UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
LEXINGTON

IN RE: ONGLYZA (SAXAGLIPTIN) AND KOMBIGLYZE XR (SAXAGLIPTIN AND METFORMIN) PRODUCTS LIABILITY LITIGATION	**MASTER FILE NO. 5:18-MD-2809-KKC** **MDL DOCKET NO. 2809** **ALL CASES** **MEMORANDUM OPINION AND ORDER**

*** *** *** ***

This matter comes before the undersigned pursuant to a referral from Judge Caldwell to handle the discovery disputes in this case. Plaintiffs filed a Motion to Compel supplemental discovery responses. [DE 349]. Defendants filed a Response [DE 363] and Plaintiffs replied [DE 365]. The Court conducted a hearing to better understand the arguments of the parties. Having reviewed the written materials as well as the arguments presented by counsel, the matter is fully ripe. Plaintiffs' Motion to Compel will be granted in part and denied in part for the reasons stated below.

I. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

This case is a multidistrict litigation arising from allegations that the Type 2 diabetes medication saxagliptin, sold under the brand names Onglyza and Kombliglyze XR, allegedly caused heart failure and/or increased the risk of adverse cardiac events. Defendants Bristol-Myers Squibb Company ("BMS") and AstraZeneca ("AZ") jointly studied, developed, and made submissions to the Food and Drug Administration ("FDA"). [DE 363 Page ID# 2205]. According to Defendants, "AstraZeneca acquired BMS's interest in saxagliptin in February 2014; as part of

that acquisition, BMS subsequently transferred its data from the development of saxagliptin to AstraZeneca." [DE 363 Page ID# 2205].

The District Court bifurcated discovery in this case to address general causation first. [DE 179]. As part of Plaintiffs' causation discovery, they requested all clinical and non-clinical (e.g., animal studies) trial documents, all pharmacovigilance documents other than the MedWatch Reports and Detailed Case Reports (DCRs), and custodial communication files for seventeen employees. Plaintiffs further requested that all documents be produced in "eCTD format" where that format is available.[1] Defendants argued that much of this information had been produced; they did not understand or know what additional information Plaintiffs were seeking; the information was not readily available in eCTD format and did not have to be produced that way regardless; the clinical and non-clinical trials requested were irrelevant; the request for custodial files was disproportionate to the needs of general causation discovery. [*See*, generally, DE 363]. Plaintiffs respond that the data received to date is "unusable" because it is missing metadata and parent/child information. Both parties highlighted the delays of the other, as well as the numerous meetings they have conducted in (failed) efforts to resolve the discovery disputes without judicial interference.

At the hearing, the Court questioned the parties, taking each of the three broad categories—clinical/non-clinical trials, pharmacoviligence, custodial files—in turn. Both parties' positions at the hearing were not wholly consistent with their positions in their briefs, although this appeared

[1] Electronic Common Technical Document, or "eCTD" format, is the format used in applications, amendments, supplements, and reports to the FDA. While disagreeing in their briefs about whether eCTD is "native" format for Defendants' files, the parties ultimately agreed that eCTD is the format in which Defendants store the information they send to the FDA. Defendants noted there are additional documents related to the information sent to the FDA that Defendants store in other formats.

to be due to the parties' trying to resolve the dispute. The parties were able to agree on some points at the hearing. The Court's rulings on the contested items are below.

II. ANALYSIS

Rule 26(b)(1) allows discovery of "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case[.]" FED. R. CIV. P. 26(b)(1). In the discovery context, relevance is "construed broadly to encompass any matter than bears on, or that reasonably could lead to other matter that could bear on any party's claim or defense." *Albritton v. CVS Caremark Corp.*, 2016 WL 3580790 (W.D. Ky. June 28, 2016). Keeping in mind the balance between allowing broad discovery and the proportional discovery needs at the general causation phase of this litigation, the Court finds as follows:

A. CLINICAL AND NON-CLINICAL TRIALS

1. Non-clinical Data

At the hearing, Defendants stated they have identified 15 non-clinical studies that appear to be responsive to Plaintiffs' request for production of documents 13-24 and relevant to the issues in this lawsuit. Defendants have identified over 100 non-clinical studies involving saxagliptin, most of which did not study heart failure. To the extent Defendants have not produced any of these 15 studies and/or their supporting, underlying data, they must do so as soon as practicable. The Court will not require Defendants to produce additional non-clinical studies and data beyond the 15 Defendants identified. Defendants may redact documents as appropriate; however, because these are not clinical trials involving patients, the Court expects these redactions will be very limited. It appeared that the parties reached an agreement at the hearing consistent with this ruling, but in an effort to avoid further dispute on this point, the Court grants the Motion to Compel as to the 15 non-clinal studies Defendants identified.

2. Clinical Trial Data

The parties disagree on two points regarding clinical trial data: (1) what should be produced; and (2) how it should be produced.

