IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

SALLY KAMMERER and KARL KAMMERER, Plaintiffs, v. WYETH, and WYETH PHARMACEUTICALS, Defendants.	)	8:04CV196 MEMORANDUM AND ORDER

This matter is before the court on the following motions: defendants' motion to exclude the testimony of Dr. Suzanne Parisian, Dr. Cheryl Blume and Dr. Donald Austin, Filing No. 53; defendants' motion to exclude the testimony of Michael T. Maloney, Ph.D., and Raymond S. Hartman, Ph.D., Filing No. 57; defendants' motion to exclude the testimony of Matthew Hollon, Dr. Adriane Fugh-Berman, and Dr. Warren Keegan, Filing No. 63; defendants' motion to exclude any general and specific causation opinion that hormone therapy causes estrogen-receptor-positive/progesterone-receptor-negative (ER+/PR-) breast cancer (hereinafter, "causation *Daubert* motion)," Filing No. 68; defendants' motion to exclude expert testimony that estrogen + progestin hormone therapy causes estrogen receptor positive / HER2-Positive[1] (ER+/HER2+) breast cancer or caused Ms. Kammerer's ER+/HER2+ breast cancer (hereinafter, "HER2 *Daubert* motion"), Filing

[1]HER2 stands for the Human Epidermal Growth Factor Receptor 2 ("HER2") which is a receptor found on the surface of normal breast cells. Filing No. 73, Defendants' Brief at 10. The normal HER2 gene is considered a "proto-oncogene," a gene found in healthy cells but which, when mutated, is known to cause cancer. *Id.* at 13. Once a proto-oncogene has mutated, it is then referred to as an "oncogene." *Id.* at 14-15. Wyeth argues that scientific evidence establishes that if a tumor tests positive for HER2 overexpression, the tumor can grow in the absence of estrogen. *Id.* at 44. Ms. Kammerer's tumor has tested positive for HER2 overexpression. *Id.* at 27.

No. 72; plaintiffs' motion to exclude to the testimony of Dr. Thomas Stovall, Filing No. 74; plaintiffs' motion for leave to supplement responses in opposition to Wyeth's *Daubert* motions relating to alleged HER2 and PR- [progesterone receptor negative] status of plaintiff's breast cancer, Filing No. 149; and defendants' motion to strike plaintiffs' supplemental materials relating to HER2 status of plaintiff's breast cancer, or, in the alternative, to supplement the record.

The court notes at the outset that it appears the parties have multiple expert witnesses retained to testify concerning single elements of negligence, causation and damages. The parties are on notice that the court will not allow cumulative expert testimony at trial. Unless an expert brings special expertise to an issue, a party will not be allowed to provide more than one expert for each such issue. The court will contact the parties to schedule a hearing to discuss trial logistical and legal issues.

I. LAW

Rule 702 permits a witness to testify in the form of an opinion when that expert possesses scientific, technical, or other specialized knowledge that will assist the trier of fact. Fed. R. Evid. 702. The central inquiry under Rule 702 is whether the proffered expert's testimony is sufficiently reliable. *First Nat'l Bank v. Benham*, 423 F.3d 855, 861 (8th Cir. 2005). The burden of establishing reliability rests on the proponent of the expert testimony. *Barrett v. Rhodia*, 606 F.3d 975,980 (8th Cir. 2010) (quoting *Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757 (8th Cir. 2006)). The testimony must be based on scientific, technical, or other specialized knowledge. *United States v. Cawthorn*, 429 F.3d 793, 799 (8th Cir. 2005). "Knowledge" requires more than a subjective belief or an

unsupported speculation; it requires an appropriate level of validation. *Id.* at 799-800 (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 590 (1993)).

Rule 702 sets out three general standards for determining the reliability and relevance of proffered expert testimony. First, the proffered testimony must be based on sufficient facts or data. Fed. R. Evid. 702(1). Second, it must be the product of reliable principles and methods. Fed. R. Evid. 702(2). Third, the expert must have applied those principles and methods reliably to the facts of the case. Fed. R. Evid. 702(3). Rule 702 reflects a "relax[ation of] the traditional barriers to opinion testimony," and the court's inquiry is intended to be flexible. *In re Prempro Prods. Liab. Litig. (Scroggin),* 586 F.3d 547, 565 (8th Cir. 2009); *see Daubert,* 509 U.S. 579, 588, 594 (1993). The district court must assess whether the methodology used by the proposed expert is valid and whether it was properly applied. *In re Prempro (Scroggin)*, 586 F.3d at 565. In *Daubert,* the Supreme Court listed four factors for consideration: (1) whether the theory or technique applied can be tested, (2) whether the theory or technique has been subject to peer review or publication, (3) the known or potential rate of error, and (4) general acceptance. *Daubert*, 509 U.S. at 593-95; *In re Prempro (Scroggin)*, 586 F.3d at 565 n.11 (noting that those factors do not constitute a definitive checklist or test).

