IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

SADIE MILLER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No.: 4:14-cv-00652-SRB
	)	
BAYER HEALTHCARE PHARMACEUTICALS INC., et al.	)	
	)	
Defendants.	)	

ORDER

Before the Court is Defendants' Omnibus Motion to Exclude the General Causation and Labeling Opinions of Plaintiff's Experts (Doc. #65). For the reasons explained below, Plaintiff's motion is denied.

I. Background

Plaintiff disclosed four expert witnesses to testify at trial: Dr. Rosa Tang, Dr. Frederick Fraunfelder, Dr. David Ross, and Dr. John Maggio. In Defendants' omnibus motion, Defendants argue Plaintiff's experts are unqualified to offer their opinions and suggest Plaintiff's experts utilize an unreliable methodology to reach their conclusions. Defendants request the Court exclude "[e]ach expert's general causation opinions, and the labeling opinions that flow from those opinions[.]" (Doc. #66, p. 7).

II. Legal Standard

When the admissibility of expert testimony is challenged, the district court must make "a preliminary determination of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592 – 93. The party seeking to introduce the expert's

testimony bears the burden of establishing its admissibility by a preponderance of the evidence. Lauzon v. Senco Products, Inc., 270 F.3d 681, 686 (8th Cir. 2001). Under Federal Rule of Evidence 702, a witness may give an expert opinion if the following conditions are met: (a) the expert's scientific, technical or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Under Fed. R. Evid. 702 and the guidance set forth in Daubert, expert testimony should be liberally admitted. Johnson v. Mead Johnson & Co., LLC, 754 F.3d 557, 562 (8th Cir. 2014) (citing U.S. v. Finch, 630 F.3d 1057, 1062 (8th Cir. 2011) (holding that doubts about usefulness of expert testimony are resolved in favor of admissibility)); Robinson v. GEICO Gen. Ins. Co., 447 F.3d 1096, 1100 (8th Cir. 2006) (holding that expert testimony should be admitted if it "advances the trier of fact's understanding to any degree"); Lauzon, 270 F.3d at 686 (Rule 702 "clearly is one of admissibility rather than exclusion"). "As long as the expert's ... testimony rests upon 'good grounds, based on what is known' it should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset." Id. (citing Daubert, 509 U.S. at 590, 596). Exclusion of expert opinion is proper only "if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury[.]" Lawrey v. Good Samaritan Hosp., 751 F.3d 947, 952-53 (8th Cir. 2014) (quoting Neb. Plastics, Inc. v. Holland Colors Americas, Inc., 408 F.3d 410, 416 (8th Cir. 2005)).

"When evaluating the methodology that an expert witness applies, it may be important to consider (1) whether the theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of

error; and (4) whether the theory has been generally accepted." Shuck v. CNH Am., LLC., 498 F.3d 868, 874 (8th Cir. 2007) (internal quotation marks omitted) (quoting Peitzmeier v. Hennessy Indus., Inc., 97 F.3d 293, 297 (8th Cir. 1996)). "These factors are not exclusive, however, and . . . the Daubert reliability factors should only be relied upon to the extent that they are relevant and the district court must customize its inquiry to fit the facts of each particular case." Id. (internal quotation marks omitted) (citing Jaurequi v. Carter Mfg. Co., 173 F.3d 1076, 1083 (8th Cir. 1999)). Rule 403 of the Federal Rules of Evidence further provides expert testimony should be excluded "if its probative value is substantially outweighed by a" risk of "unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence."

III. Analysis

Defendants seek to exclude Plaintiff's experts by challenging their qualifications and the methodology used by Plaintiff's experts to reach their general causation and labeling opinions.

A. Qualification

Defendants challenge the qualifications of Dr. Rosa Tang, Dr. Frederick Fraunfelder, Dr. David Ross, and Dr. John Maggio to offer general causation and labeling opinions. Specifically, Defendants state "Dr. Tang does not actually reach a general causation opinion, and Drs. Fraunfelder, Maggio, and Ross are unqualified to do so." (Doc. #66, p. 19). Defendants acknowledge Dr. Tang specializes in IIH but allege the remaining three experts "do not have the relevant experience with IIH." Id. Defendants contend that "[n]one of them have ever treated patients with IIH and, with the exception of Dr. Fraunfelder, none of them have ever diagnosed IIH." Id. Defendants further allege Plaintiff's experts are not qualified to provide expert testimony because they "have no training in epidemiology, the medical field that specializes in

assessing causal relationships." Id. at p. 20.

Conversely, Plaintiff contends her experts are treaters, teachers, and research scientists, and are qualified to provide their opinions about the alleged dangers of a prescribed product based on their education, training, and experience. Plaintiff contends each of the "experts are immensely qualified" to give general causation opinions. (Doc. #85, p. 15). Plaintiff states all four "experts have the education and training that qualify them to offer the jury assistance." Id. at p. 16. Plaintiff rejects Defendants' contention that the experts are not qualified to offer causation opinions "because they are not trained as epidemiologists," and explains case law does not require causation opinion solely from an epidemiologist. Id. at p. 17. Likewise, Plaintiff rejects the argument that Plaintiff's experts are not qualified to offer labeling opinions simply because they do not have regulatory experience.

