UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: ZOFRAN (ONDANSETRON) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 1:15-md-2657-FDS**
This Document Relates To:	)	
All Actions	)	

MEMORANDUM AND ORDER ON PLAINTIFFS' MOTION TO STRIKE EVIDENCE FROM GSK'S RENEWED MOTION FOR SUMMARY JUDGMENT BASED ON PREEMPTION

SAYLOR, J.

This is a multi-district litigation ("MDL") proceeding arising out of product-liability claims that the use of the drug Zofran (ondansetron) by pregnant women caused certain types of birth defects in their children.

On July 19, 2018, defendant GlaxoSmithKline LLC ("GSK") moved for summary judgment based on federal preemption—in substance, on the ground that state-law claims of failure to provide an adequate warning label were preempted by federal law. Among other things, GSK contends that the federal Food and Drug Administration has twice rejected label changes containing warnings similar to those that plaintiffs contend should have been provided. The Court denied that motion on February 5, 2019, having concluded that the issue was one of fact for the jury to decide and that there were disputed issues of material fact precluding summary judgment.

On May 20, 2019, the Supreme Court held in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1679 (2019), that the issue of federal preemption in a pharmaceutical product

liability case must be treated "not as a matter of fact for a jury but as a matter of law for the judge to decide." This Court then vacated the relevant portions of its February 5 order.

On July 22, 2019, GSK renewed its motion for summary judgment on preemption grounds.[1] When it renewed its motion, it submitted four witness declarations, which had not been submitted with its original motion, and 139 other exhibits consisting almost entirely of items such as deposition transcripts, internal GSK documents, journal articles, and documents from the FDA. Plaintiffs have moved to strike all evidence submitted with GSK's motion that was not previously part of the summary judgment record.

For the following reasons, plaintiffs' motion to strike will be granted as to the declarations of Dr. Dena Hixon, Dr. Gary Shaw, and Dr. Patrick Wier, which are GSK's Exhibits 1, 3, and 4, and will otherwise be denied.

I. Background

A. The Preemption Issue Generally

Zofran is an anti-emetic—that is, a drug that prevents or treats nausea or vomiting. It was initially approved by the Food and Drug Administration in 1991 for the prevention of nausea and vomiting induced by chemotherapy or radiation therapy and post-operative nausea and vomiting.

Zofran was not approved, and never has been approved, for the prevention of nausea and vomiting in pregnancy. Nonetheless, Zofran has been prescribed off-label to pregnant women for many years. According to plaintiffs, that widespread practice was due in large part to unlawful marketing practices by GSK that sought to promote off-label usage.

At some point, the FDA became aware that Zofran was being prescribed to pregnant

[1] GSK filed an initial version of the motion on July 18, 2019, but filed the full, unredacted motion and its attached exhibits on July 22, 2019. (*See* Docket Nos. 1594, 1595, 1601, 1602).

women in significant numbers. In 2010, the FDA requested that GSK provide supplemental information concerning the safety of Zofran when used during pregnancy. In response, GSK provided an analysis of the then-available safety data. The FDA did not require any labeling changes. In 2013, a citizen petition requested that the FDA revise the Zofran label to indicate an increased risk to fetal safety if ingested during pregnancy. The FDA rejected that request. In 2015, the current manufacturer of Zofran, Novartis, submitted a proposed label change to provide, among other things, a warning that use in pregnancy could cause harm to the fetus and is not recommended. That, too, was rejected.

In short, whether Zofran poses a risk to fetal safety has been considered, and rejected, by the FDA on multiple occasions since the drug's initial approval. Even today, it is not contraindicated for use during pregnancy, and its label contains no enhanced form of warning for such use. Indeed, the current label states that "[a]vailable data do not reliably inform the association of Zofran and adverse fetal outcomes."

Plaintiffs nonetheless contend that ingestion of Zofran during pregnancy in fact causes birth defects, that the label should contain such a warning, and that GSK's failure to provide such a warning should result in tort liability under state law. Plaintiffs contend that the FDA's initial approval of Zofran in 1991, and its subsequent rejection of label changes, were based on incomplete information—essentially, because GSK withheld certain data from the FDA and made material misrepresentations. GSK denies that it withheld information and contends that any state-law failure-to-warn claims are preempted by federal law.

B. Procedural Background

The present dispute principally concerns the filing of additional declarations by GSK in support of its renewed motion for summary judgment, which plaintiffs contend are untimely expert disclosures. A review of the procedural background is necessary to address that issue.

On May 17, 2018, this Court issued MDL Order No. 25. Among other things, that order provided that discovery as to "Phase 3," which was defined as "discovery as to general causation and preemption issues," should conclude by June 29, 2018, and "may proceed" after that date "only by agreement of the parties or by leave of court upon good cause shown." (MDL Order No. 25 (Docket No. 1006)). It further provided that "any motion for summary judgment based on preemption" should be filed by June 15, 2018. (*Id.*).

MDL Order No. 25 also set a timetable for "[e]xpert discovery on general causation and general liability issues." (*Id.*).[2] It provided that plaintiffs were to serve "expert disclosures under Fed. R. Civ. P. 26(a)(2), including expert reports," by July 16, 2018, and that GSK was to do so by August 6, 2018. (*Id.*).

On June 11, 2018, the Court extended the deadlines for GSK to file a summary judgment motion on preemption to July 2, 2018. (Docket No 1030).

On June 27, 2018, the Court extended the deadlines for expert disclosures concerning general liability issues. (Docket No. 1036). Under the revised deadlines, plaintiffs' expert disclosures were to be served by July 31, 2018, and GSK's were to be served by September 21, 2018. (*Id.*).

On July 2, 2018, GSK timely filed its initial motion for summary judgment based on federal preemption. GSK submitted a number of exhibits with that motion, but did not submit any expert affidavits. (*See* Hill Decl. (Docket No. 1042)).

On August 1, 2018, plaintiffs filed an opposition to GSK's motion for summary

[2] "General liability" issues, in context, clearly include matters (such as a preemption defense) that would be applicable to all (or multiple) cases. It is distinguishable from, among other things, "specific liability" issues (such as, for example, whether a complaint in a specific case was filed outside the limitations period), "general causation" issues (whether Zofran was capable of causing certain types of birth defects) and "specific causation" issues (whether Zofran actually caused the birth defects in a specific individual).

judgment. Plaintiffs submitted a number of exhibits with that opposition, but did not submit an expert affidavit on regulatory or preemption issues. (*See* Jenner Decl. (Docket No. 1105)).

On August 6, 2018, GSK timely disclosed an expert report of Dr. Gary Shaw, one of its general causation experts. (GSK's Opp., Ex. J). Dr. Shaw's report did not directly touch on preemption issues.

On August 15, 2018, GSK filed a reply memorandum, together with multiple exhibits, in support of its motion for summary judgment on preemption. Again, no expert report on regulatory or preemption issues was submitted. (*See* Hill Decl. (Docket No. 1126)).

