SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEPARTMENT 304

COORDINATION PROCEEDING SPECIAL TITLE [RULE 3.550] **DILANTIN PRODUCT CASES**	JUDICIAL COUNCIL COORDINATION PROCEEDING NO. 4994 ORDER RE: PLAINTIFFS' MOTION TO COMPEL

INTRODUCTION

The above-entitled matter came on regularly for hearing on May 29, 2019. The appearances are as stated in the record. At the hearing, the Court ordered Pfizer Inc., Pharmacia LLC f/k/a Pharmacia Corporation, Parke, Davis & Company LLC as successor-in-interest of Parke, Davis & Company, and Warner-Lambert Company LLC f/k/a Warner-Lambert Company ("Pfizer Defendants") to submit a declaration regarding the timing for the production of the at-issue adverse event reports and source documents.[1] The Pfizer Defendants made the requisite, timely submission on June 7, 2019. Having reviewed and considered the argument and written submissions of all parties and being fully advised, the Court grants the motion (as limited in Plaintiffs' reply).

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[1] See Gramling Dec. (filed June 7, 2019), ¶¶ 3-5.

BACKGROUND

This action concerns Plaintiffs who are alleged to have have suffered cerebellar atrophy reactions after taking Dilantin products to treat epilepsy. (See Oppo., 1:19-2:12.) Here, Plaintiffs seek to (1) use their proposed adverse event ("AE") search terms to search Pfizer Defendants' adverse event safety database ("PfAST") to generate Dilantin-related adverse event reports ("AER"), and (2) order Pfizer defendants to produce source code documents pertaining to "cerebellar atrophy" only. (See Notice, 1:26-2:6; see also Reply, 8:14-9:5.) The parties have already agreed to run a search for certain AER search terms. (See Sheehan Dec., Ex. 5 [Proposed Order, Ex. A].)[2] Therefore, the crux of the dispute is whether Pfizer Defendants should be forced to run AE searches for 25 disputed AE search terms. (See Sheehan Dec., Ex. 5 [Proposed Order, Ex. B].)

LEGAL STANDARDS

I. General

The burden ultimately rests with the responding party to justify any objection. (See *Fairmont Ins. Co. v. Superior Court* (2000) 22 Cal.4th 245, 255 [citing *Coy v. Superior Court* (1962) 58 Cal.2d 210, 220-221].)

II. Requests for Production of Documents.

C.C.P. § 2031.310(a) provides:

> (a) On receipt of a response to demand for inspection, copying, testing, or sampling, the demanding party may move for an order compelling further response to the demand if the demanding party deems that any of the following apply:
>
> (1) A statement of compliance with the demand is incomplete.
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> (2) A representation of inability to comply is inadequate, incomplete, or evasive.
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> (3) An objection in the response is without merit or too general.

(C.C.P. § 2031.310(a).)

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[2] Because the parties agreed to these terms, the Court does not substantively address them here. This is especially true since Pfizer Defendants admit that if they search the agreed-upon AE preferred terms, it would necessarily capture all 77 terms (preferred and lower level) itemized in Sheehan Dec., Ex. 5 [Proposed Order, Ex. A]. (See Oppo., 10:15-11:6.)

DISCUSSION AND ANALYSIS

I. Relevance (AERs)

California Code of Civil procedure, section 2017.010 states, in relevant part, that discovery may be obtained on "any matter, not privileged, that is *relevant* to the subject matter involved in the pending action…if the matter either is itself admissible in evidence or appears reasonably calculated to lead to the discovery of admissible evidence." (*Id.* [emphasis supplied].) Courts have construed the discovery statutes broadly, so as to uphold the right to discovery. (See Cal. Prac. Guide Civ. Pro. Before Trial Ch. 8B-2.)

Relevancy depends on size and complexity of the case and must be considered with regard to the burden and value of the information sought (among other factors). (See *Bridgestone/Firestone, Inc. v. Sup.Ct. (Rios)* (1992) 7 Cal.4th, 1384, 1391.) The trial court has the discretion to narrow the scope of discovery on a case-by-case basis by issuing a protective order, where the burden, expense, or intrusiveness of that discovery *clearly outweighs* the likelihood that information requested will lead to admissible discovery. (Weil & Brown, *Cal. Prac. Guide Civ. Pro. Before Trial* § 8:74.1; see also *Ibarra v. Sup. Ct.* (2013) 217 Cal.App.4th 695, 706 ["an opposition to a motion for disclosure may be deemed as a motion for a protective order in the interests of justice. In this case, trial court abused discretion in failing to issue a protective order"].) In order to determine, whether to compel or limit discovery, courts engage in a benefits vs. burdens approach, taking into account:

- the *stakes* in the case (because a given cost of production may be reasonable in a large case but not a smaller one);
- the availability of *less burdensome, alternative sources* of the proposed discovery;
- *materiality* of the information sought (i.e., how peripheral or collateral it is to a claim or defense in the case); and
- *Utility* of the information (i.e., how useful it will be to prove a material issue in the case).

