Feng's opinion and Figure 1 in the Harbecke study, he concluded that there was a "potential for detection of the [vaccine] strain in up to 15% of the patients" in the SPS. 12/4/23 Poznansky Dep. at 346:15-21; 370:14-24; 372:22-373:13.

The issue presented before this Court, and which is to be explained by Dr. Poznansky is whether the shingles experienced by the three bellwether Plaintiffs in this case were as a result of the original varicella-zoster virus, the vaccine strain of varicella, or some combination of both. The difficulty of this connection is a result of the way in which the Zostavax vaccine works. As stated before, both the original strain and the vaccine strain lay dormant within a person indefinitely. Both strains lay dormant in the same dorsal root ganglion and both strains have the potential to cause a shingles reaction. There have been well documented occurrences of the Zostavax vaccine causing shingles and it is not disputed by the Defendants that Zostavax has the potential to cause the related injury in the Group A cases shingles. The contention lies in Dr. Poznansky's explanation of specific causation for each of these bellwether Plaintiffs.

The opinion offered by Dr. Poznansky in this litigation is a novel opinion which has already been rejected by the Eastern District of Pennsylvania and the Third Circuit. While novel opinions are by no means barred within the state of New Jersey, such opinions require that the expert's approach is scientifically sound, meaning that the methodology Dr. Poznansky employed to reach his conclusions and the data on which he relied is the same methodology and data that other researchers exploring the issue would use. This requires that Plaintiffs show reliable scientific evidence that support both: (1) that the Zostavax vaccine could cause herpes zoster (general causation); and (2) that the Plaintiffs' individual use of the Defendants' vaccine caused them to

develop shingles (specific causation). Throughout this litigation and at least since the April 2023 opinion of this Court, the issue of general causation has been largely resolved. This leaves us with a question of the reliable scientific evidence which he relied on is the same methodology or data that other scientists would use.

While a differential diagnosis opinion does not require absolute certainty, the opinion must be reached within a reasonable degree of medical certainty. State v. Freeman, 223 N.J. Super. 92, 116 (App. Div. 1988) (explaining that "medical expert testimony 'must be couched in terms of reasonable medical certainty or probability; opinions as to possibility are inadmissible.'"). For those reasons, the Court does not find Dr. Poznansky's opinion on mixed reaction and SPS errors as to the specific causation of the Plaintiffs shingles appropriate to be presented in front of a jury because it is not within a degree of reasonable medical certainty.

Immune Senescence

Dr. Poznansky also opines that each Plaintiff received Zostavax when their immune system was aged and senescing, and therefore vulnerable to a weakened immune response to the vaccine strain, making them more vulnerable to shingles reactivating in the Plaintiff after vaccination. Pl. Opp. At 7.

It is not in dispute that immune systems naturally degrade with age in a process called senescence or immune senescence. Elderly individuals, 60 years old and older, experience a greater risk of developing diseases, such as shingles, due to their declining immune system. Prior Plaintiff Rep. Gollakner at 3. Cell mediated immunity ("CMI") is an immune response that does not involve antibodies, but rather involves T cells that destroy viruses within infected cells. See Id. at 2-3; M. J. Levin et al., *Varicella-Zoster Virus-Specific Immune Responses in Elderly Recipients of a Herpes Zoster Vaccine*, 197 J. INFECTIOUS DISEASES 825 (2008). CMI is the

mechanism that controls VZV reactivation. Ibid. Like the immune system overall, CMI also deceases with age. Ibid. All parties agree with the above foundation that immune systems and CMI naturally wane with age. See Order, In re Zostavax, No. 629 (Apr. 17, 2023). All parties also agree that Zostavax increases an individual's VZV CMI. M. J. Levin et al., *Varicella-Zoster Virus-Specific Immune Responses in Elderly Recipients of a Herpes Zoster Vaccine*, 197 J. INFECTIOUS DISEASES 825, 833 (2008).

This Court found previously and has not been presented with any new evidence to contradict the finding that contrary to Dr. Poznansky's CMI Theory—that "Zostavax increases an individual's VZV CMI." See Order, In re Zostavax, No. 629 (Apr. 17, 2023). Dr. Poznansky does not present any new studies or evidence on this issue and instead seemingly relies upon the prior CMI opinion already given that Zostavax represents a new virus that is being introduced to the immune system. Dr. Poznansky continues to rely upon the differences in protein between the wild type and vaccine type virus for the proposition that it represents a new virus that is not appropriate to be introduced to an ailing immune system.

