IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOLOFT (SERTRALINE HYDROCHLORIDE) PRODUCTS LIABILITY LITIGATION	:	**MDL NO. 2342** **12-MD-2342**
	:	**HON. CYNTHIA M. RUFE**
THIS DOCUMENT RELATES TO:	:	
ALL ACTIONS	:	

MEMORANDUM OPINION

Rufe, J. **January , 2015**

I. BACKGROUND

Zoloft (sertraline hydrochloride) is a prescription antidepressant, commonly used to treat depression, anxiety, and other mental health conditions.[1] Plaintiffs in this multi-district litigation ("MDL") allege that Zoloft, when taken during pregnancy, causes birth defects in the children born to exposed mothers. The Plaintiffs' Steering Committee ("PSC") offered the testimony of four expert witnesses on the issue of general causation.[2] After extensive proceedings pursuant to *Daubert v. Merrill Dow Pharmaceuticals, Inc.*,[3] the Court determined that because Dr. Anick Bérard failed to base her opinion upon scientifically valid methodology and reasoning, the opinion had to be excluded from consideration by a jury.[4] By separate opinion, the Court excluded the opinions of the PSC's three other witnesses, Drs. Thomas Sadler, Robert Cabrera,

[1] Zoloft is one of a class of drugs known as selective serotonin reuptake inhibitors (SSRIs). Serotonin is a neurotransmitter produced endogenously by humans and other animals. The SSRIs do not contain serotonin; rather, they alter the availability of the serotonin produced by the body.

[2] The PSC initially put forward additional proposed expert witnesses but withdrew them.

[3] 509 U.S. 579 (1993).

[4] *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, --- F. Supp. 2d ---, No. 12-md-2342, 2014 WL 2921648, at *12 (E.D. Pa. June 27, 2014).

and Michael Levin, in part, ruling that these experts could not testify that Zoloft caused birth defects in humans but could testify as to the limited question of the existence of plausible biological mechanisms in which altered concentrations of serotonin in a developing embryo could cause birth defects.[5]

The PSC now seeks to introduce expert testimony by Nicholas Jewell, Ph.D., a professor at the University of California, Berkeley in the Division of Biostatistics, School of Public Health, and in the Department of Statistics. The PSC represents that based "on the existing studies that were in evidence at the past *Daubert* hearing [and] . . . the results of several scientific studies that were not available at the time Dr. Bérard authored her report . . . Dr. Jewell will opine that *in utero* exposure to Zoloft can cause congenital heart defects."[6] Defendants (collectively, "Pfizer") oppose the motion.

II. LEGAL STANDARD

The PSC presents two bases for the Court to permit the introduction of Dr. Jewell's testimony. First, the PSC seeks to amend the relevant scheduling orders for good cause pursuant to Federal Rule of Civil Procedure Rule 16(b)(4).[7] Alternatively, the PSC argues that to deny the opportunity to present Dr. Jewell would constitute exclusion of the testimony as a discovery sanction under Rule 37(b)(2)(B)[8] because the PSC failed to identify Dr. Jewell in the time frame

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[5] *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, --- F. Supp. 2d ---, No. 12-md-2342, 2014 WL 3943916, at * 13 (E.D. Pa. Aug. 12, 2014).

[6] PSC Motion at 8 & n.9.

[7] Rule 16 provides in relevant part that a schedule "may be modified only for good cause and with the judge's consent."

[8] Rule 37 provides in relevant part:

(b) Failure to Comply with a Court Order.

. . .

set by the Court and that such a sanction is unwarranted. Under these Rules, the Court has "considerable" discretion in determining whether to allow the new expert and is guided by five factors: 1) prejudice or surprise to the opposing party; 2) the ability of the opposing party to cure the prejudice; 3) the disruption of the orderly and efficient trial of the case; 4) bad faith or willfulness; and 5) the importance of the evidence.[9]

III. DISCUSSION

A district court is not required to "provide a plaintiff with an open-ended and never-ending opportunity to meet a *Daubert* challenge until [the] plaintiff 'gets it right.'"[10] At the same time, the district courts have an "independent responsibility for the proper management of

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(2) Sanctions Sought in the District Where the Action Is Pending.

(A) For Not Obeying a Discovery Order. If a party or a party's officer, director, or managing agent--or a witness designated under Rule 30(b)(6) or 31(a)(4)--fails to obey an order to provide or permit discovery, including an order under Rule 26(f), 35, or 37(a), the court where the action is pending may issue further just orders. They may include the following:

(i) directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action, as the prevailing party claims;

(ii) prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence;

(iii) striking pleadings in whole or in part;

(iv) staying further proceedings until the order is obeyed;

(v) dismissing the action or proceeding in whole or in part;

(vi) rendering a default judgment against the disobedient party; or

(vii) treating as contempt of court the failure to obey any order except an order to submit to a physical or mental examination.

(B) For Not Producing a Person for Examination. If a party fails to comply with an order under Rule 35(a) requiring it to produce another person for examination, the court may issue any of the orders listed in Rule 37(b)(2)(A)(i)-(vi), unless the disobedient party shows that it cannot produce the other person.

[9] *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 298 (3d Cir. 2012); *In re Paoli R.R. PCB Litig. ("Paoli II")*, 35 F.3d 717, 791 (3d Cir. 1994).

