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	MDL No. 2848 Master Docket No. 18-md-2848

MEMORANDUM OF LAW IN SUPPORT OF THE PLAINTIFF EXECUTIVE COMMITTEE'S MOTION TO COMPEL PRODUCTION OF ADVERSE EVENT DATA AND STANDARD OPERATING PROCEDURES

I. INTRODUCTION

The Plaintiff Executive Committee ("PEC") respectfully submits this memorandum in support of its Motion to Compel Production of Merck's Adverse Event Database.

This is now the PEC's third motion to compel, and it is necessitated once again by Merck's repeated unwillingness to produce documents that: (1) are clearly relevant to the claims and defenses at issue in this MDL; and (2) are proportional to the needs of this MDL and not unduly burdensome. The discovery at issue in the present motion (and the two before it) is discovery that is typically produced in MDLs without issue. *See e.g. Rix, et al. v. Sanchez, et al.*, CV-2005-1219-S, pp.1-2 (Ala.Cir.Ct. Mar 2, 2010) (drug manufacturer admitting, with respect to a request for *all* adverse event data, that "this type [of] documentation is only produced in MDL matters.").[1] Merck's continued efforts to thwart discovery are preventing the PEC from efficiently conducting discovery in this MDL and are prejudicing the PEC's ability to move this MDL forward in a timely manner, particularly with respect to the Bellwether trials. Merck's actions cannot be condoned.

[1] Annexed hereto as Ex. A.

The present motion seeks to compel Merck to produce: (1) certain fields of data for *all* adverse events reported to Merck related to its Zostavax,[2] U.S. and foreign, that can be found in Merck's adverse event database; and (2) *all* of its standard operating procedures ("SOPs") related thereto (RFP No. 19).[3] The adverse event discovery sought here is extremely relevant to issues at the forefront of this litigation—mainly, whether Zostavax causes an increased risk of the injuries alleged in this MDL, whether Merck was on notice of Zostavax's increased risk of said injuries, and whether its instructions and warnings were adequate. As discussed below, not only is this information routinely produced during discovery,[4] it is also routinely admitted at trial as evidence of notice and/or causation and has, in fact, been admitted at trial as evidence against Merck. *See In re Fosamax Prods. Liab. Litig.,* 2013 U.S. Dist. LEXIS 6631, **9-10 (S.D.N.Y. 2013)("Adverse event reports received by Merck until the time of Plaintiff's injury are admissible if used as evidence that Merck was on notice of potentially serious jaw injuries.").

Merck has not and cannot justifiably argue that it would suffer an undue burden if it were compelled to produce the information requested by the PEC. [redacted] *Infra* at pp. 3-4, 15-17. [redacted]s

[2] The PEC also seeks this information relating to the Oka/Merck strain of which Zostavax is comprised, but that request is not at issue here.

[3] Annexed hereto as Ex. B are relevant excerpts from the PEC's First Request for Production of Documents.

[4] *See Rix, et al. v. Sanchez, et al.*, CV-2005-1219-S, pp.1-2, Ex. A; *In re Pradaxa (Dabigatran) Etexilate Prods. Liab. Litig.*, MDL 2385, Case Management Order No. 17A, No. 5 (Nov. 20, 2012), annexed hereto as Ex. C; *In re Abilify (Aripiprazole) Prods. Liab. Litig.* (MDL 2734), Stipulated Order regarding Production of Adverse Event Information (Apr. 6, 2017), annexed hereto as Ex. D; *In re: Zofran (Ondansetron) Prods. Liab. Litig.*, (MDL-2657), Plaintiffs' and GSK's Joint Status Report on Plaintiffs' Motion to Compel (Apr. 6, 2018), annexed hereto as Ex. E; *In re Neurontin,* 04-CV-6704, Court Order Granting Plaintiffs' Motion to Compel Adverse Event Data in Full (S.D.N.Y. Feb. 22, 2005), annexed hereto as Ex. F.

[redacted]. *Infra* at pp. 16-17. Accordingly, the PEC respectfully submits that Merck be compelled to produce the adverse event discovery subject to this motion.

Additionally, given that Merck will likely raise objections to the present motion that were never raised before during the parties' meet-and-confers on this issue (as it did with the PEC's prior motions), the PEC respectfully requests that it be given the opportunity to submit a reply brief within seven days of the filing of Merck's opposition to the present motion.

