IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

In re:	:	**MDL Docket No. 4:03CV01507-WRW**
	:	**4:05CV00718-WRW**
PREMPRO PRODUCTS LIABILITY LITIGATION	:	
MARY INGRAM, ET AL.	:	**PLAINTIFFS**
v.	:	
WYETH, INC., et. al.	:	**DEFENDANTS**

ORDER

Pending is Defendants' Motion to Exclude Drs. Parisian, Blume, and Austin regarding Failure to Test (Doc. No. 21). Responses, replies, and supplements have been filed. Oral arguments were heard on June 24, 2010. After careful review of the pleadings and supporting arguments, the Court finds that Defendants' motion should be GRANTED.

I. STANDARD

A. Burden of Proof

The admission of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which reads:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.[1]

When a party proffers an expert witness, deciding whether Rule 702 is satisfied is a preliminary issue governed by Federal Rule of Evidence 104(a).[2] Rule 104(a) requires the proponent of evidence

[1] Fed. R. Evid. 702.

[2] *U.S. v. Martinez*, 3 F.3d 1191, 1196 n.10 (8th Cir. 1993).

to establish its admissibility by a preponderance of the evidence.[3] In determining admissibility, the court is not bound by any of the rules of evidence, except with regard to privilege.[4]

B. Legal Standard for Admissibility

The central inquiry under Rule 702 is whether the proffered expert's testimony is sufficiently reliable.[5] The trial court serves a gate-keeping function, ensuring that any expert testimony is reliable and relevant.[6] It is essential "that the courts administer the Federal Rules of Evidence in order to achieve the 'end[s] that the Rules themselves set forth, not only so that proceedings may be 'justly determined,' but also so 'that the truth may be ascertained.'"[7]

To be admissible, expert testimony must satisfy the two prongs of Rule 702.[8] First, it must be based on scientific, technical, or other specialized knowledge.[9] If the testimony is scientific, it must be grounded in the methods and procedures of science.[10] Likewise, "knowledge" involves more than a subjective belief or an unsupported speculation, requiring instead an appropriate level of validation.[11] Second, the testimony must be relevant, in that it must help the trier of fact either

---

[3]*Bourjaily v. U.S.*, 483 U.S. 171 (1987).

[4]Fed. R. Evid. 104(a).

[5]*First Nat'l Bank v. Benham*, 423 F.3d 855, 861 (8th Cir. 2005).

[6]*Id.*

[7]*General Electric Company v. Joiner*, 522 U.S. 136, 149 (1997) (Breyer, J., concurring) (citing Fed. R. Evid. 102).

[8]*U.S. v. Cawthorn*, 429 F.3d 793, 799 (8th Cir. 2005).

[9]*Id.*

[10]*Id.*

[11]*Id.* at 799-800 (quoting *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 590 (1993)).

understand the evidence or determine a fact at issue.[12] The burden of establishing relevancy and reliability rests on the proponent of the expert testimony.[13]

Courts have used a variety of factors to determine the reliability of proffered expert testimony. The most frequently discussed factors are those derived from the Supreme Court's opinion in *Daubert*, where the Court established that the trial court may consider:

> (1) whether the theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operation; and (4) whether the theory or technique is generally accepted in the scientific community.[14]

Because the inquiry is "flexible and fact-specific, a court should use, adapt, or reject *Daubert* factors" as needed, based on the facts of a particular case.[15]

The most recent amendments to Rule 702 added three general standards for courts to use in determining the reliability and relevance of proffered expert testimony. First, the proffered testimony must be based on sufficient facts or data.[16] Second, it must be the product of reliable principles and methods.[17] Third, the expert must have applied those principles and methods reliably to the facts of the case.[18]

---

[12]*Id.* at 799.

[13]*Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278-78 (5th Cir. 1998).

[14]*Benham*, 423 F.3d at 861 (citing *Daubert*, 509 U.S. at 593-94).

[15]*Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005).

[16]Fed. R. Evid. 702(1).

[17]Fed. R. Evid. 702(2).

[18]Fed. R. Evid. 702(3).

The focus is not on the expert's conclusion, but on the methodology.[19] The proponent of the testimony "need not prove . . . that the expert's testimony is correct, but . . . must prove by a preponderance of the evidence that the testimony is reliable."[20] Determining the validity of an expert's conclusions is the duty of the finder of fact.

II. DISCUSSION

A. Standard of Care and Failure to Test

Plaintiff has failed to meet her burden of showing that Drs. Parisian, Blume, and Austin may be designated as expert witnesses. The witnesses' proposed expert testimony is not expert in nature because Plaintiff is unable to point to the existence of a reasonable standard of care or a custom and practice established by either industry or governmental standards regarding Defendants' duty to test.

At the outset, the Court recognizes that this motion sets forth a very narrow issue: whether Drs. Parisian, Blume, and Austin can be designated as experts to testify about the reasonable standard of care that Defendants should have followed in the continued testing of HRT after it was placed on the market. There is no question that Drs. Parisian, Blume, and Austin have sufficient expertise in their respective fields; however, their expertise does not qualify them to provide a jury with a reasonable standard of care or a custom and practice, for no other reason than one has not been shown to exist. In other words, their testimony could only be a subjective opinion on what they believe Defendants **could have done** rather than what industry or governmental standards **require** them to do.[21]

---

[19] *Moore*, 151 F.3d at 275-76.

