THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOSTAVAX (ZOSTER VACCINE LIVE) PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL CASES**	**MDL No. 2848** **CIVIL ACTION NO. 2:18-md-02848-HB**

DEFENDANTS MERCK & CO., INC. AND MERCK SHARP & DOHME CORP.'S OPPOSITION TO THE PLAINTIFF EXECUTIVE COMMITTEE'S MOTION TO COMPEL PRODUCTION OF ADVERSE EVENT DATA AND STANDARD OPERATING PROCEDURES

Defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. (collectively, "Merck") file this opposition to the Plaintiff Executive Committee's motion to compel production of adverse event data and standard operating procedures ("PEC's Motion") (Doc. 308).

I. INTRODUCTION

The PEC's Motion claims to seek "*all* relevant and responsive adverse event data related to ZOSTAVAX® – data that is critically relevant to the claims and defenses at issue in this MDL," and thus, seeks to compel production of Merck's entire adverse event database ("Merck Adverse Event Reporting and Review System," termed "MARRS") as it relates to ZOSTAVAX®. PEC's Memo. in Supp. of Third Mot. (Doc. 308-1) at 5 ("PEC's Memo."). What the PEC actually seeks is data describing adverse events that not a single plaintiff in this MDL purports to have ever experienced. The PEC seeks this data despite the fact that Merck has already produced well-over 30,000 pages of information on every adverse event report that it has submitted to the FDA as well as to foreign regulatory agencies since the FDA approved ZOSTAVAX® for use in 2006, in the form of "15-day Alert reports," Periodic Adverse Drug Experience Reports ("PADERs")[1] and

[1] Federal regulation requires pharmaceutical manufacturers to report to the FDA certain information received concerning adverse experiences with the product. See 21 C.F.R. § 314.80. Such reporting includes "15-day 'Alert reports'" which provide information for "adverse drug experience[s] that [are] both serious and unexpected, whether foreign or domestic" within 15 days of the manufacturer initially receiving the information. 21 C.F.R. § 314.80(c)(1). In addition, the FDA requires manufacturers to submit "Periodic Adverse Drug Experience Reports" (PADER) at quarterly intervals for the first three years after approval of a product and then annually thereafter. These periodic reports provide information received by a manufacturer on all reportable adverse experiences, except the previously submitted 15-day Alert reports. 21 C.F.R. § 314.80(c)(2). Each PADER includes a copy of an "Individual Case Safety Report" for every serious and expected (i.e. labeled) adverse experience report received by the manufacturer during the applicable reporting period and for every nonserious adverse experience report received during the period as well. 21 C.F.R. § 314.80(c)(2)(ii)(B).

Each Individual Case Safety Report included in the PADER provides, among other information, patient identifying information (e.g., age, gender, date of birth) and identifying information for the individual initially reporting the adverse experience to the manufacturer (e.g.,

Periodic Safety Update Reports ("PSURs").[2] The PEC further purports to need "narrative fields" for every report contained in this database despite the fact that Merck has already provided narratives for the adverse events reported in 15-day Alert Reports and for nearly all of the PADERS submitted to the FDA.[3] And the PEC flatly refuses to even discuss Merck's offer to negotiate stipulated search terms that would isolate and capture the adverse events related to plaintiffs' alleged injuries, insisting instead that Merck undertake the burden of redacting thousands of irrelevant adverse event reports in order to comply with federal privacy regulations.

The PEC offers little rationale to bolster its overly broad requests for the entire contents of Merck's adverse event reporting database, beyond the general pronouncement that it has sought and obtained this type of data in other MDLs. The caselaw and other MDL filings, however, belie the PEC's assertions and in fact establish that the preferred practice is to limit such productions to adverse events tied to the injuries alleged in plaintiffs' complaints – i.e., what Merck has offered to produce. Significantly, the PEC fails to explain how the production of unrelated adverse event

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name, address, telephone number, type of report (consumer or healthcare professional), occupation if a healthcare provider, etc.). 21 C.F.R. § 314.80(f). Except in limited circumstances not applicable here, such identifying information must be redacted prior to production. See 21 C.F.R. § 20.63. In addition, each Individual Case Safety Report form includes a "[d]escription of adverse drug experience (including a concise medical narrative)." 21 C.F.R. § 314.80(f)(2)(iv).

[2] Periodic Safety Update Reports ("PSUR") are "pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of a medicinal product at defined time points after its authorization" and present "a comprehensive and critical analysis of the risk-benefit balance of the product, taking into account new or emerging safety information in the context of cumulative information on risk and benefits." Ex. 1, European Medicines Agency, Periodic Safety Update Reports (emphasis omitted). PSURs do not include copies of Individual Case Safety Records.