For the first time in this opinion Dr. Poznansky cites to Frontiers in Immunol. Griffoni et al. 2023 to bolster his immune senescence theory stating: "This has been particularly evident with the SARS CoV-2 pandemic in which the majority of serious disease and death was seen in patients over the age of 60, and this was associated with less effective immune responses to the virus. Hence the immune response to the vOka strain would be less than that to the wild type virus." Pl. Opinion at 10. While this again relies on the already rejected notion that the vaccine represents a new virus, the new literature cited to by Dr. Poznansky specifically stated the addition of a COVID-19 vaccination saw "immune defects rescued via the delivery of additional signal to potentiate the immune response." Leaving alone that these vaccinations and viruses are different, the Court finds

that this literature supports the well-worn position of the literature in this case, that indicated that Zostavax was a safe and effective measure to protect against shingles for those above the age of 60. Rafael Harpaz et al., at 15-19.

For the same reasons this Court previously rejected this immune senescence opinion, the Court cannot find any new testimony or literature provided by Dr. Poznansky that would lead this Court to a different conclusion. Importantly, Dr. Poznansky continues to affirm that his CMI theory applies to any Plaintiff over the age of 60 who had received the Zostavax vaccine. Poznansky Dep. 168:9-20. Which further shows that even to the extent that Dr. Poznansky's opinion was appropriate, it would not move the needle on specific causation and would only add to the general causation component which is not in dispute. While a differential diagnosis opinion does not require absolute certainty, the opinion must be reached within a reasonable degree of medical certainty. State v. Freeman, 223 N.J. Super. 92, 116 (App. Div. 1988) (explaining that "medical expert testimony 'must be couched in terms of reasonable medical certainty or probability; opinions as to possibility are inadmissible.'"). For those reasons, the Court does not find Dr. Poznansky's opinion on immune senescence as to the specific causation of the Plaintiffs shingles appropriate to be presented in front of a jury because it is not within a degree of reasonable medical certainty.

LATENCY

Plaintiffs in opposition argues that "[t]he shorter the latency, the greater the likelihood of causation associated between the vaccine and the diagnosis of HZ." Pl. Opp. At 15. However, this is not a specific point that is contended by Dr. Poznansky in his opinion. The piece of expert testimony the Plaintiffs point to for this is that Marilyn Meuse experienced her shingles 4-5 days after vaccination. It is unaddressed whether four-five days post vaccination would be sufficient

time for the vaccine strain to replicate, spread, become latent and then reactivate. Absent any study or data on this subject, a judge and a jury are only left to conjecture to determine whether this recitation that is made ranging from plaintiffs who had shingles five days post vaccination and eight years post vaccination should be weighed in the exact same way or differently.

The scientific consensus to, the "[c]lose temporal association of an adverse event with administration of vOka [vaccine-strain VZV] does not by itself establish that vOka is the cause of that event." Gershon AA, et al. *Live Attenuated Varicella Vaccine: Prevention of Varicella and of Zoster*. J INFECT DIS. (2021). This Poznansky opinion again is not sufficiently supported by studies nor is the novel opinion of Dr. Poznansky consistent on this point. The weight that he affords someone who received the vaccine last week seems to weigh the same as someone who received the vaccine eight years ago, so long as they are over the age of 60. Dr. Poznansky does not explain in any sufficient detail his reasoning for holding these two latency periods on equal pedestals. While a differential diagnosis opinion does not require absolute certainty, the opinion must be reached within a reasonable degree of medical certainty. State v. Freeman, 223 N.J. Super. 92, 116 (App. Div. 1988) (explaining that "medical expert testimony 'must be couched in terms of reasonable medical certainty or probability; opinions as to possibility are inadmissible.'"). For those reasons, the Court does not find Dr. Poznansky's opinion on latency as to the specific causation of the Plaintiffs shingles appropriate to be presented in front of a jury because it is not within a degree of reasonable medical certainty.

SPECIFIC CAUSATION OPINIONS OF DR. POZNANSKY COMMON TO ALL PLAINTIFFS

An expert's methodology should remain consistent throughout, especially when presenting a novel opinion. Within the first set of bellwether Plaintiffs, Dr. Poznansky testified that the factors he considered

most significant when issuing his opinions were the age, sex, and certainty of vaccine administration for each bellwether Plaintiff. 2/16/23 104 Hr'g Tr. at 82:23-83:3; 87:18-24. At both the 2023 104 hearing and his prior deposition, Dr. Poznansky testified that neither the presence or absence of the other factors make it more likely that the shingles was either naturally occurring or from Zostavax. Specifically, Dr. Poznansky testified that the presence or absence of all the forementioned factors are relevant for both naturally occurring and vaccine-induced shingles. 2/16/23 104 Hr'g Tr. at 87:5-7; 4/13/22 Poznansky Dep. 421:10-422:2.

Dr. Poznansky made several key findings of fact common to all Plaintiffs. These findings begin to underscore the concerns that the Court had in the first opinion, which is, these opinions are cookie cutter and provide no substantive basis why one individual contracted shingles over another. Put differently, it is imperative this time around for Dr. Poznansky to show that simply the fact that a Plaintiff received the Zostavax vaccine and filed a lawsuit as the two check boxes needed in order for Dr. Poznansky to determine that their shingles were more likely than not the result of Zostavax.