II. BACKGROUND FACTS

In its First Request for Production, the PEC requested Merck's complete file relating to adverse reactions relating to the use of Zostavax, which included a request for Merck's SOPs relating to adverse event reporting.[5] This request was for both U.S. and foreign adverse event data.[6]

Through discussions with Merck's counsel [redacted] The PEC is seeking production of Merck's entire adverse event database relating to Zostavax.

[5] Ex. B, pp. 8-9.

[6] *Id.*

[7] [redacted]

[8] [redacted]

To be clear, to satisfy this request, the PEC is requesting that Merck produce a ***locked, searchable spreadsheet in native format containing fields of information regarding each and every adverse report it received related to Zostavax.*** The PEC is not requesting, at this time, that Merck produce copies of the source documents underlying these reports.[9]

Merck has not claimed that it cannot produce the spreadsheet requested by the PEC. Rather, until very recently, Merck simply issued a blanket objection to producing any adverse event data (except as it relates to a particular plaintiff).[10] However, on May 17, 2019, Merck changed its position and offered to produce only the following to the PEC:

> [redacted] reportable adverse experience reports received by Merck for the injuries Plaintiffs allege in their complaints, the only adverse events at issue in this litigation. By way of re-producing document productions made in other ZOSTAVAX® litigation, Merck has previously produced to the MDL Plaintiffs standard operating procedures relating to adverse experience

[redacted]

[9] The PEC reserves their right to request the source documents underlying this request.

[10] The PEC's request for this information has been outstanding since October 19, 2018 and, in addition to Merck objecting to producing this information in its formal response to the PEC's First RPF, the parties met-and-conferred on February 1, 2019, February 20, 2019 and March 4, 2019 about this issue, and wrote back and forth regarding Merck's non-custodial databases[redacted], on February 3, 2019, February 25, 2019, March 5, 2019 and March 8, 2019. On March 4, 2019, the PEC reiterated that it was entitled to all of the data [redacted] oth foreign and domestic, and Merck stated that it would only be producing adverse event data if it was responsive to a particular DFS. When asked what the basis for Merck's position was, Merck claimed that it had already provided the PEC with PSURs and that was enough. There was no agreement or even implication by Merck that it would meet-and-confer further on this issue. In fact, following the meet-and-confer, on March 8, 2019, Merck sent a letter to the PEC reinforcing that "Merck is only offering to produce information that may be responsive to the agreed-upon DFS, if any and to the extent available, for these databases." (Annexed hereto as Ex. I is a copy of said letter dated March 8, 2019.) Again, there were no mention that further negotiations or discussions could be had on this issue, and the PEC believed this issue ripe for adjudication by the Court, mentioning it to the Court on two separate occasions and notifying the Court and Merck in a prior motion that a motion to compel on this issue would be forthcoming. However, when the PEC reached out to Merck to see if it objected to filing certain documents related to this motion under seal, Merck followed-up claiming surprise that the PEC would be filing the present motion. (Annexed hereto as Ex. J is an email correspondence between the PEC and Merck's counsel regarding this issue.) Thereafter, Merck agreed to meet-and-confer further, and made a counteroffer to the PEC's request. (*Id.*) As discussed herein, because Merck's proposal would not satisfy its obligations under the Federal Rules of Civil Procedure, the PEC could not accept Merck's offer.

> reporting, and Merck is not offering to produce any additional standard operating procedures.[11]

The PEC could not and cannot accept Merck's offer for various reasons.

First, Merck's offer as to adverse event data production does not clarify the format of the information that would be produced, nor does it appear to allow for the production of such data in a searchable format. In a meet-and-confer between the parties that took place on June 3, 2019, the PEC asked Merck's counsel to elaborate on what [redacted] advised that such would not be discussed until the parties had resolved other areas of dispute. As such, Merck's offer remains unclear in this regard and the PEC stands by their request for all data to be produced in a searchable spreadsheet in native format. *See e.g.* Ex. C, *In Re Pradaxa,* Amended Case Mgmt. Order Number 17A, p.2 (the full worldwide Pradaxa case data from defendants' adverse event database shall be produced to the PSC with the same general capabilities that Defendants have with regard to the [adverse event] database.)

Second, Merck's offer would deprive the PEC of access to *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 that may shed light on the question of whether Zostavax causes the injuries alleged in this MDL. *See In re Neurontin*, 04-CV-6704 (S.D.N.Y. Feb. 22, 2005)(ordering production of adverse event database and refusing to limit its production finding that "evidence of some other kind of adverse events may shed light on the question of whether a drug causes the effects at issue in a specific case" and further ordering production of references to adverse events in defendants' "medical communication" and "sales/marketing" databases.)[12]

[11] *Id.*at p. 2.
[12] *See* Ex. F.

