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 *IN CAMERA* PRODUCTION OF DOCUMENTS CONCERNING DR. APRIL ZAMBELLI-WEINER

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.

Defendant GlaxoSmithKline LLC ("GSK") has moved to compel the production of certain documents by plaintiffs and a third-party witness, April Zambelli-Weiner, Ph.D. Plaintiffs and Dr. Zambelli-Weiner have withheld the documents from production, contending that they are protected from discovery as attorney work product under Fed. R. Civ. P. 26(b)(3) and as consulting expert information under Fed. R. Civ. P. 26(b)(4)(D).[1]

Dr. Zambelli-Weiner is the co-author of an epidemiological study on which plaintiffs rely 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, with plaintiffs' counsel, on a panel at a conference in Las Vegas concerning this litigation.

[1] Plaintiffs have also on occasion characterized the documents at issue as "privileged," but there is no evidence of an attorney-client relationship between plaintiffs' counsel and Dr. Zambelli-Weiner.

When counsel for GSK sought to depose her in this case, she sought a protective order, and submitted an affidavit that included a number of falsehoods. She claimed in that affidavit, among other things, that plaintiffs' counsel had paid her for other work, not for the study at issue. Her counsel, upon discovering the falsehoods, filed a corrective notice with the Court and withdrew his appearance.

The issue before the court is whether certain documents concerning the relationship between Dr. Zambelli-Weiner and plaintiffs' counsel, which have been provided to the Court for *in camera* review, should be produced to GSK. For the reasons set forth below, the Court concludes that the documents are not protected from discovery and should be produced.

I. Background

April Zambelli-Weiner, Ph.D., is a researcher and the founder, president, and principal epidemiologist of Translational Technologies International Health Research & Economics ("TTi"). (Docket No. 1271-1, *Curriculum Vitae*).

Dr. Zambelli-Weiner is the co-author of a study published in the journal of *Reproductive Toxicology*, titled "First Trimester Ondansetron Exposure and Risk of Structural Birth Defects." (Docket No. 1271-2).[2] That study, which has become a central piece of plaintiffs' experts' causation opinions in this litigation, found a statistically significant association between early pregnancy ondansetron (Zofran) exposure and specific structural birth defects. (*Id.*).

On August 10, 2018, in anticipation of Dr. Zambelli-Weiner's forthcoming study, GSK served a set of request for production of documents and interrogatories on plaintiffs. Plaintiffs were asked to produce, among other things, all communications between plaintiffs' attorneys and

[2] *See* Zambelli-Weiner A, et al., *First Trimester Ondansetron Exposure and Risk of Structural Birth Defects*, 83 Reproductive Toxicology (2019), 14-20.

Dr. Zambelli-Weiner or her company (TTi) concerning the then-unpublished study. (Docket No. 1406-1).

On September 10, 2018, plaintiffs' counsel objected to those requests, contending that the request called for information not discoverable under Fed. R. Civ. P. 26(b)(3) and 26(b)(4)(D), and provided no responsive information. (Docket No. 1406-2).

Meanwhile, on October 29, 2018, the journal *Reproductive Toxicology* published an abstract of the study, titled "First Trimester Ondansetron Exposure and Risk of Structural Birth Defects." (Docket No. 1271-2).

GSK then issued subpoenas seeking to depose Dr. Zambelli-Weiner and a co-author, Dr. Russell Kirby. On November 26, 2018, plaintiffs moved on her behalf for a protective order seeking to prevent the depositions. (Docket No. 1224). In their motion, plaintiffs characterized Dr. Zambelli-Weiner as a research scientist. They did not reveal that she was a paid consulting expert for plaintiffs, and did not cite or rely on the protections of Rule 26(b)(3) or 26(b)(4)(D).

The Court denied the motion for a protective order on December 7, 2018. The Court stated that it would permit a deposition focused principally on the financial aspects of her relationship with plaintiffs' counsel—that is, what money was paid and how; what communications with counsel, direct or indirect, were made; and how those payments and communications may have affected the study. (Docket No. 1243).

GSK then served a subpoena *duces tecum* on Dr. Zambelli-Weiner. That prompted her to move for a protective order on January 9, 2019. (Docket No. 1271). In support of that motion, she submitted an affidavit to the Court setting forth the factual basis of her claims. (Docket No. 1272).