After an initial section on general causation, which this Court has already recognized is not in dispute, Dr. Poznansky titles the next section "Specific Causation." Which states: "I understand the term specific causation as an analytical method applied by medical doctors where competing alternative explanations of a disease outcome are considered in an iterative step-by-step process, and ruling out each alternative explanation until the most likely explanation is ruled-in." See Pl. Reports at 6.

Despite this "understanding" Dr. Poznansky proceeds in a section titled "General Clinical Differential Diagnosis Points Relevant to this Case" the "asymmetric dermatomal or multidermatomal rash with erythema, vesicles, itching, dysesthesia or hyperesthesia and neuropathic pain is pathognomonic of shingles. This evidence weighs equally to wild type and

vOka infection in this patient." Dr. Poznansky then states the fact that no PCR test was performed "weighs equally to wild type and vOka infection in this patient." See Pl. Reports at 7. He then states: "In the absence of a definitive virological molecular diagnostic test, a physician must weigh all the evidence related to the specific cause, and in this case wild type VZV, vOka or vaccine strain VZV or a mixed infection of both viral strains. This weighs equally to wild type and vOka infection in this patient." Ibid. What these paragraphs mean and how they weigh at all, let alone equally to the wild type or vaccine type infection defy logic. All of the four bulleted points in this section cannot be considered to be part of a differential diagnosis as they are recitations of known facts either about the virus or about this litigation. These points are also made with respect to all four Plaintiffs identically.

Under the next subheading "General Virological Diagnosis Points relevant to this case." Dr. Poznansky states: "The vaccine vOKA strain virus is a live infectious virus that was attenuated for growth in epithelial cells as a result of passage or culture of epithelial cell lines which are derived from immortalized epithelial cancer cell lines. These cell lines resemble the normal cells of skin but are in no way identical to primary epithelial or skin cells in the body. This evidence weighs on the side of the differential diagnosis that supports vOka or vOka combined with wild type infection as a cause of this patient's shingles." What this exactly intends to explain and how this supports a specific causation opinion in this case is unclear. While the Court has recognized the general causation issue on multiple occasions, this attempts to, under a specific causation heading, give further credence to the general causation argument. Dr. Poznansky himself has admitted that general causation data cannot inform a differential diagnosis for a specific patient, which makes his continued reliance on these general causation principles concerning to the Court.

As stated before, the notion that this vaccine can cause shingles has been conceded in this litigation. How this live attenuation process happens and how it relates to these Plaintiffs' cases of shingles is not explained at all by Dr. Poznansky. Instead, he summarily concludes that the process through which the vaccine is attenuated, weighs on the side of the differential diagnosis of specific causation. This would imply that this process makes it more likely in this patient that it is more likely than not vaccine strain than wild strain. How Dr. Poznansky comes to this opinion for all four of these cases and why this is not just a more in-depth way of stating general causation, is not clear.

Dr. Poznansky continues with these general causation opinions stating that the attenuation of the virus in skin cells rather than neural or immune cells weighs in favor as well as the ability for it to lay dormant in the ganglion root weighs in favor of this patient's shingles being vaccine strain. Dr. Poznansky next cites to the fact that viral shedding can be detected in saliva 28 days post vaccination weighs in favor as well. Dr. Poznansky tries to bolster his specific causation opinion by restating these well-known general causation points. Any attempt to relate these phenomena to these specific Plaintiffs is entirely unclear to the Court. All of these factors, while well supported opinions which support general causation, provide absolutely no insight into how Dr. Poznansky formed his specific causation opinion for these Plaintiffs. Dr. Poznansky has previously testified in this litigation, that "you can't use general causation data to directly inform your differential diagnosis about a specific patient." 2/16/23 104 Hr'g Tr. at 40:4-7. Despite this concession, Dr. Poznansky continues to utilize this reasoning throughout these opinions.

Under a second subheading labeled "specific clinical differential diagnosis points relevant to this case," Dr. Poznansky provides the following: That these Plaintiffs lacks any immune disorders, they lack rheumatoid arthritis, they lack inflammatory bowel disease, chronic

obstructive airways disease, asthma, lupus, Guillain-Barre syndrome, household family exposure to varicella, cancer, or chemotherapy and finally stress.

In all four of these cases, Dr. Poznansky analyzed the same factors, noted their absence and concluded "I have considered and ruled out these alternative causes and risk factors as the sole cause of this patient's Herpes zoster based upon the factors discussed above." Remarkably, all four bellwether Plaintiffs were differentially diagnosed on the absence of these above risk factors. However, factors unique to these Plaintiffs were never weighed either for or against vaccine strain and were ultimately never addressed by Dr. Poznansky. The Court would expect, if the presence of certain health factors weighs in favor of vaccine strain, an explanation as to why the health conditions of these specific Plaintiffs do not weigh in favor or against vaccine strain shingles.