On September 11, 2018, plaintiffs filed a supplemental memorandum of law in opposition to GSK's motion for summary judgment, together with additional exhibits. Among the exhibits was an expert report from Dr. Brian Harvey dated August 30, 2018, addressing certain regulatory and preemption issues. (*See* Jenner Decl. (Docket No. 1155), Ex. 5).

On September 13, 2018, the Court heard oral argument on the motion for summary judgment and took the matter under advisement.

On September 21, 2018, GSK timely disclosed to plaintiffs an expert report of Dr. Dena Hixon, a regulatory expert, who addressed preemption issues. (GSK's Renew. Mot. for Summ. J., Ex. 17).

On October 2, 2018, plaintiffs filed a revised version of Dr. Harvey's expert report. The revised version included an affirmation that it was signed under oath, without any change to the substance of the report.

On February 5, 2019, the Court issued its opinion denying GSK's motion for summary judgment based on preemption. Among other things, the Court held that the preemption issue involved disputed issues of material fact that should be resolved by a jury.

On February 26, 2019, the Court issued MDL Order No. 31. (Docket No. 1355). That order provided, among other things, that "GSK's case-specific expert disclosures under Fed. R. Civ. P. 26(a)(2), including expert reports," should be served by April 5, 2019. (*Id.*). The order further provided that the opposing party would be entitled to take the deposition of a "case-specific expert [who] appear[s] in more than one case for a party." (*Id.*).

On April 5, 2019, GSK made a case-specific expert disclosure to plaintiffs concerning Dr. Patrick Wier, a GSK employee. (Docket No. 1650, Ex. G). The disclosure was four pages long, and indicated that Dr. Wier would provide opinion testimony concerning Zofran animal studies at trial. (*Id.*). That disclosure was made as to the eight individual cases that were being prepared for the first trial group, not in the MDL proceeding as a whole. GSK had previously identified Dr. Wier in 2015 and 2016 as a fact witness concerning the effectiveness and safety of Zofran. (GSK's Opp. (Docket No. 1650), Exs. B, C). Based on those disclosures, plaintiffs had deposed Dr. Wier on March 28, 2018. (Wier Dep. at 1).

On May 20, 2019, the Supreme Court issued its decision in *Albrecht*. In light of that decision, the Court permitted GSK to file a renewed motion for summary judgment based on federal preemption. (Docket No. 1575). In response to questions by the parties as to what types of materials they could submit, the Court expressed a desire to decide the preemption issue on a full factual record. (July 10, 2019 Hr'g Tr. at 44:5-12). However, the Court also noted that the parties could move to strike any supporting materials that they believed were improperly submitted. (*Id.*).

On July 22, 2019, GSK filed its renewed motion for summary judgment on preemption. Attached were declarations by four witnesses: Dr. Dena Hixon, Dr. Luise Rogg, Dr. Gary Shaw, and Dr. Patrick Wier. (GSK's Renew. Mot. for Summ. J., Exs. 1-4). GSK also attached 139

other exhibits to its motion. (*Id.*, Exs. 5-143).

On August 26, 2019, plaintiffs moved to strike all four declarations and all 139 exhibits.

II. Legal Standard

A. Fed R. Civ. P. 26(a)(2)

Fed. R. Civ. P. 26(a)(2) governs the disclosure of expert testimony. "[A] party must disclose to the other parties the identity of any [expert] witness it may use at trial to present evidence . . . ." Fed. R. Civ. P. 26(a)(2)(A). If the witness "is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony," the party must also submit a "written report" with numerous detailed facts, data, exhibits, and other items. Fed. R. Civ. P. 26(a)(2)(B).[3] If the witness is not such a person, the party must nonetheless disclose "(i) the subject matter on which the witness is expected to present [expert] evidence . . . ; and (ii) a summary of the facts and opinions to which the witness is expected to testify." Fed. R. Civ. P. 26(a)(2)(C).

"A party must make these disclosures at the times and in the sequence that the court orders." Fed. R. Civ. P. 26(a)(2)(D). As with all disclosures made under Rule 26(a), parties must "supplement or correct" their expert disclosures "in a timely manner" if a party learns of an omission or error unknown to the other party or "as ordered by the court." Fed. R. Civ. P. 26(e)(1). "For an expert whose report must be disclosed under Rule 26(a)(2)(B), the party's duty to supplement extends both to information included in the report and to information given during the expert's deposition." Fed. R. Civ. P. 26(e)(2).

[3] Specifically, the party disclosing under this subsection must include "(i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; (iii) any exhibits that will be used to summarize or support them; (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years; (v) a list of all other cases in which, during the previous 4 years, the witness testified as an expert at trial or by deposition; and (vi) a statement of the compensation to be paid for the study and testimony in the case." Fed. R. Civ. P. 26(a)(2)(B)(i)-(vi).

B. Fed R. Civ. P. 26(a)(3)

Fed R. Civ. P. 26(a)(3) requires parties to disclose the evidence that they may present at trial. "[A] party must provide to the other parties and promptly file . . . : (i) the name, and if not previously provided, the address and telephone number of each witness . . . ; (ii) the designation of those witnesses whose testimony the party expects to present by deposition . . . ; and (iii) an identification of each document or other exhibit, including summaries of other evidence . . . ." Fed R. Civ. P. 26(a)(3)(A). A party must make those disclosures at the times ordered by the court, or if the court sets none, then at least 30 days before trial. Fed. R. Civ. P. 26(a)(3)(B). As with all disclosures made under Rule 26(a), parties must "supplement or correct" those disclosures "in a timely manner" if a party learns of an omission or error unknown to the other party or "as ordered by the court." Fed. R. Civ. P. 26(e)(1).

C. Fed R. Civ. P. 37

Rule 37 provides sanctions for violations of Rule 26. "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c). "[T]he required sanction in the ordinary case is mandatory preclusion." *Poulis-Minott v. Smith*, 388 F.3d 354, 358 (1st Cir. 2004) (alteration in original) (internal quotation marks omitted) (quoting *Klonoski v. Mahlab*, 156 F.3d 255, 269 (1st Cir. 1998)). But "preclusion is not a strictly mechanical exercise; district courts have some discretion in deciding whether or not to impose that onerous sanction." *Santiago-Díaz v. Laboratorio Clínicio y de Referencia del Este*, 456 F.3d 272, 276 (1st Cir. 2006). In determining the proper sanction, the court should consider "(1) the party's justification for the late disclosure; (2) the opposing party's ability to overcome any prejudice; (3) the impact on the court docket; (4) the party's history of litigation abuse; and (5) the party's

need for the late evidence." *Glass Dimensions, Inc. ex rel. Glass Dimensions, Inc. Profit Sharing Plan & Tr. v. State Street Bank & Tr. Co.*, 290 F.R.D. 11, 17 (D. Mass. 2013) (citing *Harriman v. Hancock Cty.*, 627 F.3d 22, 30 (1st Cir. 2010)); *see also Gagnon v. Teledyne Princeton, Inc.*, 437 F.3d 188, 191 (1st Cir. 2006).