Plaintiff cites to U. S. v. Shedlock, to support her contention that "[e]xpert testimony is presumed to be helpful unless it concerns matters within the everyday knowledge and experience of a lay juror." (Doc. #85, p. 16) (citing 62 F.3d 214, 219 (8th Cir. 1995) ("Expert testimony is helpful to a jury if it concerns matters beyond the knowledge of average individuals …")). In further support of Plaintiff's position, Plaintiff directs the Court to Travelers Property Cas. Co. of Am. V. Nat'l Union Ins. Co. of Pittsburgh, PA, which states that "the fit between an expert's specialized knowledge and experience and the issues before the court need not be exact, …," for the Court to determine "an expert's opinion is helpful to the trier of fact, and therefore relevant under Rule 702[.]" 557 F. Supp. 2d 1040, 1051 (W.D. Mo. 2008) (internal citation omitted).

In In re Mirena IUD Prod. Liab. Litig., previously cited by Defendants in defense of one of their own experts in this action and referenced by Plaintiff in her response to the instant motion, the court found that the clinical experts designated to offer epidemiological opinions

were not disqualified from providing expert testimony solely because they were not epidemiologists. 169 F. Supp. 3d 396, 426 (S.D.N.Y. Mar. 8, 2016). The court explained, "This level of expertise, [] is not required under Daubert … Moreover, medical doctors do not need to be epidemiologists in order to testify regarding epidemiological studies." Id. Accordingly, although the experts are not epidemiologists and the specialized knowledge and experience are not an exact match, the Court finds Dr. Rosa Tang, Dr. Frederick Fraunfelder, Dr. David Ross, and Dr. John Maggio have sufficient knowledge and experience to qualify them to be of assistance to a jury and offer general causation opinions.

In regard to labeling opinions, both parties reference Wehling v. Sandoz Pharms. Corp., which held that a retired pharmacist and toxicologist did not possess the relevant experience to present expert testimony in a pharmaceutical action because the expert was "neither a pharmacologist nor a medical doctor." No. 97-2212, 1998 WL 546097, at *4 (4th Cir. Aug. 20, 1998). As argued by Plaintiff, the Court agrees that the language of Wehling provides that the expert would presumably have been qualified had he been either a pharmacologist or a medical doctor, but the language does not indicate that the expert had to be both. Here, Dr. Maggio is a pharmacologist, and Dr. Ross, Dr. Faunfelder, and Dr. Tang are practicing physicians. Therefore, based on the evidence presented, the Court concludes Plaintiff's experts are sufficiently qualified to provide their opinions at trial.

B. Reliability of Methodology

Defendants further argue none of Plaintiff's experts utilize a reliable methodology to reach their general causation opinions. In regard to labeling opinions, Defendants claim the experts' opinions "are unsupported by any reliable methodology and are offered by persons unqualified to give them." (Doc. #66, p. 42). Defendants contend "these labeling opinions

collapse on the unreliability of the experts' underlying causation opinions and should likewise be excluded." Id.

In response, Plaintiff asserts Defendants' "contention that Plaintiff's experts cannot prove causation because 'by definition idiopathic intracranial hypertension has no known cause' is unfounded," and recognizes that each of Defendants' experts rely on and have contributed to peer-reviewed literature establishing levonorgestrel among secondary causes, or medication-induced variations of PTC/IH. (Doc. #85, p. 19). Plaintiff argues each of her experts reliably applied the evidence in this case and "fairly accounted for and considered weaknesses in that evidence." Id. at p. 31.

An expert should be disqualified "if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury[.]" Lawrey, 751 F.3d at 952-53. Yet "[a]s a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination." Loudermill v. Dow Chem. Co., 863 F.2d 566, 570 (8th Cir. 1988).

Based on a review of each experts' report and the parties' arguments, the Court finds the opinions of Plaintiff's experts are not so "fundamentally unsupported" that they must be excluded. Neb. Plastics, Inc., 408 F.3d at 416. All four experts rely on numerous scientific publications and references to support their opinions and provide a thorough analysis leading to their conclusions. Although Defendants contend the Etminan Article has been retracted by Dr. Etminan, the Court notes Plaintiff's experts rely on other pieces of scientific evidence, and the opinions of the experts do not rely solely on Dr. Etminan's study. As explained by Plaintiff, "Dr. Tang did not rely on Dr. Etminan at all. Dr. Maggio cited Etminan twice in his 55-page, multi-citation report – and it has no bearing on whether it is biologically possible that Mirena can cause

PTC/IH. Dr. Ross spends one of his 85-pages on the Etminan study. And Dr. Fraunfelder spends one paragraph of his 12-page report on the subject." (Doc. #115, pp. 2-3).

Although the experts' opinions are contrary to that of Defendants, that does not make these opinions inadmissible. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking" Plaintiff's experts' opinions and the methodology used to arrive at their conclusion. Daubert, 509 U.S. at 596 (citing Rock v. Arkansas, 483 U.S. 44, 61 (1987)).

IV. Conclusion

The Court finds the testimony of Dr. Rosa Tang, Dr. Frederick Fraunfelder, Dr. David Ross, and Dr. John Maggio is properly supported under Daubert, and their testimony "should be tested by the adversary process with competing expert testimony and cross-examination, rather than excluded by the court at the outset." See Johnson, 754 F.3d at 562. Therefore, the proposed testimony of Plaintiff's four experts is admissible.

Accordingly, it is hereby

ORDERED that Defendants' Omnibus Motion to Exclude the General Causation and Labeling Opinions of Plaintiff's Experts (Doc. #65) is **DENIED**.

IT IS SO ORDERED.

/s/ Stephen R. Bough
STEPHEN R. BOUGH, JUDGE
UNITED STATES DISTRICT COURT

Date: December 20, 2016