(Weil & Brown, *Cal. Prac. Guide Civ. Pro. Before Trial* § 8:74.1(a).) Discovery is relevant in California "if it might reasonably assist a party in evaluating its case, preparing for trial, or facilitating a settlement."

(*Glenfed Dev. Corp. v. Super. Ct.* (1997) 53 Cal.App.4th 1113, 1117.) Fishing expeditions are permissible under California law, but they can be limited when they place more burdens upon the adversary than the value of the information warrants. (See *Greyhound Corp. v. Sup.Ct. (Clay)* (1961) 56 Cal. 2d 355, 384-385.) Per the discovery of AERs in pharmaceutical tort cases, the 9th Circuit has previously held that AERs databases can be searched, notwithstanding the "relatively modest task of redacting identifying information of patients and reporters." (*In re Incretin-Based Therapies Prods. Liab. Lit.* (9th Cir. 2017) 721 Fed.Appx. 580, 583.)

a. Application.

It is undisputed that AERs have *some* relevance in pharmaceutical mass tort actions, such as the action here. However, where the parties diverge is (1) whether the 25 disputed AE terms are sufficiently relevant to *this* litigation; and (2) the magnitude of AER's significance.

i. Adverse Event Terms/Reports.

Plaintiffs argue that all 25 disputed AER search terms, and the source documents for "cerebellar atrophy," will enable Plaintiffs to" build an accurate timeline proving (i) the extent of [Pfizer] Defendants' historical knowledge of the risk of cerebellar atrophy from Dilantin, and (ii) when, how, and where (i.e., in what foreign countries and, much later, in the U.S.) Defendants responded to that knowledge." (See Reply, 1:12-16.) At the hearing, Pfizer Defendants reiterated their position that it is Plaintiffs' burden to establish how *each* of the 25 disputed AER search terms are relevant in this *action*, and Plaintiffs have not sustained their burden. (See Oppo. 11:14-19:22.) Pfizer Defendants also dispute the degree to which AERs are relevant in pharmaceutical mass tort actions in general. (See *id.* 3:4-4:4 [arguing AERs have limited value because, *inter alia*, they do not establish causation]; see also *id.* at 23:19-24:2 [attacking Plaintiffs' use of an article as an attempt to "overstate the importance of" AERs].)

The Court finds that Plaintiffs have shown the specific 25 disputed AE terms are relevant here. Indeed, Plaintiffs have tethered each AE term "to scientific literature, plaintiffs' medical records, [Pfizer] defendants' regulatory filings and [Pfizer] Defendants' adverse event reports." (Reply, 2:18-20.) Specifically, Plaintiffs meet their broad "relevance" burden through an easily-digestible chart, connecting each of the 25 disputed AER search terms to a sufficient evidentiary basis. (See Mot., 17:12-23:16 [citing

evidence to support that each of the 25 disputed AE terms is (1) a confirmed MedDRA term; (2) previously reported (or insufficiently or incorrectly reported/miscoded) by Pfizer Defendants; (3) used in medical literature related to Dilantin; (4) referenced in Plaintiffs' medical records or fact sheet; and/or (5) listed as a potential side effect on the Dilantin label]; compare *id.* with Sheehan Dec., Ex. 5 [Proposed Order, Ex. B]; see also *id.* at Ex. 29 [defining the 20 MedDRA search terms]; see also *id.* at Ex. 15 [Dr. Tackett Dec ¶¶ 12-29] [testifying that Plaintiffs' proposed 25 AE search terms "are appropriate terms to use to gather the requested safety information because the terms more closely track those of the NIH and MedDRA-ICH Committees."].) In response, Pfizer Defendants (1) provide their own chart relating to the 20 MedDRA terms showing their purported lack of relevance (as compared to their burden), and (2) attack Plaintiffs' "evidentiary basis" for each of the 25 disputed AE terms. (See Oppo., 11:14-16:12 [citing Mayo Dec., Ex. F] [Dr. Garcia Dec. ¶¶ 3-14] [testifying that the proposed terms are either "medical conditions distinct from cerebellar atrophy or they are broad symptoms that are typically caused by other medical conditions besides cerebellar atrophy."][3]; see also Oppo., 16:13-19:22 [undermining Plaintiffs' "evidentiary bas[es]" for each of the 25 AE terms].)