A party may avoid a Rule 37 sanction if it shows "that its failure to comply with the Rule was either justified or harmless and therefore deserving of some lesser sanction." *Wilson v. Bradlees of New England, Inc.*, 250 F.3d 10, 21 (1st Cir. 2001). A substantial justification, as used in Rule 37, "is one that 'could satisfy a reasonable person.'" *Pan American Grain Mfg. Co. v. Puerto Rico Ports Auth.*, 295 F.3d 108, 117 (1st Cir. 2002) (interpreting prior, similar version of Rule 37). Substantially justified "does not mean justified to a high degree, but only justified in substance or in the main—that is, justified to a degree that could satisfy a reasonable person." *Sheppard v. River Valley Fitness One, L.P.*, 428 F.3d 1, 12 (1st Cir. 2005) (internal quotations omitted). In weighing the justification for and harm caused by a disclosure violation, "[t]he Court must bear in mind the intent of the disclosure rules 'to facilitate a fair contest with the basic issues and facts disclosed to the fullest practical extent.'" *Jalbert v. Grautski*, 2009 WL 3754698, at *4 (D. Mass. Feb. 12, 2009) (quoting *Poulis-Minott*, 388 F.3d at 358).

III. Analysis

A. GSK's Exhibits 1- 4 (The Four Declarations)

1. Declaration of Dr. Dena Hixon

Exhibit 1 to GSK's renewed motion is the declaration of Dr. Dena Hixon. Dr. Hixon had previously provided an expert report in this case to plaintiffs on September 21, 2018. That prior expert report was timely submitted according to the court-ordered deadlines.

Dr. Hixon's new declaration is dated July 18, 2019. It was submitted (and therefore disclosed to plaintiffs) on July 22, 2019, more than nine months after the September 21, 2018

deadline. The issue is whether that declaration should be struck as untimely, either under Rule 26 or the Court's discovery orders.

The threshold questions are whether Dr. Hixon's declaration contains new information, and if so whether it is a supplemental or a rebuttal report within the meaning of the rules. GSK contends that Dr. Hixon's new declaration does not contain any new opinions and "is consistent with her expert report and testimony . . . ." (GSK's Opp. at 16). In her declaration, Dr. Hixon "evaluate[s] how [the] FDA would treat certain information relating to adverse event reports ('AERs') . . . for purposes of making decisions regarding [Zofran's] pregnancy-related labeling." (Hixon Decl. ¶ 6). Specifically, she expresses four opinions on that issue:

1. The disproportionality analysis ("DPA") that plaintiffs contend was faulty and provided to the FDA as part of an October 2015 safety evaluation (a) was never sent to the FDA and (b) would not have changed the FDA's labeling decision because it was "superseded in relevance" by later large epidemiologic studies. (Hixon Decl. ¶¶ 23-34).
2. Eleven cases of cardiac murmur that plaintiffs contend were not adequately reported by GSK (a) were reported to the FDA by GSK in a 2009 safety report and (b) would not have changed the FDA's labeling decision because (i) cardiac murmurs do not necessarily indicate birth defects and (ii) those cases "are inferior to the large epidemiologic studies FDA reviewed . . . ." (Hixon Decl. ¶¶ 35-45).
3. Thirteen adverse events from the Einarson study that plaintiffs contend GSK failed to properly submit to the FDA (a) incorrectly include six events from the McCauley study, and (b) were submitted to the FDA in GSK's 2011 and 2012 safety reports. In any event, (c) the FDA concurred that the Einarson study did

not show an association between first-trimester ondansetron use and birth defects, and (d) these events are superseded by the large epidemiologic studies that the FDA reviewed. (Hixon Decl. ¶¶ 46-54).

4. Although plaintiffs contend that GSK improperly failed to interrogate the FDA's safety database, FAERS, (a) GSK was not required to do so, and (b) the FDA, "far from being entirely reliant on sponsors to identify and analyze safety issues, [] conducts its own pharmacovigilance . . . ." (Hixon Decl. ¶¶ 55-61f).

Those opinions generally fall into two categories. The first category is those in which Dr. Hixon opines that GSK appropriately disclosed information to the FDA. Those opinions address a topic from her report: whether "GSK appropriately monitored [Zofran's] safety in pregnancy and complied with the regulations in collecting, analyzing and reporting pregnancy-related safety information." (Hixon Report at 4, 47-60). The second category is those in which she opines that, in any event, that information would not have changed the FDA's labeling decision. Those opinions also address a topic from her report: whether "FDA appropriately assigned [Zofran] Pregnancy Category B in the labeling, based on the data available to GSK and [the] FDA and the applicable regulations." (Hixon Report at 4, 71-72).

Both categories of opinions, however, go beyond the scope of Dr. Hixon's initial report. Each rebuts a contention by plaintiffs that she did not previously address. Specifically, each of her opinions rebuts an opinion expressed in the report of Dr. Brian Harvey, one of plaintiff's experts, which was produced after her own report. (*See* Harvey Report at 89 (cardiac murmurs), 90 (adverse events from Einarson study), 91-92 (FAERS), 92-93 (DPA), 101 (Sep. 26, 2018)). Indeed, she explicitly responds to the Harvey report. (*See* Hixon Decl. ¶ 46). And she draws upon information not relied upon in her initial report. For example, she cites to *The Nurse*

Practitioner in her discussion of heart murmurs and to the McCauley study in her discussion of the Einarson study. (Hixon Decl. ¶¶ 9, 48, 51). Neither citation appears in the list of materials that she considered for her initial report. (*See* Hixon Report at App. B).

Because Dr. Hixon's declaration relies on new information and presents new opinions, it is either a supplemental report or a rebuttal report. *See Riverfront Dev., Inc. v. Wepfer Marine, Inc.*, 2018 WL 3043325, at *4 & n.4 (W.D. Tenn. May 14, 2018) (expert's "addendum" must be either a supplemental or a rebuttal report).[4] It is not a supplemental report, because Dr. Hixon does not contend her initial report was "incomplete or incorrect." *See* Fed. R. Civ. P. 26(e)(1); *Munchkin, Inc. v. Playtex Prods., LLC*, 600 Fed. App'x. 537, 538 (9th Cir. 2015) (supplementation limited to "correcting inaccuracies" or "filling interstices"). Instead, her report "is offered to directly contradict or rebut the opposing party's expert." *See Glass Dimensions*, 290 F.R.D. at 16; Fed. R. Civ. P. 26(a)(2)(D)(ii). It is therefore a rebuttal report.