When Dr. Poznansky was asked in his deposition whether those factors would apply equally to the reactivation of wild type or vaccine strain he states: "Well, in the context of all the other things, as we've discussed, it's in the context of all the other things. So yes, for the specifics of those particular factors. But in combination with the patient's age, with the details of the possibility that the vaccine itself could cause disease, all those things are weighed together in that context." 12/4/23 Poznansky Dep. at 179:4-12. This, when compared with the expert reports authored, leaves the Court with very little information to substantiate Dr. Poznansky's differential diagnosis. While he states he is "ruling out alternative risk factors" it would appear that these risk factors weigh equally to wild type or vaccine type reactivation. This conclusion is supported by the prior opinion of Dr. Poznansky, stating that the presence or absence of risk factors are relevant for both naturally occurring and vaccine-induced shingles. 2/16/23 104 Hr'g Tr. at 87:5-7; 4/13/22 Poznansky Dep. 421:10-422:2.

Digging further into Dr. Poznansky's reasoning, he states that both the patient's age at the time of vaccination as well as the time between the Plaintiff's vaccination are factors in the occurrence of his shingles. On the point of age stratification, Dr. Poznansky states that the "most important factor" in ruling out wild strain are the published studies demonstrating a low incidence of shingles when stratified by age. 12/4/23 Poznansky Dep. at 169:20-170:12. He then states that the incidence rate ranges from less than 1% to 2-3% in a given year. Ibid. What Dr. Poznansky is comparing this statistic to is unclear. When asked for clarity on this issue, Dr. Poznansky once again offers a novel opinion. In the prior six bellwether cases dismissed in this litigation, Dr. Poznansky had testified that while age stratification was a factor, it weighed "equally" to the other factors. See Order, In re Zostavax, No. 629 (Apr. 17, 2023). Now, in this litigation he has pivoted to age stratification as the "most important factor."

When asked about this change he states, "because I was able to actually get all the clinical details that I needed on these patients that I really hadn't had with the other ones by being able to meet with the patients and talk about their presentations and histories." 12/4/23 Poznansky Dep. at 171:11-19. The Court can only interpret this to mean that the age stratification, or a Plaintiff's given risk, based on a given year at a given age is somehow influenced by the Plaintiff's interview with Dr. Poznansky as well as his review of their "clinical details." Ibid. When asked whether he is applying population statistics to these individual Plaintiffs, Dr. Poznansky flatly denies it saying, "not the way I wrote it, no." 12/4/23 Poznansky Dep. at 173:18-19. Minutes later in the exact same deposition Dr. Poznansky is asked "so you, in fact, are using the risk of naturally-occurring shingles as the most important factor in ruling out wild type in Mrs. Meuse and the other two Plaintiffs, correct?" To which he responds: "Yes, I'm using it as part of it. As part of my assessment of the differential diagnosis, I'm using that data exactly that way." 12/4/23 Poznansky Dep. at

176:3-18. This contradictory testimony is all too common throughout this further confounds the methodology and reliability of Dr. Poznansky, which has remained inconsistent throughout this litigation.

Instead of looking at these Plaintiffs' medical history and determining whether said history weighs in favor of wild strain or vaccine stain, Dr. Poznansky notes the medical history of every Plaintiff and then goes into a recitation of all of the same risk factors he had for all four Plaintiffs.

The Court will next address the differential diagnosis of the individual Plaintiffs. Dr. Poznansky testified that the risk factors analyzed in his report equally apply to the reactivation of wild-type or vaccine strain shingles. 12/4/23 Poznansky Dep. at 132:14-133:9. Therefore, it is unclear to the Court if the risk factors weigh equally, how the absence would affect Dr. Poznansky's analysis as the risk would decrease for both. Moreover, in case of Mercedes Deville, Dr. Poznansky ultimately opined that the presence of the risk factor, chronic kidney disease, led to a modifying of his opinion of "possibly" vaccine strain from more likely than not. 12/4/23 Poznansky Dep. at 49:7-11. Even in this seeming concession, it is unclear how Dr. Poznansky can come to this opinion when the risk factors weigh equally to both wild strain and vaccine strain reactivation.

While a differential diagnosis opinion does not require absolute certainty, the opinion must be reached within a reasonable degree of medical certainty. State v. Freeman, 223 N.J. Super. 92, 116 (App. Div. 1988) (explaining that "medical expert testimony 'must be couched in terms of reasonable medical certainty or probability; opinions as to possibility are inadmissible.'"). For those reasons, the Court does not find Dr. Poznansky's opinion on general causation statstic as to the specific causation of the Plaintiffs shingles appropriate to be presented in front of a jury because it is not within a degree of reasonable medical certainty.

