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	)	

ORDER ON DEFENDANT'S MOTION TO DE-DESIGNATE CERTAIN DOCUMENTS AS CONFIDENTIAL UNDER THE PROTECTIVE ORDER

SAYLOR, C.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 birth defects in their children.

Defendant GlaxoSmithKline LLC ("GSK") has moved to "de-designate"—that is, no longer treat as confidential under the relevant protective order—four documents that were produced by a third-party witness, April Zambelli-Weiner, Ph.D. She is the co-author of an epidemiological study that plaintiffs cite as evidence that Zofran causes birth defects. At the time she conducted the study, she was a paid consultant to plaintiffs' counsel. The study itself was funded by plaintiffs' counsel in the amount of $210,000. Dr. Zambelli-Weiner also participated, along with plaintiffs' counsel, on a panel at a conference in Las Vegas concerning this litigation.

The Court previously ordered Dr. Zambelli-Weiner to produce several documents concerning that study and her relationship with plaintiffs' counsel. *See In re Zofran (Ondansetron) Prod. Liab. Litig.*, 392 F. Supp. 3d 179 (D. Mass. 2019). The history of her

involvement in this litigation is set forth in greater detail in that order. *See id.* at 182-84.

The present issue is whether four of the documents produced by Dr. Zambelli-Weiner pursuant to subpoena should continue to be designated as confidential. GSK contends that the documents were improperly designated, and, alternatively, that their "de-designation" is necessary to reveal information about the study that would be material to the public, including medical researchers and regulatory agencies.

On May 18, 2016, the Court issued MDL Order No. 13, which governs the discovery of confidential and privileged materials in this litigation. (*See* MDL Order No. 13 (Dkt. No. 242)). Under the terms of that order, a party may designate any documents or material as "confidential" if it reasonably and in good faith believes that it is confidential information. (*Id.* at 1-2). That order set forth several examples of confidential information entitled to protection. (*Id.*). It also provided that "[i]f, at any time, a Party in good faith objects to a Confidentiality Designation" and the parties dispute that designation, "the disputing Party may apply by motion to the Court for a ruling as to whether the designated Discovery Material may properly be treated as confidential." (*Id.* at 8). In that event, "[t]he designating party shall have the burden of proof . . . to establish the propriety of its Confidentiality Designation." (*Id.*). Materials that are properly designated as confidential may nevertheless be disclosed by order of the Court. (*Id.* at 9-10).

GSK has objected to the confidentiality designation of four documents: (1) a Zofran study protocol prepared by Dr. Zambelli-Weiner; (2) unpublished analyses that compared the birth defects risks associated with Zofran to those with other anti-emetic medications; (3) a draft of Dr. Zambelli-Weiner's study prepared for submission to the New England Journal of Medicine; and (4) a "Causation Briefing Document" prepared for plaintiffs' counsel by Dr.

Zambelli-Weiner. (*See* GSK's Mem. (Dkt. No. 1819), Exs. 1-4).

At the outset, none of the documents at issue are of the type ordinarily considered confidential. They do not, for example, contain sensitive personal, financial, or medical information. Dr. Zambelli-Weiner contends in general terms that they all include confidential business and proprietary information, but she does so in a merely conclusory fashion. *Cf. Anderson v. Cryovac, Inc.*, 805 F.2d 1, 7 (1st Cir. 1986). Moreover, it is unclear how or why that is true. She is not, for example, engaged in the business of conducting research to develop a pharmaceutical drug or other proprietary medical product or device. Indeed, her research appears to be unrelated to any proprietary or business enterprise of any kind, except to the extent she is acting in her capacity as a paid consultant for plaintiffs' counsel. As the Court noted in its earlier order, her misrepresentations to the Court concerning the nature of that relationship at the very least diminish whatever discovery protections might otherwise apply. *See In re Zofran*, 392 F. Supp. 3d at 186. Furthermore, she has not identified how the disclosure of the disputed documents to the public could prejudice her proprietary or business interests in any way.