Initially, Defendants were unclear as to specifically what clinical trial data the Plaintiffs were seeking. Plaintiffs clarified their position at the hearing, requesting that Defendants be compelled to produce eCTD data for all clinical trials submitted to the FDA and additional, supporting data for those trials which had either a cardiac endpoint or a cardiac event, regardless of the endpoint of the study. Defendants state there are approximately 150 clinical trials submitted to the FDA in eCTD format, but only 22 of those clinical trials had a cardiac endpoint, echocardiogram, or a cardiac event. Defendants object to producing all 150 clinical trials as overbroad and not relevant to this litigation. Plaintiffs were willing to compromise as to the clinical trials produced along the lines suggested by Defendants, but the fight then moved to the format in which the documents should be produced.

To that end, Defendants objected to producing those trials in eCTD format, claiming most of the clinical trial data was previously produced in its native format. As Defendants suggest and as numerous courts have agreed, it is wholly reasonable to read "kept in the ordinary course of business" contained in Rule 34 as promoting production in native format. FED. R. CIV. P. 34(b)(2)(E)(i), 34(b)(2)(E)(iI); *see*, *e.g.*, *Landry v. Swire Oilfield Services, LLC*, 323 F.R.D. 360, 99 Fed. R. Serv. 3d 1191 (D.N.M. 2018). *See also* Manual for Complex Litigation, § 11.446 (4th ed. 2004). Further discussions, however, reveal two facts fatal to Defendants' argument. First, when they previously produced the data, Defendants failed to provide the underlying metadata. Such a production is the equivalent of manufacturing a car without an engine—a shell without much use. *See* Manual for Complex Litigation, § 11.446 (4th ed. 2004). Secondly, Defendants also acknowledge that they house the same information natively on the eCTD format. Basically,

Defendants store the information in two native formats, but simply elected to produce the version without any underlying data and not in the format commonly used by the rest of the industry and Defendants themselves.

Even with this admission, however, Defendants fear a second review of the data will greatly delay the already delayed litigation because of necessary redactions of sensitive medical information. Yet, the eCTD database is designed to prevent this very issue. For example, any individual listed in the database is identified in three ways: (1) age; (2) gender; and (3) the city and state in which the trial was conducted. Defendants argue that redaction is necessary because it is theoretically possible for a study participant's identity to be compromised because his or her birthday appears in the eCTD file along with the name of a small town in which the study took place. This theoretical risk seems fantastically improbable; further, the parties entered a Stipulated Protective Order over a year ago that should alleviate any additional concerns. [DE 171]. Thus, the Court finds that redactions are unnecessary.

The Court agrees with Plaintiffs that all of the clinical trial data submitted to the FDA is routinely produced in pharmaceutical products liability cases like this one and is necessary for the Plaintiffs and their experts to evaluate general causation even where the trial does not discuss cardiac events. *See, e.g.*, *In re Gadolinium-Based Contrast Agents Products Liability Litigation*, 2013 WL 587655 at *6 (N.D. Ohio Feb. 13, 2013) (For an alleged pharmacoviligence expert to survive a *Daubert* motion, he must have reviewed "extensive" clinical trial data.); *In re Chantix (Varenicline) Products Liability Litigation*, 889 F.Supp.2nd 1272, 1282 (N.D. Al. 2012) (Plaintiffs' experts survived a *Daubert* motion where Defendants complained that the experts should have considered *all* of the clinical trial data Defendants submitted to the FDA and produced in discovery). Accordingly, the Court compels Defendants to produce all clinical trials submitted

to the FDA. These files must be produced in eCTD format. As Defendant admitted, producing in this format without redactions will be minimally time-consuming.

Defendants are further compelled to produce the eCTD data (if it exits) and all other related or underlying data (in native or TIF format with underlying metadata, where eCTD format is unavailable) for the 22 studies they have identified that had a cardiac endpoint, an echocardiogram was conducted, or a cardiac event during the study. Defendants conceded at the hearing that this information is directly relevant and discoverable because Plaintiffs have alleged saxagliptin causes cardiac injury. Defendants may exclude from this production any international data that would implicate international privacy laws, treaties, or regulations.

Defendants are required to supplement through the date of this Order all clinical trial data as discussed herein. Regardless of the format in which the information is produced, the documents must include all metadata and parent/child information so that the documents will be functional and usable.

B. PHARMACOVIGILANCE

The parties appear to agree that all pharmacovigilance documents related to heart failure, hospitalization for heart failure, and congestive heart failure should be produced to Plaintiffs through the present date. Accordingly, the Court will grant Plaintiffs' motion to compel as to all pharmacovigilance documents related to heart failure, hospitalization for heart failure, and congestive heart failure from the earliest available date through the date of this Order. To the extent Plaintiffs request pharmacovigilance documents related to non-cardiac adverse events, the Court finds those documents are not relevant to this litigation or likely lead to the discovery of relevant evidence, and producing them would be disproportionate to the needs of this litigation at the general causation phase, and therefore denies that request.