PLAINTIFF MERCEDES DEVILLE

Mercedes Deville received the Zostavax vaccine on October 11, 2007, at the age of 67. Approximately nine years later, on September 12, 2016, she was diagnosed with shingles. No PCR test was performed on Mecedes Deville at the time of the infection. Within Dr. Poznansky's report he states "In order to refine the differential diagnosis on review of records, the patient did not have cancer, or was receiving chemotherapy, steroids, or immune suppressive drugs at the time of the development of shingles. In addition, the patient did not have diabetes or a genetic predisposition to infection, was not under stress and had not had surgery or trauma at the time of the Zostavax vaccination or subsequently prior to or during the episode of shingles." Deville Rep. at 6.

Critically, Dr. Poznansky also opines that Ms. Deville does not have: "chronic kidney disease, a disease associated with immune dysregulation and/or treatments with the potential to render the patient vulnerable to VZV reactivation and shingles. I found no evidence that Mercedes Deville suffered from chronic kidney disease that would make her more vulnerable to the development of Herpes zoster." Deville Rep. at 9.

However, only one-page later, in the same report, Dr. Poznansky stated: "On review of the patient's notes and medical records indicate that Mercedes Deville was diagnosed with chronic kidney disease. These clinical findings do not weigh in favor of vOka infection as the sole cause this patient's Shingles." Deville Rep. at 9. This baffling internal contradiction within Dr. Poznansky's own report is never offered further clarity by Dr. Poznansky. Why in one setting the lack of her having chronic kidney disease is important to his differential diagnosis and a page later the fact she has chronic kidney disease is not important to his differential diagnosis is likewise not explained. The weight Dr. Poznansky assigns to the presence of chronic kidney disease, or the lack of chronic kidney disease is also never explained.

In conclusion, Dr. Poznansky states: "I considered and ruled out wild type VZV as the sole cause of shingles in this patient, Mercedes Deville, for the following reasons which are supported by clinical findings, science and my probabilistic reasoning." Deville Rep. at 11. The purpose of a differential diagnosis in general and more precisely a specific causation opinion in this litigation is not to rule out wild strain as the sole cause of shingles. From the admission of general causation made by Defendant Merck, it is patently obvious that you can rule out wild strain as the sole cause. However, the purpose of a differential diagnosis is to rule in factors weighing in favor of vaccine strain and rule out factors weighing in favor of wild strain. The problem in this litigation and for Dr. Poznansky is a lack of literature or methodology to do this in any way that is consistent and scientific.

For instance, within his own report he contradicts the Plaintiff's diagnosis of chronic kidney disease. This is despite nearly two and a half hours of prep and a Zoom call which he had with the Plaintiff. Then, when afforded an opportunity to explain his opinion he states, "like in the case of Mrs. Deville where there was a background, one of those other factors, chemotherapy, stress, chronic renal disease, and so forth, that weighed, you know equally that would have made it much more like, well made it possibly vOka, which meant less likely than not vOka." 12/4/23 Poznansky Dep. at 152:3-17. This now would be a third opinion Dr. Poznansky has given about Ms. Deville. Dr. Poznansky concludes that continuous "stimulation for wild type" from the wild strain shingles led to his opinion that Ms. Deville did not more likely than not suffer from vaccine-induced shingles.

When pressed upon this issue further in his deposition, on the basis that Zostavax more likely than not caused their shingles, he states "but as you saw with Deville, as I was able to get more data, I was able to refine my differential diagnosis." 12/4/23 Poznansky Dep. at 159:2-19.

In response Ms. Hardway asks: "when you say you were able to get more data in Mrs. Deville's case, the data was that she had chronic kidney disease, which was already in your report, correct." Ibid. To which Dr. Poznansky responds by saying "Correct, but I hadn't weighed it correctly because, as I said, when I had spoken to the patient, she had not mentioned it, and that had, sort of, distracted me from thinking about it as a particular factor in her reactivation of her shingles." Ibid. Ultimately, Dr. Poznansky's deposition testimony in Ms. Deville's case led to the case being voluntarily dismissed on March 12, 2024.

PLAINTIFF THOMAS SZEKLINSKI

Mr. Szeklinski received the Zostavax vaccine on July 24, 2012, at the age of 66. Four years later, on July 16, 2016, at the age of 70, Mr. Szeklinski was diagnosed with shingles. In the case of Mr. Szeklinski, the process of a "differential diagnosis" is even more strained. Instead of looking at the Plaintiff's medical history and determining whether said history weighs in favor of wild strain or vaccine stain, Dr. Poznansky notes the medical history and then goes into a recitation of all of the same risk factors he had for the other three Plaintiffs. See Szeklinski Rep.

Mr. Szeklinski's expert report states: "The patient did have a past medical history significant for hypertension, hyperlipidemia, dermatitis of the ear canal and chronic gout at the time of the diagnosis of shingles." Szeklinski Rep. at 6. However, despite this recognition of preexisting conditions, Dr. Poznansky never offers further explanation on whether these factors weigh in favor or weigh against the wild strain shingles or vaccine strain shingles. This failure to assess factors specific to a given Plaintiff is especially concerning when the report goes on to state "Stress factors or trauma within months of the VZV reactivation and shingles as risk factors for the reactivation of VZV in this patient. I found no evidence that Thomas Szeklinski suffered from significant stress events that would make him more vulnerable to the development of Herpes

zoster." Szeklinski Rep. at 9. This response reads more as a generic copy and paste diagnosis to all Plaintiffs when it fails to account three pages prior, he states the patient has a past medical history of hypertension.

