IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION This Pleading Relates to: All Cases Identified on Ex. 1	MDL No. 2848 Master Docket No. 18-md-2848

Plaintiffs identified in Exhibit 1, who are represented by the law firm of Reich & Binstock, LLP ("Plaintiffs"), file this response in opposition to Merck's Motion to Dismiss brought pursuant to Fed. R. Civ. P. 41(b). For the reasons set forth herein, particularly because **PCR evidence is not dispositive as to causation in any of their cases,** Merck's motion should be denied in its entirety.[1]

I. INTRODUCTION

In the instant motion, Merck is asking the Court to hold that laboratory testing (specifically PCR testing of alleged Shingles injuries) *must* exist in every case as the *only* way to prove causation, even though the Court has already applied the proper standard, which requires a differential diagnosis and not definitive DNA evidence.

Granting Merck's motion would result in the extreme sanction of dismissing more than 1,100 Shingles-injury cases on the sole basis that none of the doctors who treated these individuals' Shingles rashes conducted an admittedly unhelpful PCR test to detect vaccine strain varicella-

[1] Plaintiffs have the right to and can prove specific causation in their individual cases without PCR testing. To this end, Plaintiffs have addressed such in the Appendix that has been annexed hereto as Ex. 2. Neither the Court's prior decision in the Group A Bellwether cases in which the Court found Dr. Poznansky's opinion to be unreliable nor this Court's Pretrial Order No. 426 affect Plaintiffs' ability to do so.

zoster virus ("VZV") contained in Zostavax ("the Oka strain") was present in their respective Shingles rashes. But Merck's motion fails both legally and factually—and Merck knows this—making this motion a waste of everyone's time and resources.

Dismissal under Federal Rule 41 is improper because the documents Merck argues Plaintiffs failed to produce—PCR test reports—have never existed. Additionally Merck has already admitted in its previous Group A Bellwether Daubert motion practice that PCR testing is *not* and *cannot* be conclusive of whether Zostavax caused or contributed to an individual's Shingles outbreak.

Merck's present motion only creates confusion by seeking dismissal under Rule 41(b). Merck argues that dismissal is warranted because Plaintiffs failed to comply with Pretrial Order No. 426 ("PTO 426"), which required Plaintiffs to produce records of laboratory testing (PCR testing) on Shingles rashes, but no such testing has ever existed because not one of the Plaintiffs' healthcare providers believed that such testing was the appropriate standard of care for the diagnosis and treatment of Shingles. Moreover, Merck has never publicly warned any healthcare provider of the need to test Shingles rashes after vaccination. Plaintiffs are not withholding documents, nor did they destroy documents. Therefore, dismissal under Rule 41(b) is wholly improper and Merck's motion should be denied on this basis alone.[2]

Nonetheless, when applying all of the factors for dismissal under Rule 41(b), as set forth in *Poulis v. State Farm Fire & Cas. Co*., 747 F.2d 863 (3d Cir. 1984), all of them weigh in favor of denying Merck's motion. The crux of Merck's motion is that Plaintiffs' claims are not meritorious under *Poulis* because Plaintiffs cannot unequivocally prove beyond question that their

[2] *See Baier v. Princeton Office Park, L.P.,* 2018 U.S. Dist. LEXIS 180612, *9 (D.N.J. Oct. 22, 2018) ("It is axiomatic that a party can not be forced to produce documents that do not exist."); *Staff Builders of Philadelphia, Inc. v. Koschitzki*, 1989 U.S. Dist. LEXIS 7027, *10 (E.D.Pa. Jun. 26, 1989.); *Bracey v. Harlow*, 2012 U.S. Dist. LEXIS 147216, *11 (W.D. Pa. Oct. 12, 2012)

Shingles rashes had the vaccine-strain of the virus present, and that the only way to do so is by PCR testing. Not only would accepting Merck's argument heighten Plaintiff's burden of proof above the criminal standard of "beyond a reasonable doubt," Merck's argument is entirely an attorney-created one that Merck's counsel has been touting ever since the Court-ordered Science Day presentations, even though Merck cannot offer any support for it. Not one of Merck's experts has adopted this position, and, in fact, Merck's experts agree with the Plaintiffs' experts when they admit that ***PCR testing cannot definitively determine whether a rash sample contains the Oka strain.***

The most egregious issue with Merck's motion (and what makes it a complete waste of the Court's time and resources), however, is the fact that Merck's counsel has already admitted to this Court that PCR is not going to be able to always detect Oka-strain when it is present in a Shingles rash. Indeed, in defending its PCR expert's opinions in the Group A Bellwether cases, Merck stated the following regarding two of its experts:

> "Drs. Ehrlich and Storch's deposition testimony merely acknowledged the obvious fact that, at some infinitesimally low number of molecules approaching zero, detectability is no longer possible. No test is 100% sensitive and 100% specific. Plaintiffs seek to impose a standard of impossibility to an extreme, requiring Merck to try to prove the negative (i.e., there was no vaccine-strain VZV DNA in any sample tested) as part of an inappropriate effort to flip their burden of proof… Nor does it even matter whether the PCR Assay is capable of detecting each and every vaccine-strain virus molecule." Doc. 906, p. 7.

