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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

Catherine Johnson, Plaintiff, vs. Wyeth LLC; Pfizer Inc., individually and as successor in interest to Pharmacia & Upjohn Co.; Wyeth Pharmaceuticals, Defendants.	CV 10-02690-PHX-FJM **ORDER**

The court has before it defendants' motion to exclude opinions of plaintiff's experts Drs. Parisian, Blume, and Austin (doc. 79), plaintiff's response (doc. 99), and defendants' reply (doc. 109). This action arises from plaintiff's ingestion of hormone replacement drugs Premarin and Provera between 1982 and 1998, which she alleges caused her to develop breast cancer.[1]

I

To be admissible, expert testimony must "help the trier of fact to understand the evidence or to determine a fact in issue," must be "based on sufficient facts or data," must be "the product of reliable principles and methods," and must be "reliably applied. . . to the facts

[1] This action was formerly part of a multidistrict litigation ("MDL") in the Eastern District of Arkansas. Plaintiff initiated an individual action here pursuant to the MDL judge's order.

of the case." Fed. R. Evid. 702. The testimony must go beyond "subjective belief or unsupported speculation" to be reliable. See Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 590, 113 S. Ct. 2786, 2795 (1993).

II

Defendants move to exclude Dr. Austin's failure to test opinions. Plaintiff stipulates that Dr. Austin's testimony will be limited to a discussion of evidence concerning the link between certain hormone replacement therapy ("HRT") drugs and cancer and the kinds of studies that can be performed on drugs, their risks, and the information that the studies can reveal. Defendants concede that their motion is moot with respect to Dr. Austin.

III

Next, defendants move to exclude Dr. Parisian and Dr. Blume's opinions that defendants failed to act as a reasonable pharmaceutical company by failing to perform additional tests on their HRT drugs. They argue that there are no objective standards that required defendants to perform additional testing. Without an objective standard to which to point, defendants contend that Dr. Parisian and Dr. Blume merely offer personal opinions that defendants acted unreasonably.

Dr. Parisian's 2007 report opines that defendants breached the standard of a "responsible United States pharmaceutical manufacturer" by not voluntarily conducting studies to investigate the risks of breast cancer and update their product warnings. Mot., ex. 20 at 16. Similarly, Dr. Blume's report states that a "reasonable pharmaceutical company would have conducted a definitive study examining the breast cancer risk associated with hormone replacement and provided these results in the product labeling." Id., ex. 21 at 29. Plaintiff was unable to point to anywhere in Dr. Blume's report or anywhere in Dr. Parisian's multiple reports that identify any FDA regulations or rules requiring defendants to test their HRT drugs after they were released on the market. By contrast, Dr. Parisian acknowledges that the "FDA was not given authority to require a company to perform safety studies for an already marketed drug." Id., ex. 20 at 9.

Alternatively, plaintiff argues that the opinions are based on experience. While expert

opinions can be based on personal experience, plaintiff has not pointed to any experience cited in the reports that the experts relied on in concluding that there is an objective standard of care for post-market testing. Indeed, both experts admitted that there is no set standard of care, because each company makes a subjective judgment as to the appropriate level of testing for its products. See Mot., ex. 15, Parisian Dep. 571:15-572:8, July 20, 2007; id., ex. 16, Blume Dep. 225:9-11, Apr. 7, 2006. Next, plaintiff argues that Drs. Parisian and Blume relied on defendants' admissions that they have a responsibility to make sure drugs are safe and appropriately tested. What plaintiff has not pointed to, however, is Dr. Blume or Dr. Parisian's identification of any internal company standard that required defendants to test their HRT products after market release.

Plaintiff also contends that she has uncovered new evidence in the form of three FDA guidances issued in 1995, 2001, and 2005 that "clearly establish how FDA expects manufacturers to react to safety signals." Response at 12. Plaintiff alleges that she stopped taking Premarin and Provera in 1998, so guidances released in 2001 and 2005 are inapplicable to the facts of this case. Even if they were issued while plaintiff was still taking HRT drugs, neither guidance demands that manufacturers must conduct further testing. The 2001 FDA guidance outlines the kind of adverse events that drug manufacturers must report to the FDA, but it does not require further testing of drugs already on the market. Id., ex. 55. The 2005 guidance provides suggestions for good practices, including investigation of safety signals through studies. Every page of the guidance, however, is marked "Contains Nonbinding Recommendations." Id., ex. 56. It is unclear whether either Dr. Parisian or Dr. Blume relied on the 1995 guidance. In any case, the guidance is similarly unhelpful. It details recommendations for conducting studies when developing combination HRT drugs. It does not, however, require manufacturers to perform additional tests on drugs already on the market. Id., ex. 54. Accordingly, Dr. Parisian and Dr. Blume cannot reliably base their opinions that defendants should have conducted additional tests on Premarin and Provera on either the 1995, 2001, or 2005 FDA guidances.