[3] Due to a change in regulatory submission practices, Merck's production of the ZOSTAVAX® regulatory file does not include copies of the Individual Case Safety Records for PADERs submitted in 2016, 2017 and 2018. The extract of the MARRS database that Merck has offered to produce would include adverse experiences reported during these time periods for the injuries the MDL plaintiffs have alleged and would include the "narrative field" for each of these reports.

reports is relevant to the claims that plaintiffs bring in *this* MDL. Instead, the Motion merely reprises the PEC's generalized attacks on the safety and efficacy of ZOSTAVAX®, without bridging the logical gap between its sweeping statements and unfounded conclusions that all adverse events purportedly have relevance to plaintiffs' claims. Finally, in the absence of any evidence, the PEC relies on speculation and conjecture as to how Merck "might" have failed to identify generalized reported symptoms as shingles, exposing their requests for the database – as well as for Merck's standard operating procedures governing adverse event reporting – as nothing more than a fishing expedition. As the PEC cannot meet its burden of showing the relevancy of cumulative and duplicative adverse event reports that have no bearing on any plaintiffs' alleged injuries, the Court should deny the PEC's motion to compel.

II. BACKGROUND

The PEC's Motion seeks the contents of Merck's entire database containing every adverse event ever reported for the ZOSTAVAX® vaccine since the FDA approved it in 2006, as well as every version of its standard operating procedures ("SOPs") related to adverse event reporting to the FDA as well as to various foreign regulatory agencies. Merck served its response and objections to the Request at issue here (Request No. 19) on November 21, 2018, objecting, in particular, to the production of "documents or information relating to alleged adverse events not at issue in this litigation," and noting that responsive documents could be found in the ZOSTAVAX® US regulatory file production, including PADERs, as well as PSURs. Despite multiple discussions on others of the PEC's requests, the PEC did not voice any objection to Merck's response to Request No. 19 until March 8, 2019. At that time, the parties noted their

respective positions, and Merck indicated a willingness to meet and confer.[4] Plaintiffs finally returned to this issue in May, and at that time Merck offered the following compromise:

> . . . Merck is willing to produce an extract of ZOSTAVAX®-related data from the MARRS database containing available information found in agreed-upon fields of data for reportable adverse experience reports received by Merck *for the injuries Plaintiffs allege in their complaints*, the only adverse events at issue in this litigation.

See Email from M. Roberts to V. Anello dated 5/17/19, Ex. J to PEC's Mot. at 2 (emphasis added). The PEC rejected Merck's proposal and filed this motion.

While the PEC maintains that the injuries alleged are simply too broad "to be broken down into specifics," the PEC's Motion nevertheless provides a discrete and concrete list of conditions that plaintiffs claim to have experienced. PEC's Memo. at 10 n.16. Standard practice in pharmaceutical products liability litigation involves using the current MedDRA[5] dictionary to

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[4] Merck heard nothing further from the PEC on this issue until May 9, 2019, when the PEC advised that it was preparing to file a motion to compel adverse event data. The next day, Merck's counsel wrote to the PEC, reminding them that "[t]he last discussion that the parties had about adverse event data was on March 8th when we learned, for the first time, that Plaintiffs wanted Merck to produce its 'whole database' of adverse event information," that Merck had advised that the parties would need to meet and confer, but "we have not heard from you." See Email from M. Roberts to V. Anello dated 5/10/19, Ex. J to PEC's Mot. at 5. On May 13, the PEC explained specifically what it sought and four days later Merck offered to produce agreed-upon fields from the MARRS database for reportable adverse events related to the injuries plaintiffs allege in their complaints. Id. at 2. The PEC rejected Merck's offer, claiming to need "all reports that relate to these injuries" that plaintiffs allegedly experienced. Id. at 1. Merck explained that this characterization paradoxically appeared to mirror Merck's offer, and invited the PEC to specify the injuries for which they sought MARRS data, "to see if a deal can be reached." Id. The PEC rebuffed Merck's offer to compromise and subsequently filed its Motion.

[5] The Medical Dictionary for Regulatory Activities (MedDRA) provides "rich and highly specific standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans." In short, medical events are coded into MedDRA terms, using its hierarchical structure: system organ class; high level group term; high level term; preferred term; and lowest level term. Thus preferred terms, placing second in specificity, offer "a distinct descriptor (single medical concept) for a symptom, sign, [or] disease diagnosis . . . ." Both the publicly available Vaccine Adverse Event Reporting System ("VAERS")

query adverse event databases based on a list of plaintiffs' alleged injuries. Nevertheless, the PEC has wholly refused to negotiate from its position that plaintiffs are entitled to the contents of the entire database.