[20] *Id* at 276.

[21] See *Zenith Elecs. Corp. v. WH-T Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005) (stating that an expert "who invokes my expertise rather than analytic strategies widely used by specialists is not an expert as Rule 702 defines that term").

For example, before FDA approval of a drug, a manufacturer must establish that there has been "adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling."[22] Defendants' drug was approved by the FDA in 1994. Plaintiff now offers Dr. Parisian to testify that Defendants violated the standard of reasonable care after the FDA approved their drug. Yet, Dr. Parisian concedes that once a drug is approved by the FDA, the FDA does little to police the drug once it is out on the market.[23]

The same would be true for Dr. Blume possibly testifying that the PhRMA Code is an established standard of care relied on by manufacturers in the field and should be admissible. First, Judge Wilson has already excluded the use of the PhRMA Code as it would likely cause confusion, undue prejudice, and delay.[24] Second, Plaintiff has failed to show how it would be admissible as a standard of care under Arkansas law. Without some established industry standard, Dr. Blume would only be able to subjectively testify about what companies **could** do by the way of testing rather than what Defendants were required to do.

At the *Daubert* hearing on June 24, 2010, Plaintiff's counsel had the opportunity to provide a defined standard of reasonable care in industry custom and practice once a drug has been approved by the FDA and placed on the market. Counsel could not do so. Plaintiff's counsel conceded that

---

[22]21 C.F.R. § 314.125(b)(2).

[23] Dr. Parisian testifed in the *Scroggin* trial that:
The FDA is the government body. Their main function is approval, and there is some postmarketing. But the life cycle of the drug actually belongs primarily to the manufacturer. They are the ones that are required to have written procedures in place to do what they call pharmacovigilance, where they are supposed to watch their product. The FDA gets called into issues when there is a major issue that gets identified. But they don't have the time or resources to monitor everyone's drugs." 4:04-cv-01169-WRW, Feb 12, 2007, Trial Tr. at 1235-1236.

[24] *Rush v. Wyeth*, 4:05-cv-00497-WRW, Doc. No. 473 (01/16/07).

there is not a defined standard for what must occur in each circumstance. In fact, he stated, "depending on the circumstance, a drug company might react differently." Plaintiff's counsel admitted the standard could be different in every circumstance – and therein lies the rub – there is no set standard. Drs. Parisian, Blume, and Austin cannot be qualified as experts simply to testify what they believe Defendants could have done versus what they should have done.[25]

In sum, the testimony Plaintiff seeks to elicit from these doctors is too subjective and not expert in nature. "[T]he word knowledge connotes more than a subjective belief or unsupported speculation."[26] "Proposed testimony must be supported by appropriate validation – *i.e.*, good grounds, based on what is known."[27] Because Plaintiff cannot show some independent objective validation, Drs. Parisian, Blume, and Austin should not be permitted to testify as experts; they simply would be providing their own subjective beliefs about what could have been done.

B. Available Tests

Plaintiff claims that even if her witnesses are precluded from testifying that Defendants violated the reasonable standard of care and were negligent in their failure to continue testing their drug, they still should be able to testify about the types of studies available, their costs, and their

[25] See *Joiner*, 522 U.S. at 146 (finding that "[b]ut nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered"). The term "ipse dixit" is a legal term meaning "something asserted but not proved." It is literally translated "he himself said it." Black's Law Dictionary 905 (9th ed. 2009).

[26] *Daubert*, 509 U.S. at 590.

[27] *Id*. at 591.

trustworthiness.[28] Defendants counter that "such testimony would be a backdoor attempt to suggest that Wyeth should have conducted those studies."[29]

At present time, the Court is unwilling to preclude all testimony from these witnesses as Defendants request. Depending on a number of factors unknown at this time, this testimony could become relevant and admissible at trial. The Rules of Evidence will govern the admissibility at trial. Nevertheless, Defendants' point is well taken and Drs. Parisian, Blume, and Austin may not testify as to what tests would have been "appropriate" for Defendants to conduct.

III. CONCLUSION

Based on the findings of fact and conclusions of law above, Defendants' Motion to Exclude the Testimony of Drs. Parisian, Blume, and Austin regarding Failure to Test (Doc. No. 21) is GRANTED.

Pursuant to 28 U.S.C. § 636(b)(1)(A) and Local Rule 72.1, the parties have a right of appeal to District Judge Wilson through filing a motion which is due by 5:00 p.m. on September 22, 2010. The specific requirements for appeal are set out in 28 U.S.C. § 636(b)(1)(A) and Local Rule 72.1. The appeal should relate directly to the findings of the Court in this Order and be limited to five (5) pages.

IT IS SO ORDERED this 16th day of September, 2010.

JOE J. VOLPE
UNITED STATES MAGISTRATE JUDGE

[28] *Laferrara v. Wyeth*, Case No. 4:04-cv-02271 WRW, Doc. No. 48, p. 2.

[29] *Id* at Doc. No. 57, p. 3.