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 to handle another discovery dispute. Plaintiffs filed a Motion to Compel and for Sanctions. [DE 479]. Defendants filed a Response [DE 503] and Plaintiffs replied [DE 508]. Defendants filed a motion for Leave to File a Sur-Reply, which the Court granted. [Sur-Reply at DE 519]. This matter is now ripe for a decision.

I. CURRENT DISPUTE[1]

A full recitation of the facts leading to this dispute is well-documented in the record. [*See, e.g.*, DEs 490 and 399]. The parties are currently engaged in discovery on the issue of general causation, attempting to answer the question of whether the prescription drugs manufactured by

[1] The Court refers to the documents at issue throughout by the exhibit numbers as designated by the parties in the document, to the extent possible, regardless of how they are designated on the docket. As noted in footnote 2, the designation of contested documents in the motion, response, reply, and sur-reply is convoluted, to say the least. Further muddying the murky waters, the docket reflects the motion was filed redacted at DE 479 and 480 and unredacted at DE 483; the response was filed at 503; the reply was filed redacted at DE 512 and unredacted at DE 513; the sur-reply was filed at DE 519. The Court has attempted to be as coherent and consistent as possible in its references to the docket.

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Defendants caused the users to have a cardiac event or be at a higher risk for a cardiac event. The parties have found themselves at yet another impasse in a discovery dispute. Plaintiffs allege Defendants have used FED. R. CIV. P. 26 and the parties' Stipulated Protective Order [DE 171] as justification to redact documents in discovery improperly. More specifically, Plaintiffs allege Defendants have repeatedly produced the same discovery in various stages of redaction, requiring Plaintiffs to "review, re-review, and re-review again the same set of documents" which "demonstrate[s] that Defendants' ulterior motive is exploitation of the discovery process to conceal and obstruct at Plaintiffs' expense." [DE 479 at Page ID # 3630].

Plaintiffs describe the documents at issue in the instant motion as "exemplars." However, the Court cannot and will not make sweeping declarations about documents and redactions not before it. The Court cannot determine the propriety of redactions sight unseen.[2] The Court will only rule on the redactions and other issues raised regarding the documents before it.[3] Hopefully

[2] The Court can scarcely determine the propriety of the documents it *can* see because the parties have unfortunately failed to consistently identify the relevant documents. In some instances, the parties refer to the documents by the Bates Stamp number but do not note the document's exhibit number (*e.g.*, "Plaintiffs first received the problematic, redacted document when Defendants clawed back and replaced the cited EU Risk Management Plan document with the redacted version (ONG007258693)." [Reply, DE 513 at Page ID # 7256]); in other instances, the parties refer to the document at issue generally but give the Court no indication of where or whether it can be found in the record (*e.g.*, "Defendants also redacted non-responsive material from two reports from a software analytics tool used by the AstraZeneca pharmacovigilance department to analyze data from several sources and databases to track potential safety signals for various medications." DE 503 at Page ID # 7060). Additionally, the exhibits were mis-numbered in some instances (*see, e.g.*, DE 480-19, document designated as Ex. 10 is Ex. 11, to the best of the Court's understanding). Exhibits 5C-F and 6C-F are never specifically mentioned but are attached to the Motion. Ultimately, the above-described inconsistencies have greatly impaired the Court's ability to provide a narrowly-tailored opinion as the arguments raised by the parties.

[3] These disputed documents are attached to Plaintiffs' Motion to Compel [DE 479 and 480] as Ex. 3, 5A-E, 6A-F, 7, 8, 9, 11, 12, 13, and 14 and Reply [DE 512 and 513] at Ex. 3, 4, 6, 7, 8, 9, and 10. Exhibits 1, 2, 4, 10, 15, 16, 17 and 18 to the Motion [DE 479 and 480] and Reply [DE 512 and 513] Ex. 1, 2, and 5 are supporting documents and the Court's understanding is that Plaintiff does not raise a discovery issue related to these documents.

the Court's ruling will provide some guidance to the parties on the Court's view of these issues to avoid similar disputes in the future.