Third, as to the Merck's adverse-event related SOPs, and particularly Merck's statement that it would not be producing additional SOPs because it had previously produced such to the PEC, this statement is both ambiguous and misleading because it implies that Merck has produced all SOPs requested by the PEC. Such is not the case.

As discussed below, the PEC is entitled to *all* SOPs relating to Merck's adverse event reporting dating back to when Merck first began collecting such data to present, and Merck has not produced this. In response to Merck's offer above, the PEC asked Merck to identify by Bates number all SOPs it claimed to have produced dating back to when Zostavax was first introduced to the U.S. market to the present, but Merck stated that it did not agree with the PEC's characterization of what was relayed in its offer.[13] At a follow-up meet-and-confer with Merck and when asked again by the PEC to clarify its discovery response regarding SOPs, Merck advised that it stood by its objections and responses and it was the PEC's burden to first tell Merck whether the PEC had searched for the SOPs and were unable to locate them. Further, when Merck claimed it would be burdensome for it to produce *all* of the SOPs to the PEC, the PEC asked Merck's counsel if they had spoken to Merck to determine where the SOPs were stored in the ordinary course of business to support this claim of burden, but Merck's counsel could not provide an answer.

Given that the parties are currently at an impasse regarding what discovery should be produced to the PEC related to adverse event data and SOPs, the PEC files the present motion respectfully requesting this Court compel Merck to produce: (1) a locked, searchable spreadsheet in native format containing certain fields of information regarding each and every adverse report

[13] Ex. J, p. 1.

Merck received related to Zostavax; and (2) any and all SOPs related to Merck's adverse event reporting.

III. LEGAL STANDARD

A. Legal Standard

As the Court is aware from prior status conferences, this motion is being filed because of Merck's continued refusal to produce documents that are clearly relevant to this litigation and would not be unduly burdensome for it to produce. The PEC incorporates the legal standards and arguments set forth in its prior motions [Docs. 152 and 237] and addresses here only those areas in contention.

B. Merck Should be Compelled to Produce Its Adverse Event Database for Zostavax

1. Merck's Adverse Event Database is Relevant

Adverse event reports are at the heart of the PEC's claims here. They will serve as evidence of whether Zostavax can cause the injuries alleged in this MDL, what Merck knew or should have known about these alleged injuries and when they knew or should have been aware of them. Additionally, Merck has access to at least 23,556 adverse event reports for the first ten years that this vaccine was on the market.[14] Further, when the FDA approved Zostavax for sale, it mandated that Merck perform several post market studies as part of the deal for its approval, including mandating that Merck collect and analyze adverse experiences in their subjects.[15] The need for studies show that the FDA was not convinced of Zostavax's safety and effectiveness when it was approved, and it also makes *all* post-market adverse even data relevant to this litigation.

[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5739308/

[15] http://wayback.archive-it.org/7993/20170723093336/https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm132873.htm

This information is extremely important to the claims in this litigation because this vaccine has been given to millions, yet it is virtually untested in the public domain due to the risks associated with administering a live virus in a clinical setting. [redacted] The PEC needs the data collected by Merck in order to refute Merck's claims that Zostavax is safe and effective.

This Court, and numerous other courts, have held that adverse event data is relevant, discoverable, and admissible at trial— including at least one MDL Court in which Merck was the named defendant. *See In re Fosamax Prods. Liab. Litig.,* 2013 U.S. Dist. LEXIS 6631, **9-10 (Adverse event reports received by Merck until the time of Plaintiff's injury are admissible if used as evidence that Merck was on notice of potentially serious jaw injuries."); *Terry v. McNeil-PPC, Inc.*,181 F. Supp. 3d 278, 286 (E.D.Pa. 2016)("AERs would be admissible to show notice"); *In re Avandia Mktg., Sales Practices & Prods. Liab. Litigation*, 817 F. Supp. 2d 535, 550, n.79 (E.D.Pa. 2011)(finding adverse event data is relevant and admissible for, at a minimum, demonstrating notice of a potential risk); *Golod v. Hoffman La Roche*, 964 F. Supp. 841, 855 (S.D.N.Y. 1997)(finding that adverse event reports are not hearsay because they are offered as evidence that the defendant "was on notice of a potentially serious optical side effects, and thus 'should have known' and warned of such a risk"); *In re Yasmin & Yaz (Drospirenone) Mktg*., 2011 U.S. Dist. LEXIS 147935, *12 (S.D.Ill. 2011)(denying motion *in limine* to exclude evidence about adverse event reports to prove causation or comparative risk); *Schedin v. Ortho-Mcneil-Janssen Pharms., Inc.,* 808 F. Supp. 2d 1125 (D.Minn. Aug. 2011)("The Court had denied its previously filed motion *in limine* regarding AERs, finding that the evidence was admissible to show notice and could also support a finding of causation."); *In re Neurontin Prods. Liab. Litig*., 612 F. Supp. 2d 116, 153-57 (D. Mass. 2009)(denying Defendants' motion to exclude expert testimony on general causation,