III. ARGUMENT

A. The Court Should Deny the PEC's Irrelevant Request for Data Regarding Adverse Events that Plaintiffs Have Undisputedly Never Experienced.

1. The PEC Cannot Demonstrate that Adverse Event Reports Unrelated to Plaintiffs' Alleged Injuries Have Any Relevance to Their Claims.

The PEC offers no support for its assertion that adverse events concerning symptoms no plaintiff in this MDL has ever experienced have any relevance to this litigation, beyond hollow, sweeping pronouncements that "any and all knowledge . . . regarding adverse event reports and the safety of the drug is relevant to causation and knowledge." See PEC's Memo. at 9; Teva Pharms. USA, Inc. v. Amgen, Inc. 2011 WL 13225286, *1 (E.D. Pa. Jan. 24, 2011) ("[T]he party seeking discovery must demonstrate the relevancy of the requested information"). Instead, the PEC cites to a line of cases holding that adverse event reports ("AER") are discoverable because courts have found them admissible at trial to prove notice. PEC's Memo. at 8-9. This signifies nothing, as the parties' dispute hinges not on the discoverability of *any* AERs, but rather the discoverability of AERs that have no ties to plaintiffs' claimed injuries. See Terry v. McNeil-PPC, Inc., (In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig.) 181 F. Supp. 3d 278, 286–87 (E.D. Pa. 2016) (agreeing that any AERs presented for the purpose of notice must be limited to those "similar to the circumstances of this case (i.e., persons who developed acute liver failure/damage at or just above 4 g, persons who were fasting/malnourished). Other AERs

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and MARRS utilize MedDRA terminology when adverse events are coded into the databases. https://www.meddra.org/how-to-use/support-documentation/english.

would likely be irrelevant to the case"). To illustrate the point, attached are several ZOSTAVAX® reports for injuries that are plainly irrelevant to any of the claims raised in this litigation, specifically: urinary tract infection, gout, tooth extraction, ankle fracture, arthropod bite and road traffic accident. See Ex. 2, Line Listings of Adverse Event Reports. The PEC offers no "fact-specific" showing as to the conceivable relevance of such data to plaintiffs' claims. Rhone-Poulenc Rorer, Inc. v. Home Indem. Co., 1991 WL 183842, at *3 (E.D. Pa. 1991).

Rather, the PEC's Motion merely rehashes stock allegations regarding the safety and efficacy of ZOSTAVAX®. First, it seeks to recast the FDA's request for post-marketing analysis of adverse experiences as evidence that the FDA "was not convinced of Zostavax's safety and effectiveness," which somehow "makes *all* post-market adverse event data relevant to this litigation." PEC's Memo. at 7. Putting aside the PEC's peculiar position that the FDA approved a product as safe and effective, and yet did not believe it was safe, the PEC fails to link any of these superficial attacks directed at the vaccine in general to the specific data that it is seeking. See also PEC's Memo. at 8 (proclaiming that adverse events reporting unrelated conditions are "extremely important to the claims in this litigation because this vaccine has been given to millions, yet it is virtually untested," notwithstanding the fact that the safety of ZOSTAVAX® has been evaluated in hundreds of thousands of vaccine recipients[6]).

[6] *See* Oxman, M., et al., A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults, N. Engl J Med 2005, 352:2271-84 at 2276; Murray A, et al., Safety and tolerability of zoster vaccine in adults ≥ 60 years old, Human Vaccines 7:11, 1130-1136 (Nov. 2011) at 1131; Baxter R. et al., Safety of Zostavax – A cohort study in a managed care organization, Vaccine 30 (2012) 6636-6641 at 6638; Schmader, K., et al., Efficacy, Safety, and Tolerability of Herpes Zoster Vaccine in Persons Aged 50-59 Years, CID 2012, 54(7): 922-28 at 925; Tseng, H., et al., Safety of zoster vaccine in adults from a large managed-care cohort; a Vaccine Safety Datalink study, Journal of Internal Medicine 2012, 271: 510-520 at 515.