District courts apply a number of nonexclusive factors in performing this role, including "whether the expertise was developed for litigation or naturally flowed from the expert's research;" whether the expert ruled out other alternative explanations; and whether the expert sufficiently connected the proposed testimony with the facts of the case. *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686-87 (8th Cir. 2001). "There is no single requirement for admissibility as long as the proffer indicates that the expert evidence is

reliable and relevant." *In re Prempro (Scroggin)*, 586 F.3d at 565 (quoting *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005)). "[N]othing in Rule 702, *Daubert*, or its progeny requires 'that an expert resolve an ultimate issue of fact to a scientific absolute in order to be admissible.'" *Kudabeck v. Kroger Co.*, 338 F.3d 856, 861(8th Cir. 2003) (quoting *Bonner v. ISP Tech., Inc.*, 259 F.3d 924, 929 (8th Cir. 2001)). Importantly, any doubts regarding the usefulness of an expert's testimony are to be resolved in favor of admissibility. *Marmo* v. *Tyson Fresh Meats, Inc.*, 457 F.3d 748, 757-58 (8th Cir. 2006). When the analytical gap between the data and proffered opinion is too great, the opinion must be excluded. *Id.*

II. DISCUSSION

A. Motions to Supplement and to Strike

As a threshold matter, the court will address the parties' pending motions to supplement the record and to strike. Plaintiffs filed two motions to supplement their response to Wyeth's HER2 *Daubert* motion with a district court opinion and an expert report from another hormone therapy products liability case, *Kaufman v. Pfizer Pharms., Inc.*, No. 1:02-CV-22692 (S. D. Fla. July 26, 2011) (*Kaufman* case). See Filing No. 149 & Filing No. 177, Motions; Filing No. 150, Index of Evid., Ex. 1, Order; Ex. 2, Expert Report of Elizabeth Naftalis, M.D., in the *Kaufman* case. One of the plaintiffs' motions was granted by text order, prompting the defendant to move to strike that evidence, characterizing it as the "new, 24-page expert report by Dr. Elizabeth Naftalis regarding the HER2 breast cancer of a separate plaintiff from an entirely different case." *See* Filing No. 177, Motion to Further Supplement; Filing No. 179, Order; Filing No. 181, Motion to Strike. The plaintiffs concede that the district court opinion in *Kaufman* is not controlling, and

contend only that it is "instructive" in connection with the court's consideration of the pending HER2 *Daubert* motion. Filing No. 149, Motion at 2. In opposition to the plaintiffs' motion to supplement, Wyeth submits a later order from the *Kaufman* case, reconsidering the earlier order and ordering Dr. Naftalis to submit another expert report. Filing No. 164, Ex. 2, *Kaufman* case, Order dated Aug. 18, 2011. That expert report is the subject of the plaintiffs' motion to further supplement the record. Filing No. 177, Index of Evid., Ex. 2. Wyeth contends that Dr. Naftalis's report in the *Kaufman* case contains "brand new opinions about the role of the HER2 oncogene and brand new epidemiology that she had never disclosed before and, to this day, has never been questioned about in a deposition," argues that Dr. Naftalis should not be permitted to offer these "new, detailed opinions about the role of HER2," and requests that Dr. Naftalis's *Kaufman* report be stricken from the record and the plaintiffs "should not be allowed to rely on the opinions set forth in that report in the *Daubert* proceedings in this case or at trial." *See* Filing No. 182, Defendants' Brief at 4.

Wyeth has also submitted evidence in opposition to the plaintiffs' motions, to support its contention that Dr. Naftalis has changed the methodology that had been approved by the Eighth Circuit Court of Appeals in *In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 565 (8th Cir. 2009). *See* Filing No. 161, Defendants' Brief at 4. Wyeth argues that the additional evidence shows that Dr. Naftalis's opinions on causation with respect to HER2 cancers are unsupported and should be excluded under *Daubert*. *Id.*

The record in this case shows that on January 7, 2011, Dr. Elizabeth Z. Naftalis, M.D., submitted a 39-page expert report specific to this case. After one of the defendants' experts testified concerning HER2 cancers, she supplemented her earlier report with a

report, stating that the HER2 status of plaintiff Sally Kammerer's cancer would not change the opinions she expressed in her earlier report. The supplemental report was filed after Dr. Naftalis had been deposed in this case on March 30, 2011, and after Wyeth's experts prepared and submitted their reports, but before the depositions of some of the defendants' experts. Wyeth did not move to strike Dr. Naftalis's supplemental report and the evidence it seeks to proffer in its alternative motion to supplement addresses the HER2 causation issue. Wyeth's *Daubert* motion is directed at both Dr. Naftalis's original and supplementary reports.