Instead of explaining that Mr. Szeklinski's stress was being managed, that his chronic gout was under control, or that any of these prior mentioned medical factors do not weigh into the differential diagnosis at all, Dr. Poznansky ignores them altogether. It is unclear to this Court why instead of addressing the conditions of Plaintiff and either explaining that these factors do not weigh in favor of wild strain or vaccine strain or that the factors weigh in favor of wild strain only or vaccine strain only, Dr. Poznansky decides to ignore the only medical history we have for this Plaintiff and instead bases his "differential diagnosis" on factors that are not at issue or in dispute.

Instead of addressing what conditions this Plaintiff has and ruling those out, Dr. Poznansky choses to "rule out" a list of factors of which he provided no scientific support to why those factors weigh in favor of the vaccine strain. Even granting Dr. Poznansky the fact this scientific support exists, he then fails to determine how and to what degree this matters, instead just blankly asserting it weighs in favor of the vaccine-induced shingles. How or why these factors only impact the activation of wild strain and do not have an equal effect on vaccine strain is left entirely unexplained citing no evidence for this proposition or offering his own novel explanation of this interaction. The Court finds that the opinion of Dr. Poznansky has failed to perform a reliable differential diagnosis. Accordingly, the Court will grant Defendants' Motion and exclude Dr. Poznansky's specific causation opinions for Mr. Szeklinski.

PLAINTIFF MARILYN MEUSE

Marilyn Meuse received the Zostavax vaccine on August 23, 2014. Four to five days later, she was diagnosed with shingles. Despite the latency period for Ms. Meuse being dramatically

closer in time to the actual vaccination Dr. Poznansky seemingly makes no greater weighting of this fact, instead stating the exact same factors and stating the latency as "one of the factors" but still providing age stratification as the "most important factor." In his summary paragraph, Dr. Poznansky states in all expert reports: "It is also documented that the patient received the Zostavax containing live vOka strain VZV when her immune system was aged and therefore vulnerable to a weakened immune response to that variant of the virus, and therefore potentiating the vOka strain VZV's capability of replicating, spreading, becoming latent and then reactivating in this patient after vaccination." Meuse Rep. at 10.

It is unaddressed whether four-five days post vaccination would be sufficient time for VZ to replicate, spread, become latent and then reactivate. Absent any study or data on this subject, a judge and a jury are only left to conjecture to determine whether this recitation that is made ranging from plaintiffs who had shingles five days post vaccination and eight years post vaccination should be weighed in the exact same way or differently.

In Dr. Poznansky's deposition he says that he "put quite a bit of weigh on the fact that the patient had an injection of live virus and four to five days later developed a rash." 12/4/23 Poznansky Dep. at 155:8-156:9. Further, when presented with a plotted chart of all of the different Plaintiffs latency from vaccination to shingles infection, Dr. Poznansky said he could not state where a differential diagnosis would weigh on the side of a wild type or vaccine type infection. 12/4/23 Poznansky Dep. at 157:8-21.

The other factors Dr. Poznansky goes through in Mrs. Meuse's report are the exact same, verbatim as addressed in the above Plaintiff's reports and for the sake of brevity will not be readdressed. Dr. Poznansky has failed to perform a reliable differential diagnosis. Accordingly,

the Court will grant Defendants' Motion and exclude Dr. Poznansky's specific causation opinions for Ms. Meuse.

PLAINTIFF ROBERT WALKER

Robert Walker received the Zostavax vaccine on December 7, 2011. Eleven months later on November 12, 2022, at the age of 67, Mr. Walker was diagnosed with shingles. The Court finds, for all intents and purposes, the opinions and basis for those opinions offered on behalf of Mr. Walker are identical to those offered on behalf Ms. Deville, Mr. Szeklinski, Ms. Meuse. However, Mr. Walker did have two conditions unique to his case, he had both a local steroid injection to his knee as well as ongoing tinnitus which Dr. Poznansky claims he still deals with currently. Despite the onset of a unique moniker, the tinnitus, Dr. Poznansky does not state whether the onset of tinnitus weighs in favor or against vaccine strain shingles. Moreover, Dr. Poznansky fails to explain why the use of steroids is a risk factor in some circumstances but the injection of a steroid into the knee does not qualify.

Accordingly, the Court must again find that Plaintiff has not demonstrated the soundness of Dr. Poznansky's methodology, in both terms of his approach to reasoning and to his use of data, from the perspective of others within the relevant scientific community.