On January 18, 2019, the Court denied the motion for a protective order. (Docket No.

1292).

That same day, counsel for Dr. Zambelli-Weiner filed an emergency motion to withdraw his appearance, notifying the Court that he had learned that "factual representations" made in her affidavit were "inaccurate." (Docket No. 1293). Counsel also filed a "Notice Advising the Court of Factual Inaccuracies" in the affidavit and motion for protective order. (Docket No. 1294). That notice included the following statements:

> 9. At the time the Motion for Protective Order and Affidavit were filed, all counsel for Dr. Zambelli-Weiner believed that the factual assertions contained in those documents were accurate. Thereafter, Attorney Marder received information indicating that certain of the factual assertions in Dr. Zambelli-Weiner's Motion for Protective Order and Affidavit were inaccurate.
>
> 10. As required by Massachusetts Rule of Professional Conduct 3.3 and Maryland Rule of Professional Conduct 19-303.3, Attorney Marder remonstrated with Dr. Zambelli-Weiner about the inaccuracies in the Motion for Protective Order and her Affidavit.
>
> 11. Undersigned Counsel can no longer represent to this Court that all of the factual assertions in Dr. Zambelli-Weiner's Motion for Protective Order and Affidavit are accurate.

(*Id.*).

As events later proved, the affidavit contained at least three false statements. First, Dr. Zambelli-Weiner swore that she had "not been retained as an expert witness by any party in this case." (Docket No. 1272). In fact, she had been a paid consulting expert to plaintiffs since at least December 9, 2014. Second, she swore that she had "no direct factual information about the litigation." (*Id.*). That, too, was false. Her work as a consulting expert clearly was focused on this litigation; moreover, she had participated in a presentation on the litigation with plaintiffs' counsel at a conference in Las Vegas called "Mass Torts Made Perfect" in October 2015. Third, she swore that none of the funds paid by the plaintiff law firms "were paid to directly fund the study," but were instead "paid to my company for unrelated work." (*Id.*). In fact, her company

was paid more than $200,000 for her work on the study.

In January 2019, *Reproductive Toxicology* published the full article reporting Dr. Zambelli-Weiner's study.

On January 29, 2019, through new counsel, Dr. Zambelli-Weiner served a supplemental affidavit on GSK. That affidavit acknowledged for the first time that TTi had entered into two "consulting arrangements" with Grant & Eisenhofer P.A., one of the law firms represented on plaintiffs' steering committee. (Docket No. 1406-5). According to the affidavit, the two "arrangements" covered two specific time periods: December 10, 2014, to "approximately" March 2015, and March 29, 2017, to "approximately" November 2017. (*Id.*).

On January 30, 3019, GSK served a second set of interrogatories and fifth set of requests for production on plaintiffs concerning Dr. Zambelli-Weiner. (Docket No. 1406-6).

On February 1 and 22, 2019, Dr. Zambelli-Weiner was deposed by GSK. Among other things, she testified that she had received $13,500 between December 2014 and March 2015 in her first consulting arrangement with Grant & Eisenhofer. She further testified that she had received approximately $200,000 for her second consulting arrangement with the firm.

On March 1, 2019, plaintiffs responded to GSK's second set of interrogatories and fifth set of requests for production concerning Dr. Zambelli-Weiner. In that response, plaintiffs stated, among other things, that "Plaintiffs' Leadership Attorneys paid $210,000 as financial support relating to a study that was ultimately completed and published by Zambelli-Weiner A, et al., ..." (Docket No. 1406-7).

On March 8, 2019, GSK moved to compel the production of full responses by plaintiffs and Dr. Zambelli-Weiner to its discovery requests. (Docket Nos. 1388, 1405).

On March 19, 2019, plaintiffs and Dr. Zambelli-Weiner filed a cross-motion for a

protective order, again contending that the documents are protected from discovery under Fed. R. Civ. P. 26(b)(3) and 26(b)(4)(D). (Docket No. 1411).

At the hearing on the motion to compel, the Court ordered Dr. Zambelli-Weiner and plaintiffs to produce the withheld documents for *in camera* review. The parties subsequently delivered their document production to the Court.

After reviewing the documents *in camera*, and for the reasons set forth below, the Court will direct that the documents are not protected as attorney work product or consulting expert information and should be produced to GSK.