Dr. Naftalis's *Kaufman* report was submitted to the court as additional support for the plaintiffs' argument in opposition to Wyeth's *Daubert* motion, and not as substantive evidence in this case. The evidence is nothing more than additional authority for a legal argument. The court is capable of disregarding irrelevant evidence, and will afford the purported "supplemental evidence" the weight it deserves, as this court is not bound by the decision of another federal district court. Defendants' attempts to refute the information in the *Kaufman* report with an evidence criticizing Dr. Naftalis's credentials and opinions present a classic battle of the experts, and goes to the weight, not the admissibility of the evidence.

The court finds the plaintiffs' motion to supplement the record should be granted and the defendants' motion to strike should be denied, but the court will similarly grant the defendants' alternative motion to supplement the record with the evidence submitted in Filing No. 186. The court has considered that evidence in determination of the parties' *Daubert* motions.

B. Defendants' Motion to exclude testimony of Dr. Suzanne Parisian, Dr. Cheryl Blume, and Dr. Donald Austin

Plaintiffs have designated three experts—Drs. Suzanne Parisian, Dr. Cheryl Blume, and Dr. Donald Austin—to testify with respect to regulatory matters.[2] Essentially, these witnesses will testify regarding about pharmaceutical companies' approval processes and testing practices. Wyeth contends that witnesses' proposed expert testimony is not expert in nature because plaintiffs cannot point to the existence of a reasonable standard of care or a custom and practice established by either industry or governmental standards regarding a duty to test pharmaceuticals.

Dr. Parisian is regulatory expert with a pathology background. She is a medical doctor and former Medical Officer at the Food and Drug Administration ("FDA"). Dr. Cheryl Blume was a longtime executive of a pharmaceutical company and she has a Ph.D. in pharmacology and toxicology. The plaintiffs have shown that these experts are qualified, based on their training and experience, to testify with respect to the regulatory approval process and post-marketing surveillance obligations. The court finds the defendants' *Daubert* motion should be denied. These witnesses have specialized knowledge with respect to regulatory procedures, labeling, industry standards, government regulations, statutes, internal policies, FDA standards, industry recommendations, customs or practice, administrative rules, and other factors that can assist the trier of fact in determining the reasonableness of a corporation's conduct. The court will allow such testimony only to the extent it is relevant. The court finds Wyeth's challenge to these experts' testimony is more

[2]Plaintiffs concede that Wyeth's motion is moot as to Dr. Donald Austin, plaintiffs' generic causation expert, because plaintiffs do not "intend to elicit any testimony from Dr. Austin about whether or not Wyeth acted 'reasonably.'" They will not elicit any testimony regarding what a "reasonable company" would have or should have done with respect to testing from that witness. Filing No. 108, Plaintiffs' Brief at 1.

properly a challenge to the weight and not the admissibility of the evidence. Accordingly, the court finds the *Daubert* motion should be denied.

C. Defendants' Motion to Strike testimony of Dr. Michael T. Maloney, Ph.D., and Raymond S. Hartman, Ph.D.

Dr. Michael T. Maloney, Ph.D., and Raymond S. Hartman, Ph.D., have been designated to testify with respect to punitive damages. Dr. Maloney is an economist and valuation expert. Dr. Hartman is also an economist, and he has conducted a forensic analysis to quantify and qualify the importance of the hormone therapy business to the Wyeth. Plaintiffs have shown these witnesses are qualified to testify to issues that may be relevant to the issue of punitive damages.

Defendants seek exclusion of the experts' testimony as irrelevant because punitive damages are not recoverable under Nebraska law. The court's grant of the defendants' motion for summary judgment on the punitive damages issue is dispositive of this aspect of the motion. Accordingly the experts' testimony is irrelevant and the court will grant the defendants' motion.