Plaintiff's next argument, that FDA regulations "establish a duty to study, if not an

absolute statutory requirement for study," response at 12, is unpersuasive. To support this point, plaintiff points to Dr. Parisian's observation that FDA regulations require drug companies to alter label warnings once an association between a drug and cancer is revealed, and that a company must study its products before applying for a labeling change. These concepts do not, without a further link, establish a basis for Dr. Parisian's opinion that defendants were required to perform further testing in this case. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146, 118 S. Ct. 512, 519 (1997) (Daubert does not require courts to admit opinion testimony if there is "too great an analytical gap between the data and the opinion proffered"). Finally, plaintiffs contend that the PhRMA Code of Pharmaceutical Marketing Practices constitutes a written industry standard. Although this code addresses ethical interactions between pharmaceutical manufacturers and healthcare professionals, it does not establish industry standards for post-market drug testing.[2]

An expert witness cannot opine that defendants breached a standard of care unless that standard exists. Because plaintiff cannot point to any objective standard relied on by Dr. Parisian or Dr. Blume that required defendants to perform additional testing, plaintiff has not shown that the failure to test opinions are anything more than "subjective belief or unsupported speculation." Daubert, 509 U.S. at 590, 113 S. Ct. at 2795. Consequently, they are unreliable and inadmissible. We join several courts - including the MDL court - that have excluded Dr. Parisian and Dr. Blume's failure to test opinions in HRT litigation. See, e.g., Hines v. Wyeth, 2:04-0690, 2011 WL 2680842, at *6 (S.D. W.Va. July 8, 2011) (excluding Dr. Parisian's failure to test opinion); Rivera Adams v. Wyeth, 03-1713 (JAF), 2010 WL 5072061, at *3 (D.P.R. Dec. 3, 2010) (excluding Drs. Parisian and Austin's failure to test opinions); In re Prempro Prods. Liab. Litig., 4:03CV01507-WRW, 4:05CV00718-WRW, 2010 WL 5663003, at *3 (E.D. Ark. Sept. 16, 2010) (excluding Drs. Parisian, Blume, and Austin's failure to test opinions).

[2] For example, the code discusses appropriate items that manufacturers can give to healthcare professionals. Reply, ex. 4.

IV

Defendants argue that we should exclude Dr. Parisian and Dr. Blume's testimony entirely. They complain that, based on experiences in other HRT trials, "their testimony amounts to little more than reading portions of documents and offering personal commentary untethered to any objective standard." Mot. at 8. Plaintiff responds that these experts will offer testimony in other areas, including FDA regulation, types of available studies, drug labeling standards and whether defendants' drug labels were accurate, and the scope of the FDA's authority. Defendants acknowledge that this type of testimony "ordinarily would not be objectionable, if that were in fact what these witnesses did." Reply at 9.

We are unwilling to exclude helpful expert testimony in its entirety based on conjecture about what might happen at trial. The FDA drug approval process, FDA regulations, and protocols of drug labeling are topics that are likely unfamiliar to a layperson, and expert testimony on these topics will be helpful to the jury's understanding of the complex issues in this case. To be clear, this court will not permit either Dr. Parisian or Dr. Blume to merely recite or summarize documents. See In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (limiting Dr. Parisian's commentary on documents and exhibits to "explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge."). They must provide some analysis, opinion, or expertise when testifying about the FDA regulatory process and drug labeling. Objections to narrative testimony, however, are best made at trial.

Finally, defendants object to portions of Dr. Parisian and Dr. Blume's expert reports that offer opinions on defendants' corporate intent, motive, and knowledge. Both expert reports frequently and improperly opine about Wyeth's intent. See, e.g., Mot., ex. 20 at 28 ("[t]he intent of Wyeth's paper was. . ."); id., ex. 21 at 23 ("[i]nternal Wyeth documents demonstrate that the company did not intend. . ."). Dr. Parisian and Dr. Blume may not offer opinions concerning defendants' motive, intent, knowledge, or other state of mind.

V

IT IS ORDERED GRANTING IN PART defendants' motion to exclude opinions of plaintiff's experts Drs. Parisian, Blume, and Austin (doc. 79). Defendants' motion to exclude Dr. Austin's testimony is **DENIED** on grounds of mootness. Defendants' motion to exclude Dr. Parisian and Dr. Blume's failure to test opinions is **GRANTED**. Defendants' motion to exclude all of Dr. Parisian and Dr. Blume's testimony is **DENIED**. Our ruling is without prejudice to defendants making appropriate objections at trial.

DATED this 11th day of April, 2012.

Frederick J. Martone

Frederick J. Martone
United States District Judge