II. Legal Standard

A. Rule 26(b)(3)

Fed. R. Civ. P. 26(b)(3) essentially codifies the work-product doctrine. It provides as follows:

> (3) ***Trial Preparation: Materials***.
>
> > (A) *Documents and Tangible Things*. Ordinarily, a party may not discover documents and tangible things that are prepared in anticipation of litigation or for trial by or for another party or its representative (including the other party's . . . consultant . . .). But, subject to Rule 26(b)(4), those materials may be discovered if:
> >
> > > (i) they are otherwise discoverable under Rule 26(b)(1); and
> > >
> > > (ii) the party shows that it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means.
> >
> > (B) *Protection Against Disclosure*. If the court orders discovery of those materials, it must protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of a party's attorney or other representative concerning the litigation.

Fed. R. Civ. P. 26(b)(3).

Rule 26(b)(3) is limited to "things that are prepared . . . by or for another party or its

representative." Fed. R. Civ. P. 26(b)(3)(A); *see also F.T.C. v. Grolier Inc.*, 462 U.S. 19, 25 (1983) (stating that "the literal language of the Rule protects materials prepared for any litigation or trial as long as they were prepared by or for a party to the subsequent litigation"). The reviewing court must consider two questions: First, were the documents prepared in anticipation of litigation? Second, has the party seeking discovery made a showing of substantial need and an inability without undue hardship, to obtain their substantial equivalent by other means? *See Hoffman v. Owens-Illinois Glass Co.*, 107 F.R.D. 793, 794-95 (D. Mass. 1985).

B. Rule 26(b)(4)(D)

Fed. R. Civ. P. 26(b)(4)(D) addresses discovery directed to consulting experts. It provides in relevant part as follows:

> (4) ***Trial Preparation: Experts.***
>
> . . .
>
> (D) *Expert Employed Only for Trial Preparation*. Ordinarily, a party may not, by interrogatories or deposition, discover facts known or opinions held by an expert who has been retained or specially employed by another party in anticipation of litigation or to prepare for trial and who is not expected to be called as a witness at trial. But a party may do so only:
>
> (i) as provided in Rule 35(b); or
>
> (ii) on showing exceptional circumstances under which it is impracticable for the party to obtain facts or opinions on the same subject by other means.

Fed. R. Civ. P. 26(b)(4)(D).

III. Analysis

A. Records Concerning the Las Vegas Conference

Some of the documents that plaintiffs have submitted for *in camera* review do not fall under the protections of Rule 26 at all. Specifically, the documents include what appear to be

slides from a presentation delivered by plaintiffs' counsel and Dr. Zambelli-Weiner at "Mass Torts Made Perfect," a conference for plaintiff attorneys held in Las Vegas in October 2015. The documents in question thus were not intended to remain confidential, and appear to have been disclosed to dozens, perhaps hundreds, of other persons.

Work-product protection can be waived by third-party disclosure. *Bryan Corp. v. Chemwerth, Inc.*, 296 F.R.D. 31, 38 (D. Mass. 2013). That waiver is not automatic, however, and occurs "only when documents are used in a manner contrary to the doctrine's purpose, when disclosure substantially increases the opportunity for potential adversaries to obtain the information." *Murphy v. Harmatz*, 2016 WL 7104831, at *6 (D. Mass. Dec. 5, 2016) (quoting *Bryan Corp.*, 296 F.R.D. at 40); *see also United States v. Massachusetts Inst. of Tech.*, 129 F.3d 681, 687 (1st Cir. 1997). "[T]he critical inquiry 'is whether disclosure of documents protected by the work product doctrine . . . [substantially] increases the opportunities for potential adversaries to obtain the information.'" *Bryan Corp.*, 296 F.R.D. at 40 (quoting *In re Raytheon Sec. Litig.*, 218 F.R.D. 354, 360 (D. Mass. 2003)).

Presenting materials at a public, or quasi-public, conference is surely antithetical to the basic premise of confidentiality. It also, no doubt, substantially increases the opportunities for potential adversaries, such as GSK, to obtain the information. The slides in question, therefore, are not protected confidential information under Rule 26(b)(3).

The documents also involve communications between plaintiffs' counsel and Dr. Zambelli-Weiner in October 2015, when she (according to plaintiffs) was no longer a consulting expert. Thus, the protections of Rule 26(b)(4)(D) likewise do not apply.