II. ANALYSIS

A. SAXAGLIPTIN EU RISK MANAGEMENT PLAN 13 JAN 2014[4] AND OTHER RE-PRODUCED DOCUMENTS[5]

As noted above, Plaintiffs complain that Defendants produced the same documents several times with varying redactions, causing Plaintiffs to have to expend time and resources to re-review those documents numerous times. Plaintiffs admit Defendants re-produced the EU Risk Management Plan, removing the contested, "technical glitch" redactions. [DE 513 at Page ID # 7257]. Plaintiffs complain the "timeline [of the correction] is curious." [DE 513 at Page ID # 7257]. Although the Court understands Plaintiffs have a grievance about how and when these documents were produced, the documents were produced with the problematic redactions removed. It does not appear there is any remaining dispute regarding the production of the EU Risk Management Plan. Thus, this issue is moot.

The Court directs Defendants to be more careful in their document production in the future; however, there is no indication Defendants did anything other than make an honest mistake and then attempt (albeit clumsily) to correct the error.[6]

[4] DE 479 and 480 at Ex. 3, 7, and 8.

[5] DE 479 and 480 at Ex. 5A-F and Ex. 6A-F. Neither party addresses Ex. 5C-F or 6C-F. It appears there is a typographical error in Plaintiffs' brief at DE 479 and 480, n. 23, referencing breaking the exhibits into six parts, 5A-B and 6A-B. Based on the Bates Stamp numbers, it appears this should have referenced Exhibits 5A-F and 6A-F. Accordingly, the Court's ruling in Section C applies to Exhibits 5A-F and 6A-F.

[6] The Court agrees that if Defendants' production and redaction errors continue to accumulate, they will look less like "honest mistakes."

B. DATE OF DEATH AND TREATMENT DURATION REDACTIONS[7]

Plaintiffs next argue Defendants have wrongfully redacted death dates and treatment durations, both unquestionably critical to the question of causation before the Court. Defendants marked these redactions as "Protected Health Information" ("PHI") pursuant to the parties' Stipulated Protective Order at DE 171. On the one hand, the Court agrees that the specific *calendar date* of death qualifies as protected health information pursuant to the parties' Stipulated Protective Order. [DE 171 at ¶1(e)]. The death and treatment dates at issue in Plaintiffs' motion, on the other hand, are dates provided in *number of study days*, not calendar dates. Thus, the information would fall outside the rigors of the Stipulated Protective Order crafted by the parties. Defendants counter the information is unnecessary as Plaintiffs have this information in "Defendants' production of the unredacted, eCTD version of the Onglyza FDA clinical trial submissions" and should "easily cross-reference[]" the documents to determine the study day of death. [DE 503 at Page ID # 7056]. Defendants acknowledge they offered to provide this death information if Plaintiffs would withdraw the instant motion.

The Court cannot conceive how this information—that Defendants have provided in another format and offered to produce here—is information that must be redacted. Defendants should not take the extra step of redacting this information and then force Plaintiffs to untangle the redactions by "cross-referencing" the data with other documents. The obviously less burdensome course is for Defendants to remove the redactions.[8]

[7] DE 479 and 480 at Ex. 11, 12, and 13; DE 513 at Ex. 3 (mislabeled as Ex. 1).

[8] The least burdensome course would have been for Defendants not to make baseless redactions in the first place, and when they did, for Plaintiffs to be willing to negotiate a solution rather than file a baseless motion for sanctions.

