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

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2848
THIS DOCUMENT RELATES TO: ALL CASES	:	CIVIL ACTION NO. 18-md-2848

MEMORANDUM IN SUPPORT OF PRETRIAL ORDER NO. 426

Bartle, J. March 30, 2022

This MDL involves Zostavax, a vaccine developed by defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. ("Merck") to prevent shingles. Some plaintiffs contend that Zostavax did the opposite, that is, that it caused them to suffer from shingles. Others claim that the Zostavax vaccination brought about different illnesses. Currently, the MDL cases are divided into two groups for management purposes. Group A includes over 1,700 actions where it is alleged that Zostavax caused the plaintiffs to contract shingles. Group B encompasses approximately 500 cases where the plaintiffs contend that Zostavax caused various illnesses other than shingles.

Merck has now filed a motion for a case management order in the Group A cases requiring each plaintiff to produce laboratory reports or other records documenting that their shingles rash samples contained the varicella-zoster virus ("VZV") from Zostavax.

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The plaintiffs' Executive Committee ("PEC") and Merck pursuant to various case management orders selected six representative bellwether Group A cases for trial. The PEC selected three and Merck selected three. One of the six fell by the wayside when plaintiff was unable to obtain a causation expert.[1] After three years of extensive fact discovery had been completed, expert reports exchanged, and experts deposed, Merck filed a series of Daubert[2] and other pre-trial motions in the remaining bellwether cases pursuant to Pretrial Order No. 376. On December 1, 2021, this court entered an order excluding the specific causation opinion of Mark Poznansky, M.D., plaintiffs' expert, in those bellwether actions. Pretrial Order No. 409; see also In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig., MDL No. 18-2848, 2021 WL 5631687 (E.D. Pa. Dec. 1, 2021), appeal filed (3d Cir. Jan. 6, 2022). As a result, plaintiffs were not able to establish a causal connection between Zostavax and the onset of their shingles. The court thereupon entered summary judgment in favor of Merck in all five cases. Pretrial Orders Nos. 411, 413, 415, 417, 419.

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1. The court granted summary judgment to Merck in Destefano v. Merck after that plaintiff failed to serve an expert causation report. Pretrial Order Nos. 363, 364; see also In re Zostavax (Zoster Vaccine Live) Prod. Liab. Litig., MDL No. 18-2848. Civ. A. No. 18-20070, 2021 WL 2808815 (E.D. Pa. July 6, 2021).

2. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

It is well-known that the VZV causes both chickenpox which typically occurs in childhood and shingles, that is herpes zoster, which occurs later in adulthood after a person has experienced chickenpox. The VZV remains in the body for life. It travels up nerve fibers from the skin and becomes dormant in nerve cells, called ganglia, near the spinal cord until it reactivates. When it reactivates, it travels down the nerve fibers and results in shingles. Virtually all persons over the age of 30 in the United States have had chickenpox and carry the so-called wild-type virus in their systems. Shingles manifests itself in a painful rash on various parts of the body. It is estimated that one out of three adults will experience shingles during his or her lifetime.

Zostavax was developed to prevent shingles in adults 50 years or older and was licensed by the Food & Drug Administration ("FDA") in 2006. It includes the Oka strain of the VZV, a live-attenuated virus that is a weakened form of the natural or wild-type virus found in the body of someone who has had chickenpox. Zostavax is not designed to produce immunity by causing a mild case of shingles but rather to prevent shingles by effecting immunity before an outbreak of shingles takes place. Zostavax's effective rate is around 50% and wanes over time. The effectiveness also declines with the age of the patient. Merck concedes that an immunocompetent adult who

receives Zostavax can develop shingles from the live-attenuated virus but contends that such an occurrence is extremely rare.

The plaintiffs maintain that 15% of those vaccinated with Zostavax who contract shingles did so because of Zostavax. Merck vigorously challenges that assertion. In any event even if plaintiffs are correct, 85% of the recipients of the Zostavax vaccine who later contracted shingles cannot relate their shingles to Zostavax. Of course, each plaintiff has the burden of proving that Zostavax caused his or her shingles. That 15% of the recipients of Zostavax may suffer from shingles as a result of being vaccinated is of no help to the issue of causation in a specific case.