Accordingly, GSK may submit Dr. Hixon's rebuttal affidavit only if it was timely. *Glass Dimensions*, 290 F.R.D. at 16. The timing of such a disclosure is governed by Fed. R. Civ. P. 26 and, if applicable, the Court's discovery orders.

Fed. R. Civ. P. 26(a)(2)(D) provides that "[a]bsent . . . a court order," expert disclosures must be made "(i) at least 90 days before the date set for trial . . . ; or (ii) if the evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another party . . . within 30 days after the other party's disclosure."

Rule 26(a)(2)(D) thus sets two deadlines for disclosures of expert reports, absent a court

[4] Accepting the declaration as simply an "extension" of her report would permit "an end-run around the normal timetable for conducting discovery." *Cf. Bentley v. Highlands Hosp. Corp.*, 2016 WL 5867496, at *3-4 (E.D. Ky. Oct. 6, 2016). "The initial disclosure deadline would lose all meaning" if parties could endlessly file rebuttal or supplemental reports by deeming them extensions of the initial disclosure. *Cf. id.*

order. There is, however, an ambiguity in the use of the word "or" in the rule. The rule could be reasonably construed to mean that a rebuttal report may be disclosed *either* 90 days before trial *or* 30 days after the other party's expert disclosure (in other words, whichever is later). Or it could be reasonably construed to mean that all expert disclosures must be made 90 days before trial, *except* for rebuttal reports, which must be disclosed within 30 days after the other party's disclosure. It appears that those courts that have considered the rule have adopted the latter interpretation, albeit without analysis. *See, e.g., EEOC v. Texas Roadhouse, Inc.*, 215 F. Supp. 3d 140, 159 (D. Mass. 2016); *Coward v. Forestar Realty, Inc.*, 282 F. Supp. 3d 1317, 1331 (N.D. Ga. 2017), and cases cited therein. The Court will adopt that interpretation here, as it appears that such an interpretation is the more sensible one; at a minimum, it provides for an orderly sequence of expert reports and responses regardless of the imminence of any trial date.

The question then becomes whether any order of the Court required disclosure of any rebuttal report by a different deadline. Unfortunately, MDL Order No. 25 is silent on that issue. It explicitly set a deadline for plaintiffs' rebuttal expert reports, but did not set one for any rebuttal report by GSK.[5] Arguably, that was unfair to GSK. GSK, however, never sought leave to modify the order, or to file any rebuttal report.[6] Nor did GSK complain about the lack of symmetry in the order.

Thus, because the Order set no deadline for the filing of a rebuttal expert report by GSK,

[5] MDL Order No. 25 further provided that discovery on preemption issues "shall conclude on June 29, 2018, except as set forth in this order." (MDL Order No. 25 (Docket No. 1006) at 2). Arguably, that meant any such report was due no later than the close of preemption discovery on June 29, 2018. *See Sherrod v. Lingle*, 223 F.3d 605, 612-3 (7th Cir. 2000) (in the absence of an expert report deadline, reports were due by the close of discovery). However, that interpretation would have foreclosed any rebuttal reports by GSK, because, under the Order's timetable, they would have been due before the reports to which they would respond were ever filed.

[6] GSK had not previously proposed to submit rebuttal reports by its experts. (*See* GSK's Proposed Order (Docket No. 992), Ex. A at 4); April 25, 2018 Hr'g Tr. at 58:11-15).

the default rule of Fed. R. Civ. P. 26(a)(2)(D) applies. That means that any rebuttal report was due no later than October 26, 2018—that is, 30 days after the date of the Harvey report. (Harvey Report at 101).[7]

Applying that rule, Dr. Hixon's declaration was untimely. GSK filed the declaration on July 22, 2019, more than eleven months after the Harvey report to which it responded. It was therefore untimely under Fed. R. Civ. P. 26(a)(2)(D)(ii).

The question then becomes whether preclusion is required under Fed. R. Civ. P. 37. To determine whether the declaration should be excluded, the Court should consider the following factors: "(1) the party's justification for the late disclosure; (2) the opposing party's ability to overcome any prejudice; (3) the impact on the court docket; (4) the party's history of litigation abuse; and (5) the party's need for the late evidence." *Glass Dimensions*, 290 F.R.D. at 17. Under the circumstances, the Court finds that exclusion is warranted.

First, GSK's offered justification is not particularly persuasive. GSK contends that its late submission of Dr. Hixon's declaration is justified by the need "to arm the Court with the full record it seeks" now that the Court, and not a jury, must decide the preemption issue. (GSK's Post-Arg. Opp. at 10). But the same evidence would be considered if a jury were to decide the issue; in other words, while it is true that the factfinder has changed, the underlying factual issues are essentially identical, and the expert disclosure requirements are therefore unchanged.

Second, the admission of the declaration would prejudice plaintiffs. It presents new opinions not within the scope of Dr. Hixon's report. Plaintiffs have had no opportunity to depose

[7] It is unclear when exactly plaintiffs served the Harvey report on GSK. The report was due by July 31, 2018, but it was dated August 30, 2018 and revised on September 26, 2018. In any event, under Fed. R. Civ. P. 26(a)(2)(D)(ii) either date would have set the deadline for Hixon's rebuttal back in late 2018, and her declaration is untimely.

her about those opinions or to submit a rebuttal report by one of their experts.

Third, further discovery on this issue would likely cause further delays. The first bellwether trial is scheduled to begin in three months, and the parties are still conducting discovery regarding individual causation, product identification, and damages. Further discovery to address Dr. Hixon's rebuttal opinions, whether deposition or a rebuttal report, would delay resolution of the preemption issue, and likely delay the trial.

Fourth, and despite plaintiff's grumbling to the contrary, there is no history of litigation abuse by GSK in this matter.

Fifth, GSK does not have a compelling need for the late evidence. GSK had an opportunity to test Dr. Harvey's opinions at his deposition. (*See generally* GSK's Renew. Mot. for Summ. J., Ex. 8 (Harvey Deposition)). To the extent that GSK concluded that a deposition was inadequate, and a rebuttal report was necessary, it had an opportunity to timely file one in 2018 or to seek leave of the Court to file one thereafter.

Therefore, plaintiffs' motion to strike will be granted as to GSK's Exhibit 1, the declaration of Dr. Dena Hixon.

2. <u>Declaration of Dr. Luise Rogg</u>

Exhibit 2 to GSK's renewed motion is the declaration of Dr. Luise Rogg. Dr. Rogg did not previously submit an expert report in this matter, and plaintiffs essentially do not contend that her declaration contains expert opinions. (*See* Pls.' Mem. in Supp. at 8 (the declaration "offers new factual testimony, though not an expert opinion").[8] Accordingly, Dr. Rogg's

[8] Plaintiffs appear to contend that one statement in Dr. Rogg's declaration is an improper opinion. In that statement, Dr. Rogg says that "the DPAs included in the 2015 SERM reports provided only cumulative information and were superseded in significance by GSK's detailed analyses of the epidemiologic and pharmacovigilance data." (Rogg Decl. ¶ 15). Taken in context, that statement is better understood as a description of how Dr. Rogg and other GSK safety staff viewed the significance of those DPAs based on Dr. Rogg's personal knowledge of GSK's pharmacovigilance procedures, not as an expert opinion.

declaration is not subject to the disclosure requirements of Fed. R. Civ. P. 26(a)(2).