C. TRADE SECRETS[9]

Plaintiffs raise the issue of improper "trade secrets" redactions in their motion as related to Exhibits 7, 8, and 9 of the Motion [DE 479 and 480] and Exhibits 6, 7, 8, 9, and 10 to the Reply [DE 512 and 513]. [DE 483 at Page ID # 6940].[10] Plaintiffs argue Reply Exhibits 6, 7, 8, 9, and 10 [DE 512 and 513] are publicly available documents and therefore improperly redacted. The Court cannot determine if Plaintiffs make the same argument about Motion Exhibit 9, although it appears they do.[11]

Defendants heavily rely on the Stipulated Protective Order as a basis for their redactions, even where the documents are publicly available. [DE 519 at Page # 7573-74]. In Defendant's view, "redactions of manufacturing processes are explicitly allowed under the Stipulated Protective Order, which provides authority for them regardless of whether a separate 'trade secrets' standards is met." [DE 503 at Page ID # 7058 n. 13].

The Stipulated Protective Order [DE 171] permits Defendants to redact any "manufacturing methods or processes, including quality control procedures, and proprietary formulas" from documents designated as "Confidential Discovery Material" [DE 171 at Page ID # 851, ¶ 2(e)(3)]. Peeling the onion of defined terms in the Stipulated Protective Order, the Court finds that the "term 'Confidential Discovery Materials' means all Documents or Discovery Materials produced or discovered in response to discovery requests propounded by Plaintiffs that are designated Confidential" and the "term 'Confidential' means any information which is in the possession of a Producing Party who believes in good faith that such information is entitled to

[9] DE 479 and 480 at Ex. 9; DE 512 and 513 at Ex. 6, 7, 8, 9, and 10.

[10] Plaintiffs note Exhibit 8 is an unredacted version of Exhibit 7, thus, it appears any dispute regarding these documents is moot.

[11] Exhibit 9 at DE 479 and 480 is mentioned once in a footnote.

confidential treatment under applicable law." [DE 171 at Page ID # 850, ¶ 1(f) and 1(d), respectively].

There is no dispute between the parties that Defendants have designated Exhibit 9 of the Motion [DE 479 and 480] and Exhibits 6, 7, 8, 9, and 10 to the Reply [DE 512 and 513] as "Confidential." Therefore, they are "Confidential Discovery Material" as defined in the Stipulated Protective Order. Thus, the true dispute between the parties appears to be the designation of these exhibits as "Confidential."

Initially, the Court once again stresses its frustration at deciphering the relevant documents in dispute beyond the generalities set forth in the motion practice.[12][13] The Court's view, however, is that any document that is publicly available is not properly designated as "Confidential" under the Stipulated Protective Order. Defendants do not deny Plaintiffs' claim that the disputed "trade secret" or "manufacturing process" redactions are public information. Defendants dispute Plaintiffs' assertion that Ex. 7 and 8 to the Reply are publicly available *documents* but admit that the redacted *information* in those documents is publicly available. Defendants are silent as to whether the remaining documents with "trade secret" redactions are publicly available, leading the Court to conclude Plaintiffs' arguments are true. A publicly available document or information cannot be "entitled to confidential treatment under applicable law[]" as defined in the Stipulated

[12] *See* n. 2. *See also* Ex. 9 to the Motion, which is only mentioned at the end of footnote 20 of the Motion. Neither party clearly designates whether it is a publicly available document.

[13] Defendants argue the redactions in Ex. 6 has "no conceivable relevance" to general causation in this case because they relate to other drugs. [DE 519 at Page ID # 7574]. Defendants do not raise relevancy issues as to Exhibits 7, 8, and 9 of the Motion [DE 479 and 480] or Exhibits 7, 8, 9, and 10 to the Reply [DE 512 and 513]. Further, relevancy is not the stated reason for Defendants' redactions in Ex. 6 to the Reply; instead, they clearly mark it as redacted due to "Trade Secret – Manufacturing Production." The Court agrees that the manufacture of drugs other than those at issue in this litigation has little to relevance to general causation in this case; however, to the extent these are publicly available documents, the Court cannot justify Defendants' (newly-stated) relevancy redactions in Ex. 6, which is otherwise relevant.

Protective Order. [DE 171 at Page ID # 850, ¶ 1(d)]. Conversely, if the document or information is not publicly available and Defendants believe the document contains a manufacturing process as defined in the Stipulated Protective Order, then those documents are protected.