The court, as more fully explained in its December 1, 2021 Memorandum, ruled inadmissible the testimony of Dr. Poznansky because he failed to conduct a differential diagnosis in support of his opinion that Zostavax caused plaintiffs' injuries. Such diagnosis required him to explain why the wild-type virus from chickenpox was not responsible for plaintiffs' shingles. See In re Zostavax, 2021 WL 5631687, at *3. Merck now seeks to require the remaining Group A plaintiffs to produce specific testing evidence that the Zostavax virus as opposed to the virus from latent chickenpox caused their shingles-related injuries. What Merck requests is known as a Lone Pine order, named for a New Jersey State court

case in which a similar case management order was issued in a mass tort action. Lore v. Lone Pine Corp., 1986 WL 637507 (N.J. Super. Ct. Law Div. Nov. 18, 1986). Our Court of Appeals in Hamer v. LivaNova Deutschland GmbH, 994 F.3d 173 (3d Cir. 2021), approved the use of such orders. It has recognized that "[a] district court, administrating a multidistrict case, faces unique challenges not present when administrating cases on a routine docket." Id. at 178. It deems management orders "essential tools in helping the court weed court non-meritorious" claims. Id. While a district court must be careful not to stifle meritorious claims, it may impose a Lone Pine order so as to "require plaintiffs to furnish specific evidence like proof of a medical diagnosis, with the goal of winnowing non-compliant cases from the MDL." Id. This is exactly what Merck seeks here.

Merck's request for a Lone Pine order comes only after three years of discovery during which Merck has produced over 6,000,000 pages of documents related to Zostavax and made available nearly 40 persons for depositions. There was also specific fact discovery in the bellwether cases. Despite this outpouring of discovery and after an abundance of time for plaintiffs to review it, the opinion of plaintiffs' expert on causation has fallen short in all bellwether cases, several of which were chosen by the PEC. In none of the five bellwether

cases were the plaintiffs' rashes tested for the type of virus present. Dr. Poznansky, a professor at Harvard Medical School, was simply unable to meet the requirements of Daubert without such test results.

The defendants' request for a Lone Pine order is not unreasonable. There is compelling medical authority that a laboratory test of the shingles rash of a person who has had chickenpox is the only way to tell whether the shingles was caused by the virus strain contained in Zostavax or by the wild-virus strain from chickenpox latent in a person's body. See, e.g., 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). The rash manifesting shingles looks the same for both. Furthermore, the appearance of the shingles rash even soon after the Zostavax vaccine is administered is not indicative in and of itself of causation. See In re Zostavax, 2021 WL 5631687, at *5-7.

Significantly at this late stage, the PEC has not cited any medical literature or expert medical opinion explaining how it can be determined that Zostavax caused a person to contract shingles other than, as defendants have shown, through a testing of that person's rash. Plaintiffs in the Group A cases have not come forward with a causation expert

other than Dr. Poznansky. They have not made the court aware that they have prima facie support for any of their claims. They have not provided any guidance as to how the more than 1,700 Group A cases can proceed in a reasonable manner without a Lone Pine order. Plaintiffs, it must be remembered, have the burden of proof on causation. Simply because it may be difficult or impossible to meet that burden does not change that well-established rule of law.

It is now time for plaintiffs to come forward with the Laboratory Reports or other documentation Merck requests to enable the court to weed out non-meritorious from meritorious claims and move along these 1,700 or more cases toward a final resolution. A Lone Pine management order is the only viable way that "will promote the just and efficient conduct of [these] actions." 28 U.S.C. § 1407(a).[3]

3. Merck, of course, may seek further relief as to plaintiffs who after their respective allotted periods fail to produce laboratory reports or other documentation showing the presence of vaccine-strain shingles.