noting that the "case report data, particularly the dechallenge and rechallenge data, provides some evidence of a temporal relationship"); *In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1234-35, 1242 (W. D. Wash. 2003)(noting that "non-epidemiological sources are frequently utilized by experts in rendering scientific opinions" and find[ing] "significant the sheer volume of case reports, case series, and spontaneous reports associating PPA with hemorrhagic stroke" women."); *see also Contratto v. Ethicon, Inc.*, 225 F.R.D. 593, 598-599 (N.D. Cal. 2004) (compelling production of voluntary and mandatory adverse event reports); *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 660 (E.D. Pa. 2012) (denying Defendants' *Daubert* motion after finding "ample factual support" in the expert reports, including expert's review of defendants' safety database and identification of adverse events "that did not appear in the scientific literature or in data McNeil reported to the FDA").

Given that any and all knowledge in a drug manufacturer's possession regarding adverse event reports and the safety of the drug is relevant to causation and knowledge in personal injury, products liability actions, such information is routinely produced in such MDLs. *See e.g.* Ex. C, *In re Pradaxa (Dabigatran) Etexilate Prods. Liab. Litig.*, MDL 2385, Case Management Order No. 17A, No. 5, pp. 2-3 (ordering defendant to produce at one time its full adverse event database as it related to Pradaxa and for the parties to meet-and-confer regarding a process for defendant to produce incremental updates from the database); Ex. D, *In re Abilify (Aripiprazole) Prods. Liab. Litig.* (MDL 2734), Stipulated Order regarding Production of Adverse Event Information (Apr. 6, 2017) (the parties agreed that the defendant would produce fields from its adverse event database); Ex. E, *In re: Zofran (Ondansetron) Prods. Liab. Litig.*, (MDL-2657), Plaintiffs' and GSK's Joint Status Report on Plaintiffs' Motion to Compel (Apr. 6, 2018)(defendant agreed to produce fields from adverse event database upon agreement with the plaintiff). Notably, the *Abilify* Order and the

Zofran Order were entered after the 2015 amendments to Rule 26, thus negating any attempt Merck may make to argue that the Orders relied upon by the PEC predate the 2015 amendments.

Further, the nature of the injuries claimed in this litigation demand that *all* of Merck's adverse event data be produced. Compared to other MDL's, not only are there numerous injuries at issue,[16] these injuries are challenging to diagnose and may be referred to by such a broad universe of terms such that they cannot be broken down into specifics. Moreover, all of the adverse event data is relevant because it will likely shed light on the question of causation and whether Merck knew or should have known that Zostavax causes the numerous injuries alleged in this litigation, *See In re Neurontin*, 04-CV-6704 (ordering production of adverse event database and refusing to limit its production finding that "evidence of some other kind of adverse events may shed light on the question of whether a drug causes the effects at issue in a specific case" and further ordering production of references to adverse events in defendants' "medical communication" and "sales/marketing" databases.)[17]

In fact, in a single-event, non-MDL, products liability case in the state court of Alabama, the drug manufacturer there, Abbott Laboratories, argued against the production of *all* of its adverse event data claiming that "this type [of] documentation is only produced in MDL matters." *Rix,* CV-2005-1219-S, pp.1-2.[18] Notably, there, the Court Ordered production of *all* of Abbott's adverse event data, over Abbott's objection, finding it to be relevant regardless of the fact that it

[16] These injuries include, but are not limited to, Shingles with rash, Shingles without rash (a/k/a zoster herpete) Ramsey Hunt Syndrome, post-herpetic neurolagia, encephalitis, meningitis, hearing loss, vision difficulties, chicken pox, pneumonia, Bell's Palsy, Guillain-Barre Syndrome, transverse myelitis, acute disseminated encephalitis, stroke, heart attack and congestive heart failure.