C. CUSTODIAL FILES

Defendants have agreed that there are seven custodians responsive to Plaintiffs' requests. Defendants set these out in their supplemental brief, along with the timelines Defendants believe would be relevant to general causation and responsive to Plaintiffs' requests. [DE 378]. Plaintiffs request the seven custodial files Defendants identified, plus ten additional individuals' files. The parties further disagree on the search terms to be used to identify the responsive documents within each custodian's file, however, the parties have agreed:

> to utilize two groups of search terms to build the search string: 1) product terms, to include the various identifiers for saxagliptin and the relevant studies, and 2) general causation terms, to include terms focused on this phase of discovery. If a term hits on any term within each group, then it will be reviewed for responsiveness. The search string to implement the plan above is here:
>
> (Product Term 1 OR Product Term 2 OR . . .)
>
> AND
>
> (General Causation Term 1 OR General Causation Term 2 OR . . .).

The relevance and usefulness of custodial files at the general causation phase of this litigation is extremely limited. General causation is a battle that will be fought by the parties' respective experts, not by determining "who knew what when" from custodial files. *See In re Zoloft (Sertalinehydrochloride) Products Liability Litigation*, 176 F. Supp. 3d 483, 497 (E.D. Pa. 2016) (Internal "documents may be relevant to questions of Pfizer's knowledge and actions if Zoloft were found to cause birth defects, but do not raise a genuine issue of material fact as to causation.").

Moreover, FED. R. CIV. P. 26(b)(1) directs courts to consider "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit" in assessing whether the requested discovery is proportional to the needs of the case. FED. R. CIV. P. 26(b)(1).

> The party seeking discovery, to prevail on a motion to compel, may well need to make its own showing of many or all of the proportionality factors, including the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, and the importance of the discovery in resolving the issues, in opposition to the resisting party's showing.

Marable v. Department of Commerce, 2019 WL 4689000, at *3 (N.D. Tex. 2019).

Plaintiffs have failed to make a sufficient showing on the six proportionality factors in Rule 26(b) for the Court to require Defendants to produce seventeen custodial files which are of negligible "importance . . . in resolving the issues" at the general causation phase. FED. R. CIV. P. 26(b)(1). Not only are the requested custodial files limited in their relevance and usefulness, but Plaintiffs' delay in filing the instant Motion to Compel imposes a greater burden on whatever files Defendants are now required to comb through and produce expediently. Plaintiffs initially requested these files on May 15, 2019. Defendants stated their intent to objection on May 31, 2019 [DE 349-1], and served their objections on June 14, 2019. [DE 349-2 and 349-3]. The Court understands the parties made multiple extra-judicial attempts to resolve this issue; however, waiting until September 19, 2019, to file a motion to compel is inexcusable. The Court will not now overly burden Defendants by requiring them to search through and produce seventeen custodial files in a short period of time. The Court notes, finally, that Defendants are not entirely without blame, as they did not produce even one document in response to Plaintiffs' request for custodial files, despite their promise on May 31, 2019, to "provide a reasonably targeted production" while the parties attempted to resolve the discovery dispute. [DE 349-1 at Page ID # 2029].

In an effort in find a balance between the limited usefulness of this information, the burden of producing it, and the broad discovery permitted in the Civil Rules, the Court grants Plaintiff's

Motion to Compel production of the seven files Defendants identified[2], utilizing the search terms Defendants outlined in their supplemental brief. [DE 378 at Page ID # 2587-91]. Despite Plaintiffs' characterization of these search terms as far too narrow, Defendants have identified dozens of terms, alternate spellings, and clinical identifiers that will encompass the information that could be relevant to general causation. The timeframes to be produced for each of these seven individuals shall be the timeframes Defendants proposed, apart from Dr. Nayyar Iqbal, who served as the Head of Diabetes Development at BMS from 2008 to 2015 and then as the Clinical Vice President, Diabetes/Metabolic Diseases at AZ from 2015 to the present. Defendants propose the timeframe for his files begin in 2010, but due to his position as Head of Diabetes Development, the Court believes the timeframe should begin in 2008.

Accordingly, Plaintiffs' Motion to Compel is granted as to the seven individuals Defendants identified and denied as to the ten additional individuals Plaintiffs identified.

III. CONCLUSION

For the reasons stated herein, **IT IS ORDERED** that Plaintiffs' Motion to Compel [DE 349] is:

1) **GRANTED** as to the clinical and non-clinical trial data;
2) **GRANTED** as to the pharmacoviligence data;
3) **GRANTED IN PART** and **DENIED IN PART**, as detailed above, as to the custodial files.

Entered this 5th day of November, 2019.

[2] These seven individuals are Boaz Hirshberg, Gerard O'Malley, Pia Pollack, Brian Bryzinski, Helen Edelberg, Kristina Chadwick, and Nayyar Iqbal. [DE 378 at Page ID # 2577-80].

Signed By:
Matthew A. Stinnett MAS
United States Magistrate Judge