On balance, the Court finds Plaintiffs have met their burden to establish that their 25 disputed AE terms are relevant to this litigation. First, the dispute between the parties' medical consultants over whether the specific medical terms are *actually* relevant to this litigation tends to illustrate that Plaintiffs should be entitled to them. (Compare Mot., 17:12-23:16 and Sheehan Dec., Ex. 15 [Dr. Tackett Dec.] with Oppo., 11:14-16:12 and Mayo Dec., Ex. F [Dr. Garcia Dec.].) While certain AERs may not be ultimately permitted at trial, that is not the discovery standard. What is relevant (and sufficient) here is that Plaintiffs have provided sufficient evidence to support the relevancy for each and every disputed AE term. (See Mot., 17:12-23:16 [Plaintiffs' chart providing the evidentiary basis for the relevance of each term]].) Second, Plaintiffs have shown that AERs are generally relevant in pharmaceutical mass tort cases. (See Sheehan Dec., Ex. 24 [*In re Tylenol Mktg.* (E.D. Pa. 2016) 181 F.Supp.3d 278, 285-286]

[3] Based on Dr. Garcia's opinion, the majority of the 20 proposed MedDRA terms can be categorized as those "typically" not caused by cerebellar atrophy, rather than those that have no connection to cerebellar atrophy. (See Mayo Dec., Ex. F [Dr. Garcia Dec. ¶¶ 3-14]; see also Oppo. 11:14-18:21.) Pfizer Defendants do not provide any testimony from Dr. Garcia concerning the 5 non-MedDRA AE terms. (See Oppo., 18:21-19:22.)

["With all this in mind, AERs would be admissible to show notice."].) AERs' relevance is further supported by Pfizer Defendants' willingness to produce AERs in this action, and others. (See Sheehan Dec., Ex. 5 [Proposed Order, Ex. A]; see also Reply, 5:12-6:13 [collecting cases].)

Under the broad relevancy discovery standard, Plaintiffs' evidence is sufficient to show that all 25 disputed AER search terms are relevant.

II. Alternative Methods to Obtain AERs.

Plaintiffs' need to search Pfizer Defendants' database for AERs specifically is further supported by Pfizer Defendants' *purported* (1) previous failure to review, analyze, and report serious adverse events to the FDA; (2) "downplay" of the risk of cerebellar atrophy to the FDA, as revealed by Pfizer Defendants' internal cerebellar atrophy review[4]; and (3) insufficient or incorrect reporting and/or miscoding of MedDRA terms. (See Mot., 13:1-16:19; see also *id.* at 17:12-23:16.) If Pfizer Defendants had not engaged in such conduct, perhaps the Court would require Plaintiffs to rely on the FDA's publicly available AER documents, and/or be more willing to adopt Pfizer Defendants' perspective on whether Plaintiffs' proposed terms would have already been captured by a previously-searched MedDRA term, such a cerebellar atrophy. (Compare Mot., 13:1-16:19, 17:12-23:26, and Reply 9:6-10:12 [outlining the significance of Pfizer Defendants' underreporting AEs] with Oppo., 11:14-19:22 [arguing in part, that any claim that Pfizer Defendants miscoded AEs should not necessitate a further AER production]; see also Weil & Brown, *Cal. Prac. Guide Civ. Pro. Before Trial* § 8:74.1(a) [in weighing motions to compel, courts should consider whether the documents can be obtained from other sources].)[5]

Thus, Plaintiffs have sufficiently shown that the 25 disputed AE search terms are relevant.

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[4] Pfizer Defendants' attempt to refute arguments (1)-(2) is unpersuasive. (See Oppo., 18:17-21.) Pfizer Defendants cite to *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 350-353 for the proposition that there is no claim for "fraud on the FDA." *Buckamn Co.* held that a state law "fraud on the FDA" claim is preempted. However, it has no bearing on whether Plaintiffs' arguments and evidence entitle them to their requested discovery.

[5] Further, Pfizer Defendants argument that much of Plaintiffs' AE terms "will capture *thousands* of adverse events that are either *unrelated to Cerebellar Atrophy or are cumulative*" is unsupported by evidence. (Compare Oppo., 17:18-19:21 with Mayo Dec., Ex. C [Brothers Dec. ¶ 14] [noting only one example, that running a search for "Nervous System Disorders" "would include hundreds of Preferred Terms and *would likely* capture thousands of additional adverse events," without showing (1) that the thousands of adverse events would be "unrelated to Cerebellar Atrophy or cumulative" or that (2) voluminous adverse events would be generated for each of (or at least more than one of) the 25 AE terms].)