Plaintiffs nonetheless contend that Dr. Rogg's declaration should be struck because it unfairly offers new factual testimony. However, plaintiffs deposed her on April 11, 2017. (Rogg Dep. at 1). Thus, it appears that GSK disclosed her identity as a witness, as required by Fed. R. Civ. P. 26(a)(3), before the end of the discovery timetable set forth in MDL Order No. 25. Fed. R. Civ. P. 26(a)(3) does not require fact witnesses to file reports about their testimony prior to trial. According to GSK, it had planned to present Dr. Rogg's testimony to the jury, which it expected to decide the federal preemption issue. (GSK's Opp. at 1-2; Sep. 18, 2019 Hr'g Tr. at 28:5-11). Now that the issue is a matter of law for the Court to decide, *see Albrecht*, 139 S. Ct. at 1679, there is no reason to preclude Dr. Rogg's testimony. *Cf. Fisher v. Trainor*, 242 F.3d 24, 29 n.5 ("an initial denial of summary judgment does not foreclose, as the law of the case, a subsequent grant of summary judgment on an amplified record") (internal quotations omitted). Furthermore, plaintiffs have had an opportunity to depose her on the same topic covered by her declaration: that is, how GSK's pharmacovigilance team conducted a multidisciplinary signal evaluation of Zofran, including DPAs, in 2015. (Rogg Dep. at 84-85, 220).

In short, the submission of Dr. Rogg's declaration does not violate Fed. R. Civ. P. 26 or any order of the Court, and is otherwise not unfair or inappropriate. Accordingly, plaintiffs' motion to strike will be denied as to GSK's Exhibit 2, the declaration of Dr. Luise Rogg.

3. <u>Declaration of Dr. Gary Shaw</u>

Exhibit 3 is the declaration of Dr. Gary M. Shaw. Dr. Shaw had previously provided an expert report in this case that was disclosed to plaintiffs on August 6, 2018. The disclosure of that report complied with the Court's discovery deadlines.

GSK acknowledges that Dr. Shaw's new declaration contains opinions that are distinct

from those in his original report, but contends that those opinions should not be struck because they are narrow and directly responsive to contentions raised by plaintiffs.[9] In his initial report, he opined that "the extant epidemiologic data do not indicate an association, much less a causal association, between gestational [Zofran] exposure and any . . . birth defect." (Shaw Report at 19). Among the data upon which he relied was the Einarson study. (*Id.* at 7). Plaintiffs contend that the Einarson study improperly omitted one incidence of a birth defect known as laryngomalacia. (Resp. to GSK's Mot. for Summ. J. (Docket No. 1103) at 23). Dr. Shaw opines that any incidence of laryngomalacia was properly excluded from the Einarson study's results because laryngomalacia is a "minor malformation" and the study "did not report or discuss minor malformations." (Shaw Decl. ¶¶ 9, 14).

The opinions expressed in Dr. Shaw's new declarations are outside the scope of his initial report. His initial report briefly discussed the Einarson study, but he did not express an opinion as to how the study was conducted and whether it accurately reported its results. Nor did his report discuss laryngomalacia, the specific defect raised by plaintiffs.

The Court will not construe Dr. Shaw's declaration as a rebuttal report. Unlike Dr. Hixon's declaration, it does not respond to specific contentions by one of plaintiffs' experts. Rather, his opinions respond to a contention raised by plaintiffs in their opposition to GSK's initial motion for summary judgment based on preemption. (*See* Resp. to GSK's Mot. for Summ. J. (Docket No. 1103) at 23). Because his declaration does not "'solely [] contradict or rebut evidence on the same subject matter identified' by the opposing party's expert report," his

[9] GSK also contends that Shaw's statements and the documents he considered should not be struck because they contain factual statements. To the extent that Shaw's declaration "merely summarize[s] the conclusions" in those documents, (GSK's Post-Arg. Opp. at 8), those summaries are still expert opinions because they rely on Shaw's training in birth defects epidemiology, which is "scientific, technical or other specialized knowledge within the scope of Rule 702." *See* Fed. R. Evid. 701(c).

declaration "is more appropriately characterized as an untimely affirmative expert report." *Glass Dimensions*, 290 F.R.D. at 16-17 (quoting Fed. R. Civ. P. 26(a)(2)(D)(ii)). Therefore, his declaration, as an affirmative expert report, was not timely disclosed under MDL Order No. 25.

To determine whether the declaration should be excluded, the Court must consider the same five factors that it did as to Dr. Hixon's declaration. The analysis is largely identical, with one exception: GSK appears to have little need for Dr. Shaw's declaration. It responds to a single contention, raised in plaintiffs' brief, that the Einarson study improperly excluded a case of laryngomalacia. While the fact that plaintiffs chose to raise that contention in a brief, rather than an expert report, means that Dr. Shaw's response does not qualify as a rebuttal report, it also substantially undermines the force of plaintiffs' claim, which appears to be unsupported by expert opinion. Without such an expert report, the only bases for plaintiffs' claim that cases of laryngomalacia should have been reported in the Einarson study are their cited documents and any reasonable inferences that a non-expert could draw from them.[10] Even without Dr. Shaw's declaration, GSK is free to attack these bases, including by presenting factual evidence about largynomalacia and the design of the Einarson study.

Accordingly, plaintiffs' motion to strike GSK's Exhibit 3, the declaration of Dr. Gary Shaw, will be granted.

4. <u>Declaration of Dr. Patrick Wier</u>

Exhibit 4 to GSK's renewed motion is the declaration of Dr. Patrick Wier. Dr. Wier is a GSK employee. He has not submitted an expert report in this matter. GSK did, however, identify him as a fact witness, and plaintiffs took his deposition on March 28, 2018. GSK also

[10] For example, plaintiffs contend that laryngomalacia "fits the criteria for a birth defect attributable to drug exposure . . . ." (Resp. to GSK's Mot. for Summ. J. (Docket No. 1103) at 23). But plaintiffs' only support for that contention—an excerpt from GSK's safety database—does not even use the phrase 'birth defect,' let alone characterize laryngomalacia as one that is necessary to report. (*See* Jenner Decl. (Docket No. 1105), Ex. G).

made a case-specific expert disclosure of his opinions on April 5, 2019, that is four pages long.