Accordingly, the motion to compel is granted as to documents that are already publicly available and as to redactions that are public information even where the entire document is not public.

D. REDACTIONS LABELED "NOT RESPONSIVE"[14] [15]

Plaintiffs argue Ex. 14[16] redacts large portions of an email that appears clearly relevant, and implies the same problem exists in "otherwise responsive documents," although Plaintiffs do not identify those documents. Defendants note two examples they acknowledge are in dispute: OneNote files with responsive and nonresponsive information intermingled, and pharmacovigilance reports on adverse events other than cardiovascular events reported with Saxagliptin use. Defendants address Exhibit 14 only in a footnote, stating:

> Plaintiffs' cited example (Ex. 14 to Pls.' Mot., ONG009082955) reveals Plaintiffs' misunderstanding regarding the nature of these files. Plaintiffs claim that the "redacted material is clearly responsive" because Defendants allegedly redacted "a significant portion of the top of an email chain" regarding a regulatory submission. But the full responsive tab was produced: Dr. Edelberg copied and pasted the text

[14] DE 479 and 480 at Ex. 14.

[15] Defendants note the Court's prior holding that "pharmacovigilance documents related to non-cardiac adverse events . . . 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[.]" [DE 399 at Page ID # 2780]. The Court agrees with Defendants that this portion of the Court's prior holding is instructive on whether Defendants must produce information related to pharmacovigilance of alleged injuries or conditions other than those at issue in this lawsuit. However, no such documents are specifically before the Court and Plaintiffs did not raise the issue of pharmacovigilance documents in their motion, therefore there is no dispute about these documents upon which the Court can rule.

[16] ONG009082955, "June 16, 2014 Email from Krisztina Debreczeni to Rachpal Malhotra, et al. Re: Meeting notes: DSUR SAR Line Listing Cumulative – to implement CAPA for cases with blank investigatory causality."

> of a particular email from a larger chain in that tab. The other tabs do not include other emails in that chain.

[DE 503 at Page ID # 7061 n. 16]. Although neither party fully explains the documents at issue, the Court gleans from this footnote that Exhibit 14 was an email saved in OneNote.

As Defendants admit, lack of relevance or responsiveness does not typically justify redacting portions of documents. Defendants cite to *Beverage Distributors, Inc. v. Miller Brewing*, Co., 2010 WL 1727640, at *4 (S.D. Ohio April 28, 2010) in support of their position that their redactions due to nonresponsiveness are permissible. Defendants failed to notice that the court in *Beverage Distributors* held the defendants in that case could not redact documents for nonresponsiveness, and granted the plaintiff's motion to compel. The Court noted the competing interests involved in reaching its conclusion:

> (1) that redaction of otherwise discoverable documents is the exception rather than the rule; (2) that ordinarily, the fact that the producing party is not harmed by producing irrelevant information or by producing sensitive information which is subject to a protective order restricting its dissemination and use renders redaction both unnecessary and potentially disruptive to the orderly resolution of the case; and (3) that the Court should not be burdened with an *in camera* inspection of redacted documents merely to confirm the relevance or irrelevance of redacted information, but only when necessary to protect privileged material whose production might waive the privilege.

Id. at *4. As suggested in *Beverage Distributors*, the parties here have a Stipulated Protective Order to safeguard the information—relevant, responsive, and otherwise—that may be produced in this litigation. In one of the examples at issue, the Exhibit 14 email, the Court cannot discern the subject matter of the redacted portions of the documents—precisely the same problem Plaintiffs face. "Oftentimes, 'irrelevant information within a document that contains relevant information may be highly useful to providing context for the relevant information.'" *Shell Offshore, Inc. v. Eni Petroleum US LLC*, 2017 WL 11536165, at *5 (E.D. La. Aug. 28, 2017) (quoting *Bartholomew v. Avalon Capital Group, Inc.*, 278 F.R.D. 441, 451 (D. Minn. 2011)). The

Court finds, with the little information before it, that to the extent the entire email chain in Exhibit 14 has not been produced, it should be produced without redactions unless Defendants have a valid claim of privilege justifying redactions. The entire email chain (if not already produced) must be produced to provide the proper context of the already produced portion.