III. Burden.

a. Background Law.

To the extent any party may be refusing to respond to discovery on the basis of a burden objection, the party must quantify the burden involved in complying with this request. (See *West Pico Furniture Co. of Los Angeles v. Superior Court In and For Los Angeles County* (1961) 56 Cal.2d 407, 418 [noting that "[t]he objection of burden is valid only when that burden is demonstrated to result in injustice" and that "the trial court [has] the discretionary power . . . to balance the equities, including costs, that is to balance the purpose and need for the information as against the burden."].) "For a burdensomeness argument to be sufficiently specific to prevail, it must be based on affidavits or other evidence showing the exact nature of the burden." (*Houdini, Inc. v. Gabriel* (C.D. Cal. Oct. 21, 2005) 2005 WL 6070171, at *3.) "The objecting entity must state specifically how, despite the broad and liberal construction of federal discovery rules, each question is overly broad, unduly burdensome, or oppressive by submitting affidavits or offering evidence revealing the nature of the burden." (*Thomas v. Hickman* (E.D. Cal. Dec. 6, 2007)2007 WL 4302974, *6.)

b. Substantiation of Burden.

While Pfizer Defendants offer the Gramling[6] and Brothers[7] declarations as evidence in support of their burden, they do not offer cost or time estimates, evidence of an overly burdensome process to obtain the documents, or the like, to sufficiently substantiate their burden objections. (See Mayo Dec., Ex. C [Brothers Dec., ¶ 15] [summarily stating that "the amount of time and money Pfizer will need to spend for each of these steps will increase if the number of Preferred Terms is increased and or Pfizer deviates from its ordinary course."]; see also Mayo Dec., Ex. E [Gramling Dec. (May 13, 2019) ¶ 5] [summarily stating page-by-page review of hard copy, off-site source documents would be "extremely time consuming"]; see *id.* ¶ 6 [without providing a time or cost estimate, Gramling testifies he "expect[ed]" the source document production to take "months to complete, and require teams of technical experts and attorneys."] [8]; see also

[6] Gramling testifies to the source file/documents burden.
[7] Brothers testifies to the AE terms burden.
[8] However, the subsequent June 7, 2019 Gramling Declaration undermines Pfizer Defendants' burdensome objections. (See Gramling Dec. (filed June 7, 2019), ¶¶ 3-5.) Indeed, a rolling production of the source documents relating to the 144 of the 179 "cerebral atrophy" adverse events will be made by October 5, 2019. (*Id.*) Further, as evidenced by the the declaration, Pfizer Defendants were able to locate

Reply, 2:12-5:11; see also *In re Incretin-Based Therapies Prods. Liab. Lit., supra*, 721 Fed.Appx. at 583 [defendants failed to substantiate their unduly burdensome objection, even where they provided a cost estimate for certain source files].) Further, other evidence undermines Pfizer Defendants' burden argument. (Compare Mayo Dec., Ex. C [Brothers Dec., ¶ 15] with Sheehan Dec, Ex. 10, Brothers' Depo. 134:23-136:5 [undermining the burden argument in her declaration, Ms. Brothers testified that presently, Pfizer handles over 300 AER requests per month as a result of litigation and FDA requests, and the database is capable of easily excluding Patient Identifying Information (PII) by simply choosing the appropriate field which would "eliminate the need for . . . redaction."]; see also *id.* [database is easily searchable by specific drug or specific AE]; see also *id.* at175:15-16 [searching MedDRA terms, of which there are 20 here, "should be a relatively easy query"]; see also *id.* 137:23-139:17 ["technically . . . you can query anything you want" in the PfAST database]; see also *id.* 141:25-142:1 [same]; see also *id.* 163:2 [same]; see also *id.* at 139:17, 143:16-23 [searching non-MedDRA terms, of which there are 5 here, is also simple]; see also Oppo. 19: 5-8 [for non-MedDRA terms, Pfizer Defendants would have to use the "verbatim" or "narrative" fields in PfAST, without substantiating *why* this is so burdensome, costly, or time-consuming]; see also *id.* 20:1-9 [arguing the same for searching "cerebellar atrophy" in the "verbatim" or "narrative" field]; see also Mot., 5:5-18 [citing Sheehan Dec., Ex. 8-10 [showing that PfAST is an ESI database, which is easily searchable and organizable]; see also *id.* at 23:17-25:12 [burden lessened because (1) some source file documents are stored electronically; (2) Pfizer Defendants can withhold fields that contain PII; (3) the AE volume is limited and AERs are not privileged, which lessens the need for attorney review; and (4) the AER cannot be obtained from alternative sources, as Pfizer Defendants' PfAST database is the "only comprehensive" source].)[9]

Though there is clearly *some* burden associated with searching, reviewing, redacting, and producing the AERs associated with the 25 disputed AE terms, Pfizer Defendants (1) have not shown that the burden outweighs the need for the documents as outlined in Parts I-II, *supra*; and (2) the burden is insufficiently supported by *evidence*.