These are Merck's words. To be clear, months before the current motion was filed, Merck had already admitted to the Court that PCR testing cannot prove that "there was no vaccine strain VZV DNA in any sample tested", *id.*, making their entire motion frivolous.

The only evidence Merck offers in purported support of its position is in the form of publications, and not expert opinion. For example, Merck relies on an article authored by Rafael

Harpaz, a CDC employee, where he states that "Zoster caused by Oka/Merck strain VZV cannot be distinguished on clinical grounds from zoster caused by wild-type VZV," but this statement is only commenting on the risk of Shingles in children who received the Oka strain from the chickenpox vaccine, and not adults receiving Zostavax after already having experienced wild-type chickenpox earlier in life.[3] This distinction is important because they are two different populations with two different levels of immunity (i.e. healthy vs. weakened) where one population (the child) has been exposed to VZV only once and the other has been exposed to VZV at least twice (the adult).[4]

Moreover, the *Harpaz* publication never once states that PCR is the only way to determine if the Oka strain caused a given Shingles outbreak. In fact, this same paper goes on to state: "The risk for zoster caused specifically by Oka/Merck strain VZV is unknown because recipients of varicella vaccine might have already been infected with wild-type VZV", which is exactly what is happening in the adult population who received Zostavax.[5] None of the publications relied upon by Merck deal with or support the absolute need for PCR to know if the Oka strain caused a given Shingles rash.

Indeed, although not referenced by Merck in the present motion, the researchers at the Veterans Administration ("VA") and employees at Merck have already published a paper that specifically states that PCR results are unreliable and that a clinical history is needed to fully understand the etiology of a Shingles rash. Those researchers state:

> "Since these specimens were from vaccine-associated rashes in VZV-naive recipients of varicella vaccine, mixtures of VZV-WT and VZV-Oka would be unlikely. However, because of the cross-reactivity between VZV-WT and VZV-Oka in this assay, it is theoretically possible that a very small proportion of the DNA in a clinical specimen may be

[3] Ex. 3, Rafael Harpaz et al., Prevention of Herpes Zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 57 Morbidity & Mortality Wkly. Rep. 1, 6 (2008).
[4] Ex. 2.
[5] *Id.*

from the heterologous virus. **Thus, in some situations, both laboratory and clinical (e.g., epidemiologic history) data may be required to achieve an accurate diagnosis**"[6]

Finally, Merck is suggesting that for a claim to have merit, Plaintiffs must *conclusively* prove that the Oka strain virus was present in a given Shingles rash. While that may be a question of interest in the academic community, it is not the issue at hand. It is not Plaintiffs' burden to prove with 100% certainty that Zostavax caused their Shingles rashes, yet that is the burden Merck seeks to impose on Plaintiffs through its instant motion.

For these reasons, granting Merck's motion would be reversible error, and Merck's motion should be swiftly denied.

II. FACTUAL BACKGROUND

A. The Group A Bellwether Plaintiffs' Experts' General Causation Opinions Explain Why PCR Results Cannot be Dispositive in this Litigation.

Merck's previous concessions to the Court about the inability of PCR to detect minute amounts of the vaccine strain are precisely why PCR results cannot be considered dispositive in this litigation. The Group A Bellwether Plaintiffs' experts, Drs. Pinghui Feng and Mark Poznansky, offered general causation opinions that were never challenged by Merck under *Daubert*.[7] These experts opine that when Zostavax causes a mixed strain Shingles rash, there will always be small traces of the Oka strain in that rash, and in many cases the amount will be so small that it will not be detected by PCR.[8] Thus, the fact that Merck admits that PCR will not be able to

[6] Ex. 13 – Harbecke R., et al., A real-time PCR assay to identify and discriminate among wild-type and vaccine strains of varicella-zoster virus and herpes simplex virus in clinical specimens, and comparison with the clinical diagnoses. J Med Virol. 2009 Jul;81(7):1310-22. doi: 10.1002/jmv.21506. PMID: 19475609; PMCID: PMC4217208.

[7] Expert discovery has not been conducted in any of Plaintiffs' cases, but it is Plaintiffs' intent to utilize and/or adopt the general causation opinions of Drs. Feng and Poznansky.

[8] The reason there will be smaller amounts of Oka strain when compared to the wild-type strain has to do with the fact that the Oka strain's ability to replicate in skin is greatly reduced when compared with the wild-type strains' ability to replicate in human skin. *See* Ex. 2.

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