Dr. Wier's declaration consists of 28 pages of text, plus another 10 pages of appendices, not including his curriculum vitae. In his declaration, he attests that he has been asked to evaluate (1) whether there were material differences between the Zofran embryo-fetal development studies performed in Japan and those performed in the U.K. and (2) whether those studies individually or jointly demonstrate that Zofran could cause birth defects. (Wier Decl. ¶ 9). His answers to both those questions rely on his specialized "training, expertise, and experience, as well as [his] review and consideration of the literature and other documents . . . ." (Wier Decl. ¶ 10). He also recites his qualifications and attaches his curriculum vitae and a list of documents upon which relied. (Wier Decl. ¶¶ 1-8, Exs. B, C).

The declaration of Dr. Wier unquestionably includes expert opinions. In light of his reliance on his own specialized expertise, the declaration is not, as GSK contends, merely a synthesis or summary of medical study reports that would be admissible at trial under Fed. R. Evid. 1006. Rather, the declaration is an expert report, in both substance and form, and therefore it is subject to the requirements of Fed. R. Civ. P. 26(a)(2).

a. Whether Dr. Wier Is an Employee-Expert under Rule 26

Fed. R. Civ. P. 26(a)(2) "divides expert witnesses into two categories": those who must submit expert reports and those who need not. *See In re Prograf Antitrust Litig.*, 2014 WL 4745954, at *4 (D. Mass. 2014). Expert reports must be disclosed for two types of experts: (1) those who are "retained or specially employed to provide expert testimony in the case," and (2) those "whose duties as the party's employee regularly involve giving testimony." Fed. R. Civ. P. 26(a)(2)(B); *see also Downey v. Bob's Disc. Furniture Holdings, Inc.*, 633 F.3d 1, 6 (1st Cir. 2011). Plaintiffs first contend that Dr. Wier's duties regularly involve giving testimony, and that therefore he was required to provide an expert report.

Dr. Wier's duties do not regularly involve giving expert testimony. His primary responsibilities at GSK are "characterizing the toxicology of drugs in nonclinical test systems and understanding how drugs interact with biological test systems." (Wier Decl. ¶ 1). Thus, his primary job is as a specialized researcher, not an expert witness. *See United States v. Adam Bros. Farming, Inc.*, 2005 WL 5957827, at *4-5 (C.D. Cal. Jan. 25, 2005) (holding that Rule 26(a)(2)(B) did not apply to a wetlands scientist employed by EPA for nearly 20 years).

It is true that Dr. Wier has testified as an expert several times. He has worked at GSK for more than 25 years, and plaintiffs have identified at least six occasions on which he has served as an expert witness in that time. (Wier Dep. at 30:5-8, 32:12-37:1). There may be more, because he cannot recall how many times he has been deposed about Paxil, another GSK product. (*Id.).*[11]

However, long-term employees may testify occasionally during their careers without that testimony becoming part of their regular duties. *See Adam Bros.*, 2005 WL 5957827, at *4 (EPA scientist had testified twice in nearly 20 years at EPA). Plaintiffs have cited no case where a court required an expert report for an employee who has testified at the rate Dr. Wier has: approximately six times in a 25-year career. *Compare Tobias v. City of Los Angeles*, 2018 WL 9669923, at *9 (C.D. Cal. Dec. 7, 2018) (witness had testified in more than two hundred cases). Thus, on this record, the Court concludes that Dr. Wier's duties do not regularly involve giving expert testimony within the meaning of Rule 26(a)(2)(B).

b. <u>Whether Dr. Wier Must Provide an Expert Report</u>

Plaintiffs further contend that an employee-expert who, like Dr. Wier, does not ordinarily testify but reviews material specifically for the case must submit an expert report in compliance

[11] GSK also acknowledges that Dr. Wier has been deposed in three cases involving the drug Paxil and testified at one Paxil trial in the last four years. (GSK's Post-Arg. Opp. at 5 n.3). It is unclear to what extent that testimony overlaps with the six instances identified by plaintiffs.

with Fed. R. Civ. P. 26(a)(2)(B).[12] The federal courts are split on that question. *See Allstate Ins. Co. v. Nassiri*, 2011 WL 2975461, at *6-7 (D. Nev. July 21, 2011) (collecting cases).

Some courts have held that an employee-expert who does not ordinarily testify—what the Court will refer to as an "incidental employee-expert"—must submit a report if her opinions are based on facts or data that she reviewed specifically for the case. *See id.*; *Day v. Consolidated Rail Corp.*, 1996 WL 257654 (S.D.N.Y. May 15, 1996). That interpretation emphasizes the purpose of Rule 26(a)(2)(B), rather than its text. Those courts have reasoned that if incidental employee-experts were not required to submit reports, that would "create a category of expert trial witnesses for whom no written disclosure is required—a result plainly not contemplated by the drafters of the current version of the rules and not justified by any articulable policy." *Day*, 1996 WL 257654, at *2; *see also Prieto v. Malgor*, 361 F.3d 1313, 1318-19 (11th Cir. 2004).[13]

Other courts have held that under the plain language of the rule, no expert report is required for incidental employee-experts. *See Nassiri*, 2011 WL 2957461, at *8; *Navajo Nation v. Norris*, 189 F.R.D. 610 (E.D. Wash. 1999); *Greenhaw v. City of Cedar Rapids*, 255 F.R.D. 484, 487-8 (N.D. Iowa 2000) ("The Court must apply the Rule as it is written, not as it could have been or should have been written."). Although that interpretation has been termed "the minority view," "several relatively recent district court decisions have agreed with its interpretation of Rule 26(a)(2)(B)." *Nassiri*, 2011 WL 2975461, at *8.

The First Circuit has not addressed the question. In *Downey v. Bob's Discount Furniture*

[12] GSK concedes that "[i]n preparing his declaration, Dr. Wier sought to determine the answers to questions he did not previously know—just as he would have done in preparing to testify at trial." (GSK's Opp. at 13).

[13] Proponents of the majority view have also reasoned that it "minimize[s] unfair surprise and prejudice resulting from sketchy and vague disclosure prior to trial." *KW Plastics v. U.S. Can Co.*, 199 F.R.D. 687, 690 (M.D. Ala. 2000) (internal quotations omitted); *see also National R.R. Passenger Corp. v. Railway Express, LLC*, 268 F.R.D. 211, 215 (D. Md. 2010) (the majority view "is more consistent with the spirit of discovery").

Holdings, 633 F.3d 1 (1st Cir. 2011), the court held that a non-employee expert witness whose "opinion testimony arises not from his enlistment as an expert but, rather, from his ground-level involvement in the events giving rise to the litigation" is not "retained or specially employed" within the meaning of Rule 26(a)(2)(B). *See id.* at 6-7. In *dicta*, the court indicated that a non-employee expert who had been personally involved in the case, but who had also been "retained or specially employed to develop *additional* opinions for purposes of trial," might need to submit an expert report. *Id.* at 8 n.5 (emphasis original). That *dicta*, however, concerned non-employee experts, and interpreted the phrase "retained or specially employed" in Rule 26(a)(2)(B); it did not answer the question of whether an employee-expert who reviews material specifically for the case must, for reasons beyond the plain text of Rule 26(a)(2)(B), also submit an expert report. *See Saucedo v. Garner*, 2018 WL 1175066, at *2 n.2 (D.N.H. Mar. 5, 2018) (expert report requirements for incidental employee experts remains a live issue post-*Downey*).