BOTH THE DISTRICT COURT AND THIRD CIRCUIT DECLINED TO FOLLOW DR. POZNANSKY'S METHODOLOGY

By way of written decision dated December 1, 2021, Judge Bartle excluded the specific causation opinions and testimony of Dr. Poznansky, as to each of the five MDL bellwether plaintiffs. Judge Bartle found that Dr. Poznansky's differential diagnosis failed to "rule out the wild-type virus as the cause," leaving the jury "with nothing but speculation as to what caused

plaintiffs shingles—the wild-type virus or the live-attenuated virus." In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig., 579 F. Supp. 3d 675, 685 (E.D. Pa. 2021). After analyzing the Poznansky's reports, the District Court concluded that Poznansky failed to do so, and as such, could not offer a reliable opinion on specific causation. The District Court ultimately entered summary judgment in the five Group A bellwether cases.

In January of 2022, Merck moved for entry of a Lone Pine order that required the production of PCR tests from all Group A Plaintiffs. Plaintiffs opposed Merck's motion because (1) PCR tests had not been administered, and (2) PCR testing can only be done on existing rashes. Despite the objection, in March 2022, the District Court entered PTO 426, giving Group A Plaintiffs 90 days to produce PCR test reports. In an opinion explaining their decision, the District Court cited "compelling medical authority" suggesting "that a [PCR] test . . . is the only way to tell" whether shingles was caused by the latent chickenpox wild-type virus strain or Zostavax's live-attenuated virus strain. In re Zostavax, 2022 WL 952179, at *2. The District Court also observed that plaintiffs failed to offer "any medical literature or expert medical opinion" explaining otherwise or provide "any guidance" as to how the Group A cases could proceed without a PCR test.

Moreover, on July 16, 2024, the United States Court of Appeals for the Third Circuit entered an Order denying the appeal from Judge Bartle's Lone Pine Order of March 2022 (PTO 426), giving Group A Plaintiffs ninety (90) days to produce PCR test reports. The Plaintiffs premised their appeal on two general facets, that the Order entered by the District Court was erroneously based on the assumption that PCR tests are the only way to establish specific causation and that PTO 426 required the production of non-existent evidence. The Third Circuit did not agree.

While not binding on this Court, the District Court opinion and the upholding of the Third Circuit holds persuasive authority in this Court. This Court acknowledges that the opinions of the federal court, with the exception of United States Supreme Court opinions interpreting the United States Constitution and federal statues, are not binding precedent. In re Contest of November 8, 2011, 210 N.J. 29, 45 (2012). However, "federal opinions, including district court decisions, may have significant persuasive effect" Pressler & Verniero, Current N.J. Court Rules, Comment 3.5, on R. 1:36-3.

Combining this persuasive authority with the fact that the Plaintiffs in Group A of the MDL utilized the same expert, Dr. Poznansky, and were represented by the same attorneys, the opinion holds strong persuasive weight over this Court. If this Court was to differ with the District and Third Circuit, it would need to enumerate why that opinion is wrong or what about this group of Plaintiffs is different. Moreover, this motion to bar is premised on Dr. Poznansky's inability to meet the threshold of specific causation through his testimony, which is exactly the issue the federal court was addressing in the initial Lone Pine Order, the accompanying opinion, and the subsequent denied appeal.

While the disposition of the Third Circuit appeal does vary from ours, the ruling and reasoning are important. The Honorable Judge Roth, writing for the Third Circuit reasoned that after three years of litigation, PTO 426 was based on uncontradicted evidence that the only way to establish specific causation is through the utilization of a PCR test. In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig., Memorandum Denying Appeal No. 23-1032 at *7. (3rd Cir. 2024). The District Court and Third Circuit both note that there had not been any medical literature or expert opinion that explained how it can be determined that Zostavax was the cause of the shingles and not the chickenpox, other than through a PCR test. Ibid.

This poignant decision highlights the same issue that this Court has been contending with for the better part of two years, which is whether there can be any admissible testimony by Dr. Poznansky on the issue of specific causation. The Third Circuit has determined that the expert opinion of Dr. Poznansky, also submitted in that litigation, was not sufficient to contradict the "obvious alternative cause" of the shingles, chickenpox. Ibid. While not relying on the Third Circuit's decision, the Court found it necessary to highlight an identical case contending with an analogous issue of specific causation.

SUMMARY OF FINDINGS

The Court notes that Dr. Poznansky's specific causation opinions throughout this litigation and throughout the MDL litigation have been similar to those of the expert in the seminal New Jersey case of Accutane. In Accutane, Plaintiffs' causation expert, Dr. Kornbluth, disregarded evidence from epidemiological studies and offered his own alternative causation opinion. See In re Accutane Litigation, 234 N.J. 340, 395 (2018). Additionally, Dr. Kornbluth never submitted his opinions for peer review or publication. Ibid. The trial court, in Accutane, noted that plaintiffs' experts "strayed from their own claimed methodology in order to reach their conclusions." Id. at 396.