The PEC further reveals the tenuousness of any link between the data it seeks and plaintiffs' purported injuries by engaging in rank conjecture about what additional information they hope to discover in the MARRS narrative fields. See PEC's Memo. at 14 (speculating that "[i]t could very well be the case" that an individual with facial paralysis "was later diagnosed with Shingles in Merck's adverse event database"); id. at 14 (blindly hazarding that the narrative fields "likely contain[] significantly more information" about a report of "pain in legs," because it "could" be a symptoms of shingles without rash or Guillain Barre Syndrome). As an initial matter, Merck has offered to produce data regarding adverse events that MDL plaintiffs have purportedly experienced – which would include reports involving a patient diagnosed with facial paralysis, shingles or Guillain Barre Syndrome. Moreover, the PEC's speculation as to what the narrative fields "likely" or "could very well" contain has no basis in fact. See Quadrant Epp USA, Inc. v. Menasha Corp., 2007 WL 320286, at *1 (E.D. Pa. Jan. 29, 2007) ("[C]ourts should not grant discovery requests based on pure speculation that amount to nothing more than a 'fishing expedition' into actions ... not related to the alleged claims or defenses") (internal citations and quotation marks omitted). The PEC's attempts to conjure imaginary connections between a range of generalized symptoms and plaintiffs' claimed injuries illustrate the irrelevance and overbreadth of its requests.

2. Courts Limit the Production of Adverse Events to Those Plaintiffs Allegedly Experienced.

Contrary to the PEC's representations, it is standard practice in pharmaceutical products liability litigation to limit the production of adverse events from manufacturer databases to reports relevant to the plaintiffs' claims, which has been Merck's experience in the currently pending MDLs in which it is a defendant. See e.g., Avendt v. Covidien, Inc., 2013 WL 3941367, at *2 (E.D. Mich. July 31, 2013) (Plaintiff's requests for adverse event reports relating to all of defendant's products "is overly broad in time and scope and is unduly burdensome"), order

clarified, 2013 WL 6482107 (E.D. Mich. Dec. 10, 2013); Kelley v. Johnson & Johnson Co., 2010 WL 2431835, at *3 (M.D. Fla. June 15, 2010) (Plaintiff's request for "all adverse reports for a period covering twenty (20) years and pertaining to all adverse reports for Duragesic and the Sandoz patch […] is overbroad in its scope and reach"); Autery v. SmithKline Beecham Corp., 2010 WL 1489968, at *2 (W.D. La. Apr. 13, 2010) ("Clearly, had plaintiff sought *all* adverse or spontaneous adverse event reports, that request would be overly broad and unduly burdensome.") (emphasis added); Jones v. Abbott Labs., 2011 WL 13164887, at *2 (W.D. Tenn. Nov. 10, 2011) (granting defendant's motion for protective order in suit alleging that Humira caused decedent's lymphoma, because "plaintiffs' discovery request seeking adverse event reports for Humira involving other adverse effects that have no association with lymphoma or malignancies does not meet the broad relevancy standards of Rule 26"); Small v. Amgen, Inc., 2016 WL 7228863, at *9 (M.D. Fla. Sept. 28, 2016) (holding that "documents and information relating to adverse events other than the specific adverse event alleged by Plaintiff . . . are not relevant to the claims or defenses in this case" and that "requiring Defendants to respond to expansive discovery pertaining to adverse events other than [her] particular adverse event is not proportional to the needs of this case based on the burdensomeness of the requests"); Conklin v. Invacare Corp., 2007 WL 2492728, at *2 (W.D. Pa. Aug. 30, 2007) (denying discovery of adverse event reports regarding injuries caused by different problems not at issue in the litigation).

Nor do defendants "routinely produce[]" their entire adverse event databases in MDLs as the PEC claims. PEC's Memo. at 9. Plaintiffs in In re: Avandia Mktg., Sales Practices and Prods. Liab. Litig., similarly sought discovery of GSK's entire database of adverse drug events ("ADEs"), and GSK objected to producing data that did not involve the cardiovascular and neurovascular conditions at issue. Ex. 3, June 2009 Status Rpt. of Special Master, In re Avandia Mktg., Sales