Dr. Zambelli-Weiner further complains that GSK seeks to disclose the documents not to protect public health and safety, as it contends, but to promote its own litigation strategy and self-interest. That may well be true. But the motive of the party seeking disclosure is not the critical inquiry; private litigants are almost always acting in their own self-interest. Rather, the issues are whether the documents at issue were properly designated as confidential in the first instance, and if they were, whether de-designating them is nevertheless justified under the circumstances.

The first document is the Zofran study protocol, which sets forth the research plan for how Dr. Zambelli-Weiner and her co-authors intended to conduct their study. She first contends

that the protocol has never been published before. But that is not a basis to keep it confidential; indeed, based on multiple sources—including the journal that later published the study and the International Society of Pharmacoepidemiology ("ISPE"), of which she is a member—it appears that researchers in her field are routinely encouraged to publish such protocols. (*See* GSK's Mem., Ex. 14 at 13-14, Ex. 15 at 130:20-23, Ex. 16 at 5).[1][2]

Dr. Zambelli-Weiner further contends that the study protocol also includes proprietary plans for other, future research. However, the document that she refers to in support of that argument is an entirely different document—one that she claims is a later version of the protocol, but which is dated more than a year later and bears little resemblance to the document at issue. (*Compare* GSK's Mem., Ex. 1 *with* Zambelli-Weiner Surreply (Dkt. No. 1848), Ex. E). It is therefore unclear whether her plans for future research topics are set out in the document. If they are, it would appear to be reasonable to redact any such material prior to public disclosure. Otherwise, she has not demonstrated why the document should remain confidential.

The second document consists of the unpublished analyses comparing Zofran's birth-defect risks to those of other anti-emetic medications. It is doubtful that the document was properly deemed confidential in the first instance. It is true that it includes a header that deems it "Confidential & Proprietary" and that it was saved in a folder entitled "Internal deliverables." (*See* GSK's Mem., Ex. 2). But under ISPE guidelines, researchers have an ethical obligation to

[1] This type of study protocol, which is addressed to epidemiological research and appears unrelated to product development, is distinguishable from the "[p]roprietary design, development, research, and testing regarding products" that was defined as Confidential Information under MDL Order No. 13. (*Id.* at 2).

[2] According to GSK, the reason that study protocols are typically made public is so that other researchers can verify whether a study's authors have adhered to the protocol or adequately justified any departures from it. (See GSK Mem., Ex. 17 at 5-6). *See* Charles J. Walsh & Marc S. Klein, *From Dog Food to Prescription Drug Advertising: Litigating False Scientific Establishment Claims Under the Lanham Act*, 22 SETON HALL. L. REV. 389, 431 (1992) (explaining that adherence to a chosen study protocol "is essential to avoid 'data dredging'—looking through results without a predetermined plan until one finds data to support a claim").

report "findings that could have a significant impact on public health." (GSK's Mem., Ex. 16 at 8). And Dr. Zambelli-Weiner herself has stated that information comparing the risk of birth defects from ingesting Zofran to that of other antiemetic medications, such as that contained in this document, is the type of important public-health information that ordinarily should be shared. (GSK's Mem., Ex. 15 at 200:22-201:8).