Similarly, Dr. Poznansky has not submitted his novel opinions in this litigation for peer review or publication. Furthermore, Dr. Poznansky in nearly three years of litigation has not cited to one source that supports his thesis that Zostavax more likely than not caused these Plaintiffs shingles. More consequently, there is no explanation or literature provided why the presence of these risk factors, age, immune senescence or latency would bridge the analytical gap on specific causation for wild strain reactivation over vaccine strain reactivation.

While one may assume that one of the thirty-two sources cited by Dr. Poznansky may give insight into this area, they do not. Dr. Poznansky's opinion in all of these cases is an issue of conflating general causation with specific causation and he states as much himself. When asked if there is any scientific literature which supports the proposition that Zostavax induced shingles is higher than the risk of naturally occurring shingles, he states "in general, yes." 12/4/23 Poznansky Dep. at 165:2-7. He follows up by stating that the likelihood that each of these Plaintiffs' shingles was a result of vaccine strain is somewhere between .16 and 15% and that this percentage encompasses both a vaccine strain and a mixed strain probability. 12/4/23 Poznansky Dep. at 157:8-21.

Then when asked what the probability is that these Plaintiffs' shingles was pure wild type, he states that it's "less likely than not, so it's 49% or below." 12/4/23 Poznansky Dep. at 165:22-166:1. This same unexplained jump in logic is made time and time again. When all indications, including even general data that does not favor, Dr. Poznansky, his inscrutable matrix of risk factors and weights, supported by no published literature, is used to support this dubious proposition.

A careful consideration of the record can only lead one to the opinion that a healthy person who does not pose any of the enumerated risk factors that Dr. Poznansky cites to, and was vaccinated with Zostavax, must have had Zostavax-induced shingles. This one size fits all opinion, backed by no literature and no scientific evidence, is the exact type of testimony New Jersey Courts are tasked with gatekeeping from litigations. The introduction of Dr. Poznansky's testimony to a jury would do nothing to help the trier of fact and would serve only to further confuse them.

The Plaintiffs cite to the following block quote in their opposition, which the Court finds an accurate and well-founded recitation of the law.

> The process of differential diagnosis is undoubtedly important to the question of "specific causation". If other possible causes of an injury cannot be ruled out, or at least the probability of their contribution to causation minimized, then the "more likely than not" threshold for proving causation may not be met. But, it is also important to recognize that a fundamental assumption underlying this method is that the final, suspected "cause" remaining after this process of elimination must actually be capable of causing the injury. That is, the expert must "rule in" the suspected cause as well as "rule out" other possible causes. And, of course, expert opinion on the issue of "general causation" must be derived from a scientifically valid methodology."
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> The Federal Judicial Center's Reference Manual on Scientific Evidence, P. 613

Despite the Plaintiffs seeming lucidity of the burden before them, and with this Court recognizing that this is not an overwhelming burden, Dr. Poznansky has still failed to meet this specific causation burden. Dr. Poznansky simply cannot rule out the most plausible explanation of these Plaintiffs' shingles, the wild strain reactivation. What that leaves the Court with is an opinion that is unsatisfactory under the very scientific manual cited by Plaintiffs.

Accordingly, the Court must again find that Plaintiff has not demonstrated the soundness of Dr. Poznansky's methodology, both in terms of his approach to reasoning and to his use of data, from the perspective of others within the relevant scientific community. See Johnson & Johnson, 464 N.J. Super. At 454. The Court again finds that Dr. Poznansky's differential diagnosis fails the Daubert considerations as outlined in Accutane. There is simply too great an analytical gap between Dr. Poznansky's differential diagnosis and his specific causation opinions. In re Accutane Litigation, 234 N.J. at 400.

Instead of explaining the whys and wherefores for his opinions and providing objective support, Dr. Poznansky only offers conclusions and citations to his previous conclusions. See Townsend v. Pierre, 221 N.J. 36, 54-55 (2015); Pomerantz Paper Corp. v. New Community Corp., 207 N.J. 344, 373 (2011). Dr. Poznansky's unshared theories and opinions offered in this litigation will not "aid the trier of fact to understand the evidence and determine the issue" because it is

completely devoid of any scientific foundation. Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 526 (App. Div. 2007). Dr. Poznansky has failed to perform a reliable differential diagnosis in the area of specific causation. Ultimately, the concerns the Court had in denying the Defendant's requested relief for a Lone Pine order requiring PCR tests came to fruition. Plaintiffs once again retained Dr. Poznansky, who did little more than retell an opinion that had previously been rejected by this Court.

CONCLUSION

For the reasons stated above, the Defendant's motion to bar the opinion of Dr. Poznansky in each of the Group A bellwether cases Meuse, Szeklinski, and Walker is **GRANTED**. The Court's stay of this litigation will remain in effect until December 31, 2024, in accordance with the case management order also uploaded on this day.