Practices and Prods. Liab. Litig., No. 2:07-md-01871-CMR (Doc. 435) (E.D. Pa. June 5, 2009). The court agreed and denied plaintiffs' request to compel production of the entire database. Ex. 4, Pretrial Order No. 62, In re: Avandia Mktg., Sales Prac. & Prod. Liab. Litig., No. 2:07-md-01871-CMR (Doc. 439), at 1 (E.D. Pa. June 9, 2009). See also In re Incretin Mimetics Prods. Liab. Litig., 2014 WL 4987877, at *4 (S.D. Cal. Oct. 6, 2014) (denying motion to compel defendants' entire adverse event databases); rev'd, In re Incretin-Based Therapies Prods. Liab. Litig., 721 F. App'x 580, 583 (9th Cir. 2017) (reversing discovery order precluding production of adverse event data files when "the volume of the requested data was limited" to adverse events regarding pancreatic cancer only); Order No. 9A (Scheduling Order), Ex. 5, In re: Mirena IUD Prod. Liab. Litig., No. 7:13-md-02434-CS-LMS (Doc. 1391), ¶ 4 (S.D.N.Y. July 29, 2014) ("Defendants will also collect supplements up to and including August 1, 2014 for the following non-custodian sources: […] 3) Mirena Adverse Event Data involving reports of perforation, embedment, or migration.").

Moreover, the PEC also misleadingly suggests that all of the MDL orders attached to the Motion support its assertion that entire AE databases are "typically produced in MDLs without issue." PEC's Memo. at 1. They do not. The PEC erroneously cites In re: Zofran (Ondansetron) Prods. Liab. Litig. for this proposition; however, the defendant in that MDL only produced AE data *related to the injuries plaintiffs allegedly experienced*, precisely what Merck has already agreed to produce here. See Pls.' and GSK's Joint Status Rpt. on Pls.' Mot. to Compel, In re: Zofran® (Ondansetron) Prods. Liab. Litig., No. 1:15-md-02657 (Doc. 987) (D. Mass. Apr. 6, 2018) (indicating that GSK would produce data concerning "all reports of Zofran use in pregnancy" and "reports of QT Prolongation, Torsade de Pointes, Long QT syndrome outcomes listed in 55 reports"), Ex. E to PEC's Mot. Similarly, the stipulated order attached by the PEC in

In re Abilify (Aripiprazole) Prods. Liab. Litig. notes only that the parties have met and conferred on the fields to be produced from the adverse events database. Stipulated Order Resolving Production of Adverse Event Information, In re Abilify (Aripiprazole) Prods. Liab. Litig., No. 3:16-md-02734 (Doc. 300) (N.D. Fla. Apr. 6, 2017), Ex. D to PEC's Mot. at 1. Exhibits attached to the parties' briefing confirm that plaintiffs had agreed to negotiate a list of search terms "that have a nexus to compulsivity," the condition at issue in that litigation. See Ex. 6, Ex. C to Pls.' Mot. to Compel Defs.' Discovery Responses, In re Abilify (Aripiprazole) Prods. Liab. Litig., No. 3:16-md-02734, Doc. 536-4, at 11-12 (N.D. Fla. Sept. 12, 2017); see also Ex. 7, Resp. in Opp. to Defs' Mot. to Compel the Prod. of Pls' Online Gambling Records and For Inspection, In re: Abilify (Apripiprazole) Prods. Liab. Litig., No. 13-md-02734 (Doc. 611), at 12 (N.D. Fla. Dec. 1, 2017) (stating that "Defendants were only required to search their database for specific search terms"). Far from confirming the PEC's sweeping statements that their overbroad request is standard practice in MDLs, their own case citations show that the preferred approach is consistent with Merck's offer to produce data regarding adverse events the plaintiffs actually allege to have experienced. In addition, other courts have distinguished the few cases upon which the PEC so heavily relies. See Jones, 2011 WL 13164887, at *4 (noting that the Special Master in Rix "gave no reason for why he believed non-birth defect adverse event reports were relevant and discoverable," and that Neurontin involved allegations that the drug caused a range of symptoms associated with suicide or self-injurious behavior while in the instant case plaintiffs had not demonstrated how "adverse events that are not associated with a given condition can give rise to a safety signal for that condition").

3. Merck Has Already Produced Information for Adverse Events Reported for ZOSTAVAX® in the Form of PSURs and PADERs.

The PEC attempts to minimize the scope of the substantial information that it has already received, maintaining that lack of access to Merck's entire database "would deprive [it] of access to *all* relevant and responsive adverse event data related to Zostavax." PEC's Memo. at 5. Nothing could be further from the truth. Although the PEC focuses its argument on the PSURs previously produced,[7] the PEC fails to mention, and their rhetoric suggests that they do not recognize, that Merck long ago provided ZOSTAVAX®-related adverse event information to the PEC by way of the Periodic Adverse Drug Experience Reports ("PADERs"), as well as the 15-day Alert Reports found throughout the ZOSTAVAX® US regulatory file production. PADERs, 15-day Alert Reports, and PSURs report adverse events concerning the experiences of patients administered ZOSTAVAX® regardless of whether Merck believes that ZOSTAVAX® had any role in any alleged injury; Merck submits these reports to the FDA and ex-US regulatory agencies, respectively, in the format required by the applicable regulations. Merck produced these reports for *all* adverse events reported to the FDA as well as to foreign regulatory agencies regarding ZOSTAVAX® – an inescapable fact that renders the PEC's request for Merck's entire adverse event reporting database unnecessarily cumulative and duplicative.