In any event, even if the analyses were properly deemed confidential in the first instance, their disclosure is warranted here. The published version of Dr. Zambelli-Weiner's study emphasized that "alternative therapies" to Zofran exist and that medical practitioners should rely on "the best data to inform policy and practice." (GSK's Mem., Ex. 18 at 19). The unpublished analyses that compare the risk of ingesting Zofran to the risk of ingesting other anti-emetic medications thus seem to be potentially material omissions from her published study. Indeed, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency specifically asked Dr. Zambelli-Weiner whether she had performed such analyses. (GSK's Mem., Ex. 6). In her response to PRAC, she did not reveal that these unpublished analyses existed. (*See id.*). Two months later, PRAC recommended a change to Zofran's label, relying in part on her study. (*See* GSK's Mem., Ex. 5 at 98). Similarly, plaintiffs have indicated that they intend to submit that study to the FDA as it considers GSK's citizen petition. (*See* Pls. Mem. (Dkt. No. 1745) at 10). As both PRAC's inquiry and Dr. Zambelli-Weiner's own testimony indicate, these regulatory authorities would likely want to know of any data that may show Zofran is safer (or more dangerous) than other anti-emetics. Thus, it appears that there would be considerable public benefit in disclosing the analyses. *See Anderson*, 805 F.2d at 8 (calling public-health concerns a "compelling justification" for disclosing confidential information).[3]

[3] Again, Dr. Zambelli-Weiner argues that GSK has ulterior motives to de-designate this document because altering regulators' decisions may affect its business and even its liability in this matter. Even assuming the truth of

And again, Dr. Zambelli-Weiner has offered no compelling countervailing interest in keeping the analyses confidential.

The third document is the draft of Dr. Zambelli-Weiner's study that was prepared for submission to the New England Journal of Medicine. Dr. Zambelli-Weiner contends that this is an internal draft shared between her and her co-authors. (*See* GSK's Mem., Ex. 4). While that appears to be true, she does not explain how any differences between this draft and the study as it was later published could constitute proprietary business information, or describe any actual prejudice that might result from its disclosure. Thus, she has failed to demonstrate why the document should continue to bear the "confidential" designation.

The fourth document is a research brief prepared for plaintiffs' counsel by Dr. Zambelli-Weiner. It appears that Dr. Zambelli-Weiner prepared the brief pursuant to a consulting arrangement with the law firm of Grant & Eisenhofer, P.A., which is counsel to plaintiffs in this matter. (*See* Zambelli-Weiner Aff. (Dkt. No. 1406-5) ¶¶ 1-2; GSK's Mem., Ex. 3). The brief summarizes the state of the evidence as to whether Zofran may cause birth defects. It appears that it was created to assist plaintiffs' counsel in devising its litigation strategy and does not appear intended for publication. (*See* GSK's Mem., Ex. 3). Thus, it is plausibly proprietary and non-public business information, and the Court will assume it was properly designated in the first instance.

However, that does not mean it should remain confidential. As with the unpublished analyses, the document is almost certainly relevant to scientists and regulatory authorities evaluating the design and implementation of Dr. Zambelli-Weiner's study. Those authorities

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that statement, there are still persuasive public-interest reasons to disclose the document—namely, permitting those regulators to perform their duties more effectively by providing a more complete picture of the relevant research.

would likely consider it material that four years before the study's publication, and as part of a paid consulting arrangement with plaintiffs' counsel, she proposed conducting a similar study as an "[a]dditional [a]venue[] for [i]nquiry." (GSK's Mem., Ex. 3 at 11). Dr. Zambelli-Weiner contends that her financial relationship with plaintiffs' counsel was sufficiently disclosed in the conflict of interest statement in her published study. But that statement was only one sentence long, and indicated only that her organization had received funds from plaintiffs' counsel. It did not state or suggest that Dr. Zambelli-Weiner had consulted with counsel as to the nature of the study itself, or provide any detail about the extent of that relationship. (*See* GSK's Mem., Ex. 18 at 19). This document sheds additional light on that relationship and therefore its disclosure will also be permitted.

For the foregoing reasons, Defendant's Motion to De-Designate Certain Documents as Confidential Under the Protective Order is GRANTED. The four documents described in this Memorandum and Order shall not be considered "confidential" pursuant to MDL Order No. 13, issued May 18, 2016, except with respect to any possible redactions that Dr. Zambelli-Weiner may make that are consistent with this Memorandum and Order.

So Ordered.

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court

Dated: April 1, 2020