[17] *See.* Ex. F.

[18] *See* Ex. A, pp 1-2.

was a single event case and further regardless of the fact that the injury alleged in the case was a specifically-identified birth defect.

[redacted] Limiting the adverse event data as proposed by Merck would significantly limit the relevant information to which the PEC is entitled – information that Merck's employees had at their disposal when reporting safety and efficacy information to the FDA and foreign regulatory bodies and information that Merck and its experts will have available in this MDL. In short, Merck will have access to all relevant data regarding Zostavax's safety and effectiveness, where the PEC will not.

As to the SOPs, Merck confirmed in its offer that it in fact has standard operating procedures relating to adverse event reporting and it claims to have already produced some, though it did not clarify the source of the production (i.e. custodial vs. non-custodial). In follow-up to Merck's offer, the PEC requested that Merck identify these SOPs by Bates number so that the PEC could determine the sufficiency of Merck's production, but Merck failed to do so, instead telling the PEC that it should first look for the documents themselves and then advise Merck if it could not locate them.[19] Further, during the parties' June 3, 2019 meet-and-confer, when the PEC asked Merck's counsel to identify the central storage location for Merck's SOPs to understand where they are kept in the normal course of business, Merck's counsel could not do so.

The PEC seeks and is entitled to any and all SOPs relating to: (1) Merck's collection and retention of domestic and foreign adverse event data; (2) its tracking and validating of key safety issues; (3) its reporting of said events to regulatory agencies in the United States; and (4) its reporting of said events to the EMA and the regularity authorities of Korea, Canada, Singapore

[19] Ex. J, p. 1.

and the Netherlands,[20] dating back to when Merck first began collecting such information to present. These SOPs are extremely relevant because they show, *inter alia*, what procedures Merck followed when producing adverse event and risk data to the FDA and foreign regulatory bodies, 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. To be clear, this information is **not** being sought to show that Merck committed fraud on any regulatory agency; instead it is being sought to prove Merck's knowledge relating to the adequacy of its instructions or warnings or the truth of information represented to or concealed from plaintiffs, their pharmacists or their physicians.

2. [redacted] Do Not Satisfy the PEC's Need for Adverse Event Data

[redacted]

[20] As part of the parties' resolution of the PEC's motion to compel production of foreign regulatory communications, Merck agreed to produce certain foreign regulatory communications between these four countries.

[21] Annexed hereto as Ex. K are excerpts from Merck's Objections to the PEC's First RFP, p. 28; *see also* Merck's Opposition to the Plaintiff Executive Committee's Motion to Compel Production of Documents in Response to Plaintiffs' First Set of Requests for Production dated February 15, 2019, pp. 2-3, 14-15; *see also* Ex. J, p. 2.

[22] The adequacy and completeness of Merck's PSUR production was discussed in the PEC's prior motion to compel. [Doc. 237, pp.13-15.] Notably, even if PSURs alone were sufficient to constitute a full response to the discovery at issue (which they are **not**), Merck has not certified that its production of PSURs is complete and the PEC currently cannot determine whether Merck has produced all responsive PSURs. To the contrary, based upon its review of the documents produced by Merck to date, it appears that Merck has only produced a limited set of PSURs and they do not date back farther than 2012. Therefore, the PEC respectfully requests that Merck be ordered to: (1) identify the final PSURs it has produced by BATES Number; and (2) certify that it has produced all responsive draft and final PSURs.

[redacted]

[23] Annexed hereto as. Ex. L are excerpts from a PSUR from Merck dated June 19, 2017, *see* pp. 23-25.

[24] Annexed hereto as Ex. M.

[25] *See* Ex. L. Merck had originally produced excerpts from the June 19, 2017 PSUR and filed it as Ex. 15 to its Opposition to the PEC's First Motion to Compel [Doc. 182]. Ex. L here contains the pages of documents that were filed by Merck as well as additional excerpts from the same PSUR.

[26] *Id.* at p. 24 (original page number 721).

[redacted]

[27] *Id.*

[28] *Id.* at p. 25 (original page number 723).

[29] *See e.g.* Ex. L, pp. 3-9 (original pages 25 to 31.)