D. Defendants' Motion to Exclude the Testimony of Dr. Matthew Hollon, Dr. Adriane Fugh-Berman and Dr. Warren Keegan

Dr. Matthew Hollon, Dr. Adriane Fugh-Berman and Dr. Warren Keegan have been designated to testify about Wyeth's marketing practices for hormone therapy ("HT") medications.[3] They plan to testify that Wyeth failed to meet the reasonable standard for drug promotion. Wyeth argues that the proposed testimony of these witnesses lacks the requisite nexus to this case, absent evidence that Ms. Kammerer's doctors, Dr.

[3]Wyeth challenges only the marketing opinions in Dr. Hollon's testimony.

Anderson-Fowler and Dr. Spencer, relied on Wyeth's marketing materials. Wyeth also argues that the testimony of these witnesses is inadmissible under *Daubert* because it "improperly attempts to instruct the jury on the wrong legal standard by which to judge Wyeth's conduct and because their failure to investigate the factual basis of their opinions renders their testimony unreliable."

The plaintiffs have shown that the experts' opinions are based on the experts' extensive backgrounds, training, education, and experiences, as well as their own published, peer-reviewed articles and review of Wyeth internal documents, depositions, relevant scientific and medical literature on the effects of pharmaceutical promotion, and Wyeth sales-call notes. These witnesses clearly have knowledge of pharmaceutical marketing that is beyond a juror's common understanding. Wyeth has not demonstrated that Sally Kammerer or her physicians did not rely on Wyeth's promotional materials. There is evidence that the prescribing physicians relied on many sources in making the decision to prescribe, that Wyeth sales representative talked to the doctors, provided information to them, and may have sponsored continuing medical education seminars for them. Wyeth has not shown that the marketing-practices evidence is not relevant to issues presented in this case.

The court finds Wyeth's objections go to the weight, and not the admissibility, of the evidence and the experts' testimony is properly the subject of cross-examination, rather than exclusion. Accordingly, the court finds the motion should be denied, subject to proper foundation and a showing of relevance at trial. The court will limit the experts' testimony to matters that would be helpful to the jury and are within the expert's area of expertise.

E. Defendants' HER2 *Daubert* motion

This motion is directed at the plaintiffs' causation witness, Dr. Elizabeth Naftalis, M.D. The rejection of a *Daubert* challenge to Dr. Naftalis's testimony by the Eighth Circuit is dispositve of the defendants' motion. The Eighth Circuit specifically approved Dr. Naftalis's methodology. *Id.* at 566. The court finds that Dr. Naftalis's qualifications, opinions and bases for her opinions are sufficient under Fed. R. Evid. 702 and 703. The parties have had sufficient notice with respect to the experts' opinions in connection with HER2 issues and any purported weaknesses can be exposed in cross-examination and presentation of contrary evidence. Accordingly, the court finds the defendants' motion to exclude expert testimony that estrogen and progestin therapy causes estrogen receptive/HER2 positive breast cancer should be denied, provided she testifies within the parameters of her original and supplemental expert reports.

F. Defendants' Causation *Daubert* Motion

Wyeth moves to exclude any opinion that Prempro hormone therapy causes Estrogen-Receptor-Positive/Progesterone-Receptor-Negative (ER+/PR-) breast cancer and to exclude any specific causation opinion that caused plaintiff Sally Kammerer's ER+/PR- breast cancer, due to its scientific unreliability. In opposition to the motion, plaintiffs contend that this motion is moot because Ms. Kammerer's breast cancer is positive for both estrogen and progesterone receptors (ER+/PR+), as opposed to a different subtype of breast cancer that is ER+/PR–. Alternatively, they claim that if Wyeth maintains that Ms. Kammerer's breast cancer is ER+/PR–, then they will present expert testimony that Prempro causes both ER+/PR+ and ER+/PR– breast cancers alike. In response, the defendants argue that plaintiffs have not disclosed any expert on that issue, although they

acknowledge that several doctors have given opinions on ER+/PR– breast cancer in the MDL case. They further argue that Dr. Naftalis, who plaintiffs have designated in this case as a specific causation expert regarding ER+/PR+ and ER+/HER2+ breast cancer, also has not been disclosed as an expert to offer an opinion regarding ER+/PR– breast cancer in this case. Wyeth argues that it would be inappropriate for the court to allow Dr. Naftalis to parrot the opinions of other MDL experts on this issue at trial. Both parties have submitted voluminous scientific evidence, consisting of journal articles, deposition testimony, and trial testimony from the MDL litigation, in support of their respective positions.