Accordingly, to the extent that the documents at issue consist of materials concerning Dr. Zambelli-Weiner's participation in the "Mass Torts Made Perfect" conference in Las Vegas in

October 2015, they are not shielded from discovery and should be produced.

B. Records Concerning Facts Known or Opinions Held as a Consulting Expert

Dr. Zambelli-Weiner is a consulting, not a testifying, expert. Under normal circumstances, "facts known" or "opinions held" by her would not be discoverable through a deposition or interrogatories. Fed. R. Civ. P. 26(b)(4)(D).

As a threshold matter, the issue before the Court involves the production of documents, not interrogatories or a deposition. It therefore appears (at least on its face) that the protection of Rule 26(b)(4)(D) as to discovery of "facts known or opinions held by" a consulting expert do not apply.

Furthermore, to the extent that the documents also involve communications between plaintiffs' counsel and Dr. Zambelli-Weiner when she was not a consulting expert—for example, documents created between March 2015 and March 29, 2017—Rule 26(b)(4)(D) does not apply.

In any event, (1) this matter clearly presents an "exceptional circumstance" within the meaning of Rule 26(b)(4)(D)(ii); (2) GSK has established a "substantial need" for the materials within the meaning of Rule 26(b)(3)(A)(ii); and (3) the protection of those rules has been waived by litigation misconduct.

As noted, the epidemiological study at issue is one of the central pieces of evidence supporting plaintiffs' proof of general causation; arguably, it is the most critical single piece. Plaintiffs' counsel paid for the study, and appear to have consulted with Dr. Zambelli-Weiner during the course of the study.

It is troublesome, to say the least, for a party to engage a consulting, non-testifying expert; pay for that individual to conduct and publish a study, or otherwise affect or influence the study; engage a testifying expert who relies upon the study; and then cloak the details of the

arrangement with the consulting expert in the confidentiality protections of Rule 26(b) in order to conceal it from a party opponent and the Court. The Court can see no valid reason to permit such an arrangement to avoid the light of discovery and the adversarial process. Under the circumstances, GSK has made a showing of substantial need and an inability to obtain these documents by other means without undue hardship.

Furthermore, in this case, the consulting expert made false statements to the Court as to the nature of her relationship with plaintiffs' counsel. The Court would not have been made aware of those falsehoods but for the fact that her attorney became aware of the issue and sought to withdraw. Certainly plaintiffs' counsel did nothing at the time to correct the false impressions created by the affidavit. At a minimum, the submission of those falsehoods effectively waived whatever protections might otherwise apply. The need to discover the truth and correct the record surely outweighs any countervailing policy in favor of secrecy, particularly where plaintiffs' testifying experts have relied heavily on Dr. Zambelli-Weiner's study as a basis for their causation opinions. In order to effectively cross-examine plaintiffs' experts about those opinions at trial, GSK is entitled to review the documents. At a minimum, the documents shed additional light on the nature of the relationship between Dr. Zambelli-Weiner and plaintiffs' counsel, and go directly to the credibility of Dr. Zambelli-Weiner and the reliability of her study results.

To the extent that the documents contain plaintiffs' counsel's "mental impressions, conclusions, opinions, or legal theories"—which is doubtful at best, based on the Court's review of the materials—that protection is likewise waived. Again, plaintiffs' counsel have provided more than $200,000 to fund Dr. Zambelli-Weiner's research on Zofran; plaintiffs' experts rely on that study in support of their causation opinions; and Dr. Zambelli-Weiner has not been

forthcoming with the Court about that funding and her relationship to this litigation. Again, in order to be able to effectively cross-examine plaintiffs' experts about their causation opinions, GSK is entitled to a complete understanding as to the relationship between plaintiffs' counsel and Dr. Zambelli-Weiner.

In short, the documents that have been produced *in camera* are not protected from discovery, either as attorney work product or consulting expert information. The Court makes no finding as to the admissibility of the documents at trial.

IV. Conclusion

For the foregoing reasons, Dr. Zambelli-Weiner and plaintiffs are ordered to produce the responsive set of documents, previously produced to the Court for *in camera* review, to counsel for GSK within 7 days of this order, or by August 1, 2019.

So Ordered.

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

Dated: July 25, 2019