Moreover, the 15-day Alert Reports and PADERs produced to the PEC – which encompass *all* of the domestic adverse events reported to the FDA – contain what the PEC terms the "critically

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[7] The PEC's Motion cast doubt on the "adequacy and completeness" of Merck's PSUR production, questioning whether Merck produced "all responsive PSURs" and representing that "it appears that Merck has produced only a limited set of PSURs and they do not date back farther than 2012." PEC's Memo. at 12 n.22. The PEC, however, had to withdraw these accusations by letter to the Court on June 5th, after recognizing that Merck's counsel had confirmed that Merck did in fact produce "all PSURs from 2006 to the present and further identified the BATES number of said PSURs." See Letter from V. Anello dated 6/5/19 (Doc. 314).

relevant" narrative fields that it claims it lacks. The PEC's motion therefore asks Merck to *reproduce* this exact same information for every reported adverse event that occurred in the U.S. The wealth of information the PEC possesses further erodes its dubious assertions that it needs these adverse event reports as evidence of notice and causation,[8] as well as its professed concerns that Merck's experts will have access to reports of irrelevant and unrelated conditions that their experts will not.[9] See Teva, 2011 WL 13225286, *1 ("[D]iscovery shall not be compelled if [] 'the discovery sought is unreasonably cumulative or duplicative.'") (citing Fed. R. Civ. P. 26(b)(2)(C)). The PEC's extravagant claims that lack of access to the MARRS data in its entirety

[8] While the PEC currently has more than enough information – in the form of PADERs and PSURs – at its disposal to assess causation (and Merck does not object to producing MARRS reports tied to plaintiffs' injuries) the odds that the PEC will be able to rely on adverse event reports to demonstrate causation are exceedingly slim. Courts all over the country have long found adverse event reports inadmissible as a basis to prove causation, due primarily to their lack of controls, among other reasons. E.g., McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1250, 1252 (11th Cir. 2005) (reversing district court's admission of medical causation testimony based on AERs because "such anecdotal reports do not prove causation" and they offer "one of the least reliable sources to justify opinions about both general and individual causation"); see also In re Zoloft (Sertralinehydrochloride) Prods. Liab. Litig., 176 F. Supp. 3d 483, 497, n.86 (E.D. Pa. 2016) (noting adverse events are "insufficient to create a material question of fact on general causation), aff'd sub nom., In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig., 858 F.3d 787 (3d Cir. 2017); Leathers v. Pfizer, Inc., 233 F.R.D. 687, 694 (N.D. Ga. 2006) (granting summary judgment to defendants following exclusion of expert testimony on general causation based on unreliability of adverse event reports); Soldo v. Sandoz Pharms. Corp., 244 F. Supp. 2d 434, 539 (W.D. Pa. 2003) (collecting cases and noting "the Court of Appeals for the Third Circuit and district courts therein have held that adverse event reporting system data are not a legitimate basis for causation opinions involving pharmaceutical products").

[9] PEC's Memo. at 14-15. The PEC offers no explanation as to what use Merck's experts would put this irrelevant data with no discernable link to plaintiffs' claims, but even assuming that they should rely upon it, those data would then become discoverable if not otherwise protected.

"would significantly limit the relevant information to which the PEC is entitled" fall flat in light of the universe of information the PEC already has in its hands.

In denying similarly overbroad requests for production of adverse event reports, courts have considered it noteworthy that the information is publicly accessible via the VAERS or MAUDE[10] government databases. See Kubicki v. Medtronic, 307 F.R.D. 291 (D.D.C. Dec. 23, 2014) (ordering that plaintiffs may not seek production of adverse event reports for all models of insulin pumps as requested and noting that "the MAUDE [publicly available government] database provides the clear solution. I see no reason why that database cannot provide plaintiffs with the information they seek"). Here, the PEC not only has such access to such publicly available resources, but Merck has already produced the reports it has provided to the FDA *and* to ex-US regulatory authorities in the form of 15-day Alert Reports, PADERs and PSURs. The PEC therefore is in possession of far more information than the court found sufficient in Kubicki and this Court should similarly deny the PEC's duplicative requests. See also AVCO Corp. v. Turn & Bank Holdings, Inc., 2015 WL 12834519, at *2 (M.D. Pa. Oct. 7, 2015) ("'It is well established that discovery need not be required of documents of public record which are equally accessible to all parties.'") (quoting SEC v. Samuel H. Sloan & Co., 369 F. Supp. 994, 995 (S.D.N.Y. 1973)); Apollo v. Pa. Convention Ctr. Auth., 2013 WL 6795978, at *4 n.4 (E.D. Pa. Dec. 23, 2013) (requiring defendant to notify plaintiff of location of publicly available documents but not produce them).