The Court agrees with Defendants, however, in their analogy that OneNote files are akin to "opening a general filing cabinet and only producing the files that are relevant to this litigation." [DE 503 at Page ID # 7060]. They claim the OneNote files contain irrelevant documents about other products Defendants manufactured at that time and have redacted those entire documents or "tabs." Where the redacted information is "commercially sensitive," such as the documents in the OneNote files that relates to drugs not at issue in this lawsuit, courts have allowed "irrelevant and sensitive material [to be] redacted." *North American Rescue, Inc. v. Bound Tree Medical, LLC*, 2010 WL 1258113, at *2 (S.D. Ohio March 25, 2010). Files from apps like OneNote, Evernote, etc., are vastly different from an individual email. A OneNote file may contain various types of documents and/or notes addressing numerous issues organized only by the purview of the individual controlling the OneNote file. Where "irrelevant information within a document that contains relevant information may be highly useful to providing context for the relevant information," such a holding does not necessarily ring true for OneNote files where multiple documents and notes related to numerous issues could be contained in a single file. *Shell Offshore*, 2017 WL 11536165, at *5.

Thus, to the extent the redacted portions of Exhibit 14 are other tabs or files that are not part of the email chain entitled "June 16, 2014 Email from Krisztina Debreczeni to Rachpal Malhotra, et al." and are not responsive to the discovery requests in this litigation, they may be

properly redacted. The Court finds that this is no different than producing only the relevant files from a general filing cabinet.

E. MOTION FOR SANCTIONS

The Court will not grant Plaintiffs' request for sanctions. Defendants appear to be aggressively litigating this dispute, but so are Plaintiffs. Defendants are cautioned that they should not continue to have so many "technical challenges" as there can only be so many "errors" in even the most complex litigation. Moreover, the Court looks askance on Defendants' very questionable death date and treatment duration redactions, as explained in Section C, *supra*. Otherwise, the Court cannot find issue with Defendants' tactics.

Plaintiffs, for their part, are cautioned to consider, carefully, the necessity of a motion for sanctions prior to filing a third. The Court does not look favorably upon such motions where opposing counsels' actions—while irritating—are far from sanctionable.

F. CONCLUSION

For the reasons stated herein, **IT IS ORDERED** that:

1) Plaintiffs' Motion to Compel and for Sanctions [DE 479] is **GRANTED IN PART** as to the following:

   a) Redactions of date of death and treatment duration to Exhibits 11, 12, and 13 of the Motion and Exhibit 3 to the Reply where those dates are expressed as a number of days rather than a calendar date;

   b) Redactions for "nonresponsiveness" to Exhibit 14 that are part of the email chain entitled "June 16, 2014 Email from Krisztina Debreczeni to Rachpal Malhotra, et al.";

   c) Exhibits 9 of the Motion and Exhibits 6, 7, 8, 9, and 10 to the Reply, to the extent these are publicly available documents;

2) Plaintiffs' Motion to Compel and for Sanctions [DE 479] is **DENIED IN PART** as to the following:

   a) Redactions of pharmocovigilance information not related to heart failure and/or increased the risk of adverse cardiac events;

   b) Redaction of OneNote files due to "nonresponsiveness"; and

   c) The request for sanctions.

The undersigned enters this Memorandum Opinion pursuant to 28 U.S.C. § 636(b)(1)(A). Within fourteen (14) days after being served with a copy of this Memorandum Opinion, either party may appeal this decision to Judge Caldwell pursuant § 636(b)(1)(A) and FED. R. CIV. P. 72(a).

Entered this 19th day of August, 2020.

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