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the source documents for 144/179 rather quickly because they were stored electronically.

[9] While not determinative, Pfizer Defendants' voluminous AER productions in other cases certainly do not assist them here. (See Reply, 5:12-6:13 [collecting cases].)

IV. Source Documents.

Similar to the discussion in Part I, *supra*, Plaintiffs have established that source documents pertaining to the 25-disputed AERs are relevant. (See Mot., 10:16-12:28.) However, Pfizer Defendants argue that there is significant burden attached to producing said documents, as they are not all electronically stored. (See Oppo., 20:10-22:25; see also Gramling Dec. (June 7, 2019) ¶¶ 4-5 [testifying that some are stored electronically and some are paper files]; see also Part III, *supra*].) In reply, Plaintiffs propose an agreed-upon limitation: source documents for "cerebellar atrophy" AERs only. (See Reply., 8:14-9:4 [stating that such there should only be 68 source files to produce, assuming Pfizer Defendants' representations that they reported all cerebellar atrophy cases to the FDA is true]; see also Oppo., 22:5-7 ["Additionally . . . MedDRA terms)."].)

Based on the foregoing analysis in Parts I-IV, the Court finds that limiting the source documents for "cerebellar atrophy" AERs only is reasonable.

CONCLUSION AND ORDER

For all of the foregoing reasons, Plaintiffs' motion to compel is granted.[10] Specifically, Pfizer Defendants must (1) run the AE search terms through PfAST (as outlined in the Sheehan Dec., Ex. 5 [Proposed Order, Exs. A-B]); and (2) produce the source documents for "cerebellar atrophy" AERs only. The documents must be produced according to the timelines outlined in the June 7, 2019 Gramling Dec. (See *id.* ¶¶ 3-5.)

Because the (1) AERs will be produced by September 5, 2019; and (2) 144/179 cerebellar atrophy AER source documents will be produced by October 5, 2019, Pfizer Defendants are required to e-mail the Court bi-monthly updates on the status of their productions.[11] (See *id.*) Specifically, beginning on Friday, July 5, 2019, Pfizer Defendants must submit bi-monthly e-mails to the Court via ComplexLit@sftc.org with a status update on its document productions as outlined in this order. Pfizer

[10] All parties are reminded to review California Rule of Court 3.113(d) for page limitations for all future motions. Neither party complied with those limitations for this motion.

[11] By July 8, 2019, Pfizer Defendants will provide a declaration to the Court concerning the production of the remaining cerebellar atrophy AER source documents. (See *id.*) Pfizer Defendants must include this category of documents in its status updates to the Court.

Defendants must copy all parties on the e-mail. Specifically, Pfizer Defendants will apprise the Court of (1) the bates-stamped numbers for all documents produced as of the date of the e-mail, and (2) whether Pfizer Defendants are on track to complete its production no later than the dates testified to. If a dispute remains between the parties on these issues, the parties are instructed to ask the Court for the Court's next availability for an informal telephone conference.

The Court grants Plaintiffs' motion without prejudice to Pfizer Defendants filing, if warranted in the future, a motion for a protective order supported by specific evidence that the ongoing costs and time of production meets the burdensome standard under California law.

In addition, any party who files documents conditionally under seal related to a pending motion, must, at the same time, file a motion to seal those documents. This will avoid the unnecessary delay in issuing orders and having information in the public record that is properly subject to a sealing order later.

IT IS SO ORDERED.

Dated: June 11, 2019

Anne-Christine Massullo
Judge of the Superior Court

CERTIFICATE OF ELECTRONIC SERVICE
(CCP 1010.6(6) & CRC 2.260(g))

I, DANIAL LEMIRE, a Deputy Clerk of the Superior Court of the County of San Francisco, certify that I am not a party to the within action.

On JUN 11 2019, I electronically served THE ATTACHED DOCUMENT via File & ServeXpress on the recipients designated on the Transaction Receipt located on the File & ServeXpress website.

Dated: JUN 11 2019

T. Michael Yuen, Clerk

By: _____
DANIAL LEMIRE, Deputy Clerk