[redacted]

To this end, this is another reason why Merck's SOPs regarding its adverse event reporting are critical in this case – so the PEC can analyze the method by which Merck was reporting and/or excluding reported adverse events in their analyses of the risks associated with Zostavax.

In sum, PSURs lacks crucially relevant information regarding adverse events reported with Zostavax, and, therefore, their production does not satisfy Merck's obligation to provide the PEC with relevant adverse event data.

3. It Would Not be Burdensome for Merck to Produce [redacted] as well as Merck's adverse event reporting SOPs, Merck has not clearly articulated any justifiable argument as to why it would be unduly burdensome for it to produce the requested documents. [redacted] thus reinforcing the fact that it would not be burdensome for Merck to produce this information.

During the parties' June 3, 2019 meet-and-confer, Merck claimed for the first time that it would be burdensome for it to have to produce this information because it would have to go through tons of files and redact certain information, such as the names of individuals so as to not violate the Health Information Portability and Accountability Act ("HIPAA"). However, the PEC advised Merck that this purported burden (though not justification in and of itself to deny the PEC with the relevant information[30]) could be remedied simply by the PEC not asking Merck to pull this field of information into the requested spreadsheet. Indeed, the PEC is willing to agree to that portion of Merck's offer which is to narrow the information they seek to agreed-upon fields of data, and the parties could simply exclude from production those fields that contain this information, such as name, social security, etc.[31] Accordingly, there is no undue burden on Merck to produce this information.

As to Merck's production of SOPs, Merck claims that it would be burdensome because the PEC seeks unlimited production of all versions of SOPs that exist for Zostavax. As with all of Merck's arguments, this one too is disingenuous. Zostavax has been on the market since 2006 and claims in this litigation date back to then. [redacted] To this end, because the claims in this

[30] *See* Ex. F, *In re Neurontin*, 04-CV-6704, p. 3 (rejecting defendants' argument that production of all adverse event data would be burdensome because they would need to review a substantial amount of documents and be required under federal law to redact confidential information finding the defendants' "conclusory assertions [to be] insufficient to outweigh the articulated need for this discovery, especially in a case touching on public health.")

[31] *See e.g.* Ex. E, *In re: Zofran (Ondansetron) Prods. Liab. Litig.*, (MDL-2657), Plaintiffs' and GSK's Joint Status Report on Plaintiffs' Motion to Compel (Apr. 6, 2018)(defendant first provided plaintiffs with a list of fields available to be exported and plaintiffs narrowed the fields of data they sought).

[32] [redacted]

litigation span 2006 to present, the PEC is entitled to all SOPs that were in place during this time period and Merck has not shown that it would be unduly burdensome for it to produce them.

Indeed, as discussed with Merck during the parties' June 3, 2019 meet-and-confer, it is the PEC's experience that manufacturers generally maintain a non-custodial repository, usually as a shared filed, that contains all SOPs relating to a particular product, such as Zostavax, that Merck employees are directed to go to should they ever have a question regarding Merck's procedures for adverse event reporting, and that within this non-custodial repository current versions of these SOPs are stored as well as older "obsolete" versions. The PEC asked Merck's counsel if there existed something similar with respect to Zostavax, but Merck's counsel could not answer, instead maintaining its argument that it should not have to produce all SOPs relating to adverse event reporting.

[redacted] Thus, Merck should be able to access the SOPs sought by the PEC with relative ease.

Accordingly, because Merck cannot show how the production of its adverse event database or its adverse event SOPs would be burdensome, the PEC submits that these highly relevant documents should be produced.

[redacted]

4. The PEC Respectfully Requests the Opportunity to Submit a Reply to Any Opposition Submitted by Merck

This is the PEC's third motion to compel relevant discovery from Merck. With respect to its first two motions, Merck introduced important information in its respective oppositions that was never relayed to the PEC prior to the filing of said motions, particularly regarding burden, thus, necessitating a reply by the PEC. The PEC anticipates that the same will happen here. As such, the PEC respectfully requests that it be given the opportunity to reply to Merck's opposition and that the deadline for said reply be set at seven (7) days following the filing of Merck's opposition.

IV. CONCLUSION

WHEREFORE, the PEC respectfully requests that this Honorable Court: (1) compel Merck to produce the documents outlined herein; (2) grant the PEC the opportunity to submit a reply; and (3) grant such other and further relief the Court deems just and appropriate under the circumstances.

Dated: June 3, 2019

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