The minority view is unquestionably consistent with the actual text of Rule 26(a)(2)(B). That rule requires expert reports for two types of enumerated experts, and an incidental employee-expert is not one of those two types. "Those who drafted FRCP 26(a)(2)(B) could simply have required reports for all employee-experts if that is what they had intended." *Navajo Nation*, 189 F.R.D. at 613. Furthermore, the 2010 amendment to the rule made that distinction even more clear. The 2010 amendment—adopted ten years after courts first split on the issue—added Rule 26(a)(2)(C), which expressly provides that reports are *not* required for experts not covered by Rule 26(a)(2)(B). "While that amendment did not explicitly reject the [majority view], the fact that the Committee and the Supreme Court chose not to amend Rule 26(a)(2)(B) to adopt that position, but, instead, expanded the disclosures required for expert witnesses who are not required to prepare reports, supports the [minority interpretation]." *Nassiri*, 2011 WL

2975461, at *9; *see also* Fed. R. Civ. P. 26, Advisory Committee Notes to 2010 Amendments ("Frequent examples of [experts not required to submit reports] include . . . employees of a party who do not regularly provide expert testimony.").

There are also substantive reasons why Rule 26(a)(2)(B) would intentionally exclude incidental employee-experts. Retained experts are often professional experts who testify regularly, charge substantial fees, and publish in their field of expertise. *See Nassiri*, 2011 WL 2975461, at *8. "These matters are all relevant for impeachment purposes and Rule 26(a)(2)(B) expedites discovery" by imposing disclosure requirements that "[p]rofessional experts are arguably more likely to be familiar with and readily able to comply with . . . than employee witnesses who do not regularly testify as experts." *Id.*

The Court agrees that the minority view is faithful to the actual text of Rule 26, and is therefore correct. While Rule 26 is certainly intended as a general matter to promote the disclosure of information in litigation, the Court cannot ignore the plain wording of the rule. Accordingly, Dr. Wier, as an incidental employee-expert, was not required to provide an expert report under Rule 26(a)(2)(B).

c. Whether the Disclosure of Dr. Wier's Opinions under Rule 26(a)(2)(C) Was Timely

Because Dr. Wier is an incidental employee-expert, GSK was required to disclose "(i) the subject matter on which the witness is expected to present [expert] evidence . . . ; and (ii) a summary of the facts and opinions to which the witness is expected to testify." Fed R. Civ. P. 26(a)(2)(C). GSK did make such a disclosure on April 5, 2019. (GSK's Opp., Ex. G). Again, it was four pages long and listed his qualifications and his opinions, albeit in a somewhat generalized fashion. (GSK's Opp., Ex. G).

As noted, MDL Order No. 25 provided that for "general liability" issues, "expert

disclosures under Fed. R. Civ. P. 26(a)(2), including expert reports," were to be disclosed by August 6, 2018 (subsequently extended to September 21, 2018). By its terms, that deadline applies not only to expert reports (which Dr. Wier was not required to provide) but to expert "disclosures." And federal preemption surely qualifies as a "general liability" issue. Thus, according to that order, both the April 2019 disclosure and the July 2019 declaration were untimely.

MDL Order No. 31, in turn, provided that "case-specific" expert disclosures were to be made by April 5, 2019. According to that order, the April 2019 disclosure was timely, to the extent it was a "case-specific" expert disclosure. But Dr. Wier is not a "case-specific" expert as to the preemption issue. That issue is not to be decided by the jury, and is not specific to a single case; indeed, it arises in every case in this MDL proceeding.[14] Furthermore, the July 2019 declaration contains opinions that are not set forth in the April 2019 disclosure. While they overlap at a broad level, the declaration is far more specific and detailed, and is thus effectively a new disclosure.

In short, the disclosure of Dr. Wier's opinions concerning preemption in July 2019 was untimely under MDL Order No. 25 as a "general liability" expert disclosure, and untimely under MDL Order No. 31 as a "case-specific" expert disclosure.

d. Whether Good Cause Has Been Shown to Permit the Expert Disclosure

That leaves the question of whether the untimely disclosure of Dr. Wier's expert opinions should be excused. The inquiry could be framed either under the terms of MDL Order No. 25, which provides that the Court can modify the disclosure deadlines for "good cause shown," or

[14] To be clear, the Court is not opining as to whether Dr. Wier may testify as a case-specific expert in any individual trial on any issue other than preemption.

under Fed. R. Civ. P. 37, which would permit late disclosure if "substantially justified or harmless." For present purposes, the Court will collapse the two standards, and decide the issue under the Rule 37 framework.

GSK does not attempt to show that the late disclosure of Dr. Wier's opinions was substantially justified, except to contend in general terms that the legal landscape has changed since *Albrecht*. Again, the fact that the preemption question is to be decided by the Court, rather than a jury, is essentially irrelevant to the merits of the preemption question, and therefore the late disclosure is not justified. That leaves the question of whether the late disclosure was harmless.

It is certainly true that plaintiffs have not been entirely blindsided by Dr. Wier's declaration. To begin, plaintiffs knew as early as 2015 that Dr. Wier had knowledge "regarding the labeling, safety, and efficacy of [Zofran]." (GSK's Opp., Ex. B). GSK also disclosed in 2016 that Dr. Wier "may be knowledgeable regarding non-clinical data and studies involving [Zofran]" as well as "[Zofran] from a safety and drug surveillance perspective." (GSK's Opp., Ex. C). While those early disclosures were obviously quite broad, they were sufficient to cause plaintiffs to depose Dr. Wier. That deposition took place on March 28, 2018. At that deposition, plaintiffs asked him about many of the same topics that would later appear in his Rule 26(a)(2)(C) disclosure and in the disputed declaration. (*See, e.g.*, Wier Dep. at 40:10-41:19 (Dr. Wier's expertise), 151:10-154:5 (how to conduct and evaluate animal studies), 184:20-187:11 (how to interpret animal studies' results)).

However, the specific opinions contained in Dr. Wier's declaration were not previously disclosed to plaintiffs, and they have not had a fair opportunity to test those opinions. GSK's 2015 and 2016 disclosures were quite broad; they stated that Dr. Wier knew about Zofran safety

studies, but they did not disclose that he would present expert opinions, let alone describe those opinions. (*See* GSK's Opp., Exs. B, C). At Dr. Wier's 2018 deposition, plaintiffs had an opportunity to ask him about how to conduct, evaluate, and interpret animal studies in the abstract. (*See* Wier Dep. at 184:20-187:11, 242:8-247:15). By that point, however, he had not offered the opinions contained in his declaration—in particular, that the U.K. and Japanese animal studies' results were effectively similar, and that neither showed Zofran could cause birth defects.