3. The Burden of Producing the Entire MARRS Database Would Outweigh Any Benefit.

[10] The Vaccine Adverse Event Reporting System ("VAERS")-related database contains information on adverse events reported by individuals, healthcare professionals and vaccine manufacturers. The Manufacturer and User Facility Device Experience ("MAUDE") database houses medical device reports submitted to the FDA.

In addition to their lack of relevance, the burden that collecting, reviewing, redacting and producing data for adverse events with no connection to plaintiffs' claims would impose on Merck likewise warrants denial of the PEC's motion to compel. Federal Rule 26(b)(2)(C) "require[s]" the Court "to limit" discovery if "the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action and the importance of the discovery in resolving the issues." Niester v. Moore, 2009 WL 2179356, *2 (E.D. Pa. July 22, 2009) (citations omitted). Proportionality protects against discovery "characterized as a fishing expedition, causing needless expense and burden to all concerned." N. River Ins. Co. v. Greater N.Y. Mut. Ins. Co., 872 F. Supp. 1411, 1411-12 (E.D. Pa. 1995) (Bartle, J.).

As Merck explained to the PEC during their June 3rd meet-and-confer, production of the MARRS database fields they seek would involve extensive and burdensome reviews for redaction of information pursuant to the Health Information Portability and Accountability Act ("HIPAA"). While the PEC argues that they have effectively eliminated this burden by agreeing not to seek fields of data containing patient names and other personal identifying information ("PII"), the PEC's offer fails to account for the PII littering the narrative fields – the very fields that its Motion describes as "critically relevant" to its request. PEC's Memo. at 13, 16. The PADERs, previously produced to the PEC (all of which contain narrative fields) illustrate the point – each contains PII that required redaction prior to production. See Ex. 8, Redacted PADERs. Irrespective of the amount of information that ultimately requires redaction, someone would need to review every report to determine if it contained PII that must be redacted in accordance with applicable federal regulations. As the PEC's Motion notes, "at least 23,556 adverse event reports" exist for the first ten years that ZOSTAVAX® was on the market. PEC's Memo. at 7 n.14. To produce all of these

reports would require review and redaction of over 23,000 narrative fields, much of which the PEC already has in its possession in a different format and the vast majority of which have no nexus whatsoever to the plaintiffs' claimed injuries. The Court should deny the PEC's demand that Merck undertake this burden and expense to provide the PEC with these irrelevant documents.

B. The PEC Has Not Shown the Relevance of Adverse Event Reporting SOPs.

As an initial matter, the PEC's Motion requests SOPs never sought in discovery; rather, Request for Production No. 19(e), cited by the PEC, asked Merck to produce SOPs regarding adverse event reporting to regulatory agencies:

> Documents associated with the use of Zostavax or the Oka Strain pertaining to the submission of adverse reactions or alleged adverse reactions to any regulatory authority, whether in the U.S. or foreign, including standard operating procedures used to identify which adverse events that would be, or will be, reported to any regulatory agency, and the manner and timeframe in which the adverse events will be reported and analyzed.

Request for Production No. 19(e). Contrary to the PEC's representations, its discovery requests did not seek "SOPs relating to: (1) Merck's collection and retention of domestic and foreign adverse event data; [or] (2) its tracking and validating of key safety issues." PEC's Memo. at 11. Because the PEC cannot move to compel discovery that it has never sought in the manner required by the Federal Rules, Merck will not address those requests that appeared for the first time in the PEC's Motion. See Richman v. GEICO Gen. Ins. Co., 2013 WL 12145865, at *5 (E.D. Pa. Feb. 27, 2013) (compelling discovery that has not been properly requested under the Federal Rules of Civil Procedure would be a "manifest injustice") (citing Camiolo v. State Farm Fire and Cas. Co., 334 F.3d 345, 359 (3d Cir. 2003)); Petrucelli v. Bohringer & Ratzinger, 46 F.3d 1298, 1310 (3d Cir. 1995) (affirming denial of motion to compel because "[i]n order to succeed on a motion to compel discovery, a party must first prove that it sought discovery from its opponent").