[10] *In re TMI Litig.*, 199 F.3d 158, 159 (3d Cir 2000), *amending*, 193 F.3d 613 (3d Cir. 2000).

complex litigation," and plaintiffs "need[] an opportunity to be heard" on critical issues of admissibility of expert testimony.[11] Here, the Court is confident that the PSC has had a full opportunity to be heard. The Court, however, also must be confident that all of the implications for the MDL as a whole have been addressed. As the Court of Appeals has held:

> [A] sprawling multidistrict matter such as this presents a special situation, in which the district judge must be given wide latitude with regard to case management in order to effectively achieve the goals set forth by the legislation that created the Judicial Panel on Multidistrict Litigation. *See* 28 U.S.C. § 1407(a) (permitting transfers of actions "for the convenience of parties and witnesses and [for] just and efficient conduct of such actions"). At the same time, efficiency must not be achieved at the expense of preventing meritorious claims from going forward.[12]

In assessing the relevant factors in this context, the Court finds that although there is some prejudice to Pfizer, in that it will be put to the additional expense required to litigate the admissibility of Dr. Jewell's proposed testimony, this prejudice is not of a character sufficient to warrant denial of the motion. Had the PSC presented Dr. Jewell earlier, as Pfizer contends the PSC should have done, Pfizer would be in the same position with regard to the question of the admissibility of Dr. Jewell's testimony. Although the PSC and Dr. Jewell have had the benefit of the Court's prior *Daubert* rulings in the formulation of the new expert report, that does not create prejudice to Pfizer. Either Dr. Jewell's expert report and testimony will pass muster under Rule 702 or they will not. In addition, there is every possibility that Dr. Jewell will be presented as an expert witness in Zoloft cases currently pending in state courts, or in cases that may be filed in the future and therefore Pfizer likely must address his expert testimony at some point.

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[11] *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 417 (3d Cir. 1999).

[12] *In re Asbestos Prods. Liab. Litig. (No. VI)*, 718 F.3d 235, 246-247 (3d Cir. 2013), citing *In re Phenylpropanolamine (PPA) Prods. Lab. Litig.*, 460 F.3d 1217, 1231-32 (9th Cir. 2006) (holding that "[a] district judge charged with the responsibility of 'just and efficient conduct' of the multiplicity of actions in an MDL proceeding must have discretion to manage them that is commensurate with the task. The task is enormous, for the court must figure out a way to move thousands of cases toward resolution on the merits while at the same time respecting their individuality." (citation omitted)).

Although additional *Daubert* proceedings will of necessity extend the trial schedule, the MDL has moved expeditiously through the diligence and cooperation of all counsel and any delay can be addressed through the use of appropriate orders to avoid unfairness to any parties.

The Court weighs heavily the indisputable fact that the evidence is of critical importance to Plaintiffs, as "[t]he decision to admit or exclude scientific evidence and testimony . . . strongly affects the ability of a party to prevail."[13] The Court fully appreciates Pfizer's argument that the PSC had every opportunity to select its expert witnesses and now seeks a "*Daubert* do-over" after an unfavorable outcome. Had this issue arisen outside of the MDL context, this argument may have carried the day.[14] The Court in no way suggests seeking to present an additional expert only after an unfavorable *Daubert* ruling is an appropriate litigation strategy. The Court recognizes that "[s]ince *Daubert*, . . . parties relying on expert evidence have had notice of the exacting standards of reliability such evidence must meet. It is implausible to suggest, post-*Daubert*, that parties will initially present less than their best expert evidence in the expectation of a second chance should their first try fail."[15] However, the Court has no reason to conclude that the PSC has acted in bad faith or that its present predicament is the result of deliberate strategy instead of a miscalculation as to the persuasiveness of Dr. Bérard's

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[13] Manual Complex Litigation (4th), § 23.1 at 470.

[14] The Court notes that most of the appellate decisions cited by Pfizer were in the context of holding that the trial court had not abused its discretion in not allowing additional expert testimony (unsurprising, as a trial court's decision to permit additional proceedings is less likely to give rise to appealable order). Therefore, although the Court has considered the reasoning underlying the decisions carefully, the Court must exercise its discretion in determining the appropriate action for this litigation. The Court also notes that the MDL decision cited by the PSC in its supplemental filing, *In re: Rail Freight Fuel Surcharge Antitrust Litigation*, Misc. No. 07-489 (D.D.C. Nov. 26, 2014), arises in such a different context as to be inapposite.

[15] *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000) (citations and footnote omitted). The Supreme Court ruled in the context of entry of judgment as a matter of law when expert testimony is rejected at trial and thereby renders the proof insufficient for the party with that burden; and this Court does not understand it to establish a "single-strike" approach to expert evidence, particularly before trial.

testimony.[16] The Court also notes that the initial *Daubert* hearing was not futile, as the testimony of Drs. Cabrera, Sadler, and Levin has been limited, and as it appears that Dr. Jewell's proposed expert testimony encompasses a significantly more limited range of birth defects than did Dr. Bérard's. This MDL Court must consider the broader ramifications of barring an attempt to present Dr. Jewell, and has concluded that the interests of justice do not support such a step. The Court will grant the PSC's motion to permit the opportunity to offer for vetting the testimony of Dr. Jewell.[17] The PSC's motion will be granted.[18]

[16] This conclusion is buttressed by Pfizer's citation to statements by PSC counsel at the *Daubert* hearings. Pfizer does not suggest that their opposing counsel was anything but sincere in representing to the Court that "this is the best group of experts I have ever seen in one place on one subject in a courtroom in my entire career." Hr'g Tr. April 7, 2014 at 68.

[17] The Court also will consider whether any individual Plaintiffs who wish to present their own general causation experts should have the opportunity to do so.

[18] Because Pfizer's Motion for Summary Judgment was predicated on the *Daubert* rulings, the Court will dismiss this motion without prejudice and will determine after consultation with the parties the appropriate course of action with regard to motions for summary judgment as to those cases in which Dr. Jewell's proposed testimony would not provide a basis for determining general causation.