It is true that plaintiffs asked Dr. Wier about his opinion on the results from at least one of the studies that he discusses in the declaration. (*See* Wier Dep. at 300:20-21). But plaintiffs' anticipation of Dr. Wier's future opinions was, at best, only partially successful; they did not ask him about every conclusion offered in his declaration.[15] Indeed, when asked about some topics discussed in his declaration, he did not know the answer. (*Compare* Wier Dep. at 334:10-13 (Dr. Wier did not know which animal studies were submitted to the FDA) *with* Wier Decl. ¶ 13 ("The U.K. studies were submitted to and reviewed by the FDA in connection with NDA 20-007."). Under the circumstances, Dr. Wier's 2018 deposition was not a fair opportunity for plaintiffs to test the opinions that he has now offered in his declaration. Thus, to excuse the untimely expert disclosure would potentially prejudice plaintiffs by depriving them of an opportunity to test the opinions in Dr. Wier's declaration, either by deposition or by the submission of a rebuttal report.

GSK contends that plaintiffs' failure to object to Dr. Wier's April 5, 2019 disclosure shows that it was harmless. However, that disclosure did not provide adequate notice of the

[15] While it seems theoretically possible that the Court could review Dr. Wier's declaration and deposition side-by-side to determine exactly which opinions were addressed in his deposition, the Court declines to do so. It is unlikely that such a comparison would be a simple exercise, and at a minimum it would cause substantial further delay.

opinions that would appear in his later declaration. The April 2019 disclosure, which was only four pages long, described his opinions in broad terms; it said he would testify that:

- The Zofran animal studies were well-designed and well-conducted;
- The Zofran animal studies were reported in the labeling for Zofran in a way that was accurate and that met the regulatory standards and the FDA's interpretations of those standards over time;
- The Zofran animal studies were consistent with the relevant guidelines for the design and conduct of animal studies;
- The Zofran animal studies do not support a conclusion of teratogenicity in animals; [and]
- The Zofran animal studies do not support a conclusion of any treatment-related effect on congenital heart defects . . . .

(GSK's Opp. Ex. G at 3). It did not disclose at that time that he would opine that the results from the U.K. and Japanese animal studies were effectively the same. Nor did it disclose that GSK would seek to introduce those opinions on the issue of preemption, rather than use it only for case-specific issues, as the date of its submission implied. The declaration thus includes new expert opinions, filed 10 months after the court-ordered deadline, to which plaintiffs have not had a fair opportunity to respond.

Despite that, it is certainly plausible that the late disclosure of Dr. Wier's opinions did not actually result in substantial prejudice to plaintiffs. Indeed, it is unlikely that most of the information set forth in his July 2019 declaration came as a total surprise. Nonetheless, the Court cannot conclude that the late disclosure is harmless; at a minimum, if it were permitted, in fairness plaintiffs would have to be given an opportunity to reopen Dr. Wier's deposition and to submit a rebuttal report from their own expert. Accordingly, because it is not substantially justified or harmless, the declaration should be excluded under Rule 37.

The Court is mindful that the exclusion of Dr. Wier's declaration could deprive it of

useful expert testimony as it decides the issue of federal preemption. The potential importance of that testimony, however, cannot excuse a failure to comply with court-ordered deadlines. Accordingly, plaintiffs' motion to strike will be granted as to Exhibit 4.

B. Documentary Exhibits

Plaintiffs seek to strike all 139 exhibits in addition to the four witness declarations. With only a few exceptions, those exhibits appear to be (1) exhibits that were submitted with GSK's original motion for summary judgment on preemption issues; (2) transcripts of depositions taken in this case; (3) documents produced by GSK in discovery in this case; and (4) publicly available documents, such as medical journal articles and FDA documents.[16] Plaintiffs do not attack the authenticity or relevance of any individual document.[17] Instead, they complain generally about the expansion of the record from the first summary judgment notion to the second. They further complain that certain documents are "free-standing" (that is, not referred to in the expert reports) and that any exhibits that are part of declarations that have been struck should be struck as well.

As an initial matter, there is no reason why the factual record on a renewed motion for summary judgment cannot be expanded from the original motion. *See Fisher*, 242 F. 3d at 29 n.5 (noting that a "subsequent grant of summary judgment [may be made] on an amplified record"). That is particularly true where discovery was ongoing at the time of the initial denial; it is unclear, to say the least, why the Court should be prohibited from considering newly developed facts.

Next, there is nothing obviously unfair about the submission of deposition transcripts or

[16] At least three of the exhibits (Exs. 14, 15, and 16) are plaintiffs' own expert reports. Another is an excerpt from a transcript of a status conference in this proceeding. (Ex. 18).

[17] While it is unclear that every exhibit has been properly and formally authenticated within the meaning of Fed. R. Evid. 901 or 902, in the absence of any actual specific objection to any specific document, the Court will not strike any document on that basis.

documents produced in this case. If plaintiffs have been unfairly prejudiced by the use of those documents, they have not indicated how, and there is no apparent reason why they should be struck.

The publicly available documents include a number of articles from medical journals, many of which concern the safety and efficacy of Zofran. To the extent those articles were cited or relied upon by Dr. Rogg or Dr. Wier, they will not be struck. Certain others (including, for example, the Danielsson study, (GSK's Renew. Mot. for Summ. J., Ex. 66), and the Einarson study, (GSK's Renew. Mot. for Summ. J., Ex. 73), both of which are relied upon by plaintiffs) were produced in discovery in this case and will not be struck. As for the remainder, including those that are "free-standing," it is unclear what the Court is able or empowered to make of them, to the extent they are not connected to any associated expert testimony. Certainly, the Court cannot interpret them for their scientific or medical content, at least not beyond a very superficial level. Nonetheless, there is no obvious reason to strike them entirely, as it at least possible that they may have some limited evidentiary value, and plaintiffs have raised no specific objections to any of the articles.

Finally, the publicly available documents include materials submitted to or created by the FDA and other government or regulatory agencies and an excerpt from the Physicians' Desk Reference, (GSK's Renew. Mot. for Summ. J., Ex. 89). Again, there is no apparent reason why those documents should be struck, although to the extent they require expert interpretation or analysis, they will be of little or no evidentiary value.

In summary, and in the absence of specific objections by plaintiffs to specific exhibits, the Court will not strike Exhibits 5 through 143.

IV. Conclusion

For the foregoing reasons, Plaintiffs' Motion to Strike Evidence from GSK's Renewed

Motion for Summary Judgment Based on Preemption is GRANTED as to Exhibits 1, 3, and 4, and otherwise DENIED.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
United States District Judge

Dated: October 8, 2019