The PEC seeks every version of all of Merck's adverse event reporting SOPs in effect since the FDA approved ZOSTAVAX® in 2006.[11] The Court should decline to compel these SOPs because the PEC again offers no "fact specific" showing as to the relevancy of the SOPs to plaintiffs' claims. Rhone-Poulenc, 1991 WL 183842, at *3.

The PEC has failed to show that the SOPs it seeks are relevant to the core issue in this litigation – whether Merck knew or should have known of risks about which it failed to warn.[12] It claims to require these SOPs in order to analyze "whether these procedures allowed Merck to withhold certain information from these regulatory bodies and/or whether Merck was deviating from its own internal procedures when submitting data to the FDA and these other foreign regulatory agencies." PEC's Memo. at 12. Yet, in the very next sentence the PEC emphasizes that it is not seeking these SOPs to attempt to show that Merck committed fraud on the FDA; that is however the only conceivable purposes behind this request. Moreover, the PEC fails to provide any concrete basis to suggest lack of compliance with internal procedures for reporting to regulatory authorities beyond sheer conjecture. See McCurdy v. Wedgewood Capital Mgmt. Co., 1998 WL 964185, at *9 (E.D. Pa. Nov. 16, 1998) ("to compel discovery of the information would

[11] Merck made a production of Zostavax SOPs, including SOPs concerning adverse event reporting as they existed as of 2010, in a prior litigation. Merck has produced to the PEC the entirety of the document production in that case, including the SOPs. During the meet and confer process prior to the instant motion, the PEC asked Merck to identify those SOPs by Bates number. Contrary to the, at best incomplete, description of the communication exchange in the PEC's Motion, Merck responded "…I can't tell from your email whether you have attempted to find the ones that we have produced. If you are unable to find them after looking, please let me know." Email from M. Roberts to V. Anello dated 5/24/19, Ex. J to PEC's Mot. at 1. Merck never heard back from the PEC about any effort to locate the SOPs, and, by all appearances, the PEC has still made no attempt to locate them. In an effort to move the process forward, Merck is attaching hereto a list of the Bates numbers of the previously produced SOPs. Ex. 9, SOP Production List.

[12] The one document Plaintiffs cite to support their contention that the SOPs relating to adverse event reporting to regulatory agencies is located in one central repository does contain any information about the location of those SOPs.

be to authorize an unwarranted fishing expedition based on pure speculation"). Finally, the PEC has not shown how Merck's compliance with its adverse event reporting obligations is relevant to notice – and therefore, to its duty to warn. While the PEC argues that receipt of the adverse events informs whether Merck had notice of them, it does not explain how compliance with reporting requirements further informs the concept of notice or otherwise impacts Merck's duty to warn. While plaintiffs may allege that Merck withheld information from them or from their health care providers, such claims would not implicate the extent to which Merck followed the form or substance of its own procedures for reporting to regulatory authorities. For all of these reasons, the PEC's request for Merck's adverse event reporting SOPs should be denied.

The PEC also seeks SOPs regarding reporting of adverse events to the European Medicines Agency (EMA) and comparable regulatory authorities in Korea, Canada, Singapore and the Netherlands. PEC's Memo. at 11-12. As an initial matter, the PEC's statement that Merck "agreed to produce certain foreign regulatory communications between these four countries" is misleading, at best. Id. at 12 n.20. Merck agreed to produce certain documents from these countries contained in its domestic central database for regulatory submissions; however, Merck has never agreed to produce adverse event-related data from any ex-US location or foreign subsidiary. Merck objects to producing foreign SOPs as irrelevant for the same reasons articulated in its opposition to the PEC's motion to compel production of foreign documents, and refers the Court to its response filed on April 10, 2019, and incorporates the arguments set forth in that response as if fully set forth herein. See generally Ex. 10, Resp. to PEC's Mot. to Compel Prod. of Foreign Documents (Doc. 267).

IV. CONCLUSION

For the foregoing reasons, Merck respectfully requests that the Court deny the Plaintiff Executive Committee's motion to compel production of adverse event data and standard operating procedures.

Dated: June 17, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on June 17, 2019, the foregoing response to the Plaintiff Executive Committee's motion to compel production of adverse event data and standard operating procedures and proposed order were filed electronically with the Clerk of Court to be served by operation of the Court's electronic filing system on all counsel of record.

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