This dispute presents the classic "battle of experts" that is an issue for resolution by the trier of fact. There appears to be no dispute that Ms. Kammerer's cancer was estrogen receptor positive (ER+). Regardless of the cancer's progesterone-receptor status, the Eighth Circuit Court of Appeals has expressly endorsed expert testimony that hormone therapy can cause hormone-dependent breast cancer. The plaintiffs' expert evidence meets the threshold level of reliability. The defendants can expose any weaknesses in the plaintiffs' expert's opinions or theories through cross-examination.

Wyeth also argues that, because plaintiffs have withdrawn Dr. Colditz as a witness, they have no expert who has offered an opinion on ER+/PR- breast cancer. Wyeth further contends that the plaintiffs should not be allowed to rely on their specific causation expert, Dr. Elizabeth Naftalis, on this issue. Defendants have admitted that the HER2 and PR- theories are not new to the litigation.[4] As detailed above in connection with the motions to

[4]Dr. Colditz was withdrawn following his failure to make himself available for a 7-hour deposition, as ordered by the court. The allegedly "new" HER2 and PR- causation issue was acknowledged by Wyeth to "not be a completely 'new' issue in the HT litigation, it is 'new' coming from Dr. Colditz.," in the materials

strike and supplement, Wyeth has had ample notice of the issues in this litigation. The ER+/PR- theory was first brought up by their own pathology expert. The plaintiffs should be allowed to rebut that testimony. Moreover, as Wyeth argues in opposition to the plaintiffs' *Daubert* motion directed at Dr. Stovall, discussed below, review of relevant scientific literature, and the drawing conclusions based on those studies, together with training, and experience, is a scientifically reliable means of reaching a general causation opinion, as long as the expert reliably interprets the scientific literature. The plaintiffs are entitled to present causation evidence based on similar testimony, subject to establishing proper foundation and relevance. Wyeth's criticism of the probative value of any such testimony on this issue is the subject of cross-examination, not exclusion of the evidence. Accordingly, the court finds the defendants' motion to exclude causation opinions should be denied.

G. Plaintiffs' motion to exclude to the testimony of Dr. Thomas Stovall

Plaintiffs contend that Dr. Stovall has conceded under oath that he: (1) is not an expert in breast cancer; (2) has no methodology underlying his opinions; and (3) rejects the notion that this court or any other court could make a judgment on methodology. They argue that allowing Dr. Stovall to testify runs the risk of misleading the jury. Wyeth argues that Dr. Stovall reviewed the relevant scientific literature and explained the criteria he used in analyzing whether there was sufficient reliable evidence that hormone therapy causes breast cancer.

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submitted in connection with the motion to compel Dr. Colditz's deposition. *See* Filing No. 147, Defendants' Brief at 1.

Again, the *Daubert* objections go more to the weight than to the admissibility of the expert's testimony, subject to a proper showing of foundation and reliability. Plaintiffs have not shown that Dr. Stovall cannot offer testimony that would be helpful to the jury within his field of expertise. The record shows that Dr. Stovall's qualifications meet the threshold under *Daubert*. The sufficiency of the opinions and the weight to be accorded them are matters for the jury to determine. The court will properly limit the expert's testimony to matters that would be helpful to the jury and are within the expert's area of expertise. Accordingly,

IT IS ORDERED:

1. Defendants' motion to exclude the testimony of Drs. Parisian, Blume and Austin, (Filing No. 53) is denied.

2. Defendants' motion to exclude the testimony of Hollon, Fugh-Berman, Keegan (Filing No. 63) is denied.

3. Defendants' motion to exclude any general and specific causation opinion that hormone therapy causes estrogen-receptor-positive/progesterone-receptor-negative (ER+/PR-) breast cancer (Filing No. 68) is denied.

4. Defendants' motion to exclude expert testimony that estrogen + progestin hormone therapy causes estrogen receptor positive / HER2-Positive (ER+/HER2+) breast cancer or caused Ms. Kammerer's ER+/HER2+ breast cancer (Filing No. 72) is denied.

5. Plaintiffs' motion to exclude to the testimony of Dr. Thomas Stovall (Filing No. 74) is denied.

6. Defendants' motion to exclude the testimony of Dr. Maloney and Dr. Hartman (Filing No. 57) is granted.

7. Plaintiffs' motion for leave to supplement responses in opposition to Wyeth's *Daubert* motions relating to alleged HER2 and PR- status of plaintiff's breast cancer (Filing No. 149) is granted.

8. Defendants' motion to strike plaintiffs' supplemental materials relating to HER2 status of plaintiff's breast cancer (Filing No. 181) is granted in part and denied in part as set forth in this order.

DATED this 1st day of November, 2011.

BY THE COURT:

s/ Joseph F. Bataillon
Chief District Judge

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