UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

LEAH ROYCE HINES,

Plaintiff,

v. Civil Action No. 2:04-0690

WYETH, d/b/a Wyeth, Inc.;
WYETH PHARMACEUTICALS, INC.;
and PHARMACIA & UPJOHN COMPANY,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is plaintiff's expedited motion, filed July 11, 2011, for clarification or, in the alternative, for reconsideration of the court's memorandum opinion and order granting defendants' motion to preclude the testimony of Dr. Suzanne Parisian.

I. Background

Defendants moved to exclude the testimony of Dr. Parisian and two other proposed expert witnesses on May 27, 2011.[1] Defendants raised two contentions in their supporting memorandum. First, in Part I of their supporting memorandum,

[1] Inasmuch as plaintiff's current motion for clarification or reconsideration concerns only the testimony of Dr. Parisian, the court will not address the proposed testimony of the two other expert witnesses.

Defendants contended that the court should exclude Dr. Parisian from testifying to her opinion that defendants failed to act as reasonable pharmaceutical manufacturers inasmuch as they did not adequately test their pharmaceutical drugs. (Mem. Supp. Defs.' Mot. at 3-12). This "failure-to-test" opinion was unreliable, according to defendants, because Dr. Parisian could not identify an independent, objective standard by which to judge the reasonableness of their conduct. Second, in Part II of their supporting memorandum, defendants contended that the court should exclude the testimony of Dr. Parisian in its entirety, reasoning that the remainder of her testimony was "nothing more than [a] conduit[] to introduce general 'bad company' documents intended to inflame the jury." (Id. at 13).

By memorandum opinion and order entered July 8, 2011, the court granted defendants' motion to exclude Dr. Parisian's testimony. The court found defendants' first contention meritorious, concluding that Dr. Parisian's testimony concerning the reasonableness of defendants' testing procedures lacked adequate explanation or analysis, was not confined to her area of expertise, and would prove unhelpful to the jury. (Mem. Op. & Order at 11-18). The court thus determined that Dr. Parisian's testimony in this regard was inadmissible under Federal Rule of

Evidence 702 and the Supreme Court's ruling in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Notably, however, the court neglected to address the defendants' second contention, that is, whether the remainder of Dr. Parisian's testimony should likewise be excluded. Instead, the court simply granted defendants' motion to exclude the testimony of Dr. Parisian without further explaining as to what areas, if any, she could testify.

Understandably, plaintiff has now moved for an order clarifying the extent of the court's earlier ruling concerning the testimony of Dr. Parisian. Plaintiff does not challenge the court's ruling excluding Dr. Parisian from testifying to the reasonableness of defendants' testing. (See Pl.'s Mot. at 17 ("Plaintiff requests that this Court clarify its Order, permitting Dr. Parisian to provide expert testimony on issues requiring specialized knowledge in this case, but barring her from providing an ultimate opinion as to what a reasonable company would do.")). Rather, plaintiff merely requests that the court resolve the second issue presented by defendants' motion to exclude and specify whether the remainder of Dr. Parisian's testimony is likewise excluded.

Inasmuch as plaintiff is not revisiting the merits of

the court's earlier ruling, but is instead seeking a clarification due to the court's failure to resolve the remainder of defendants' motion to exclude, the court finds it appropriate to grant the clarification sought.

II. Analysis

Having benefitted from extensive briefing and oral argument on this matter, the court is satisfied to conclude that Dr. Parisian's testimony should not be excluded in its entirety. Rather, for the reasons explained below, Dr. Parisian may offer testimony on the following matters identified in plaintiff's motion:

> 1. What is the process to obtain [approval by the Food and Drug Administration ("FDA")] of prescription drugs?
>
> 2. What is an FDA advisory committee and how [does] it work?
>
> 3. What are the "changes being effected" regulation[s] and how [can] a drug company unilaterally change its label to strengthen a safety warning?
>
> 4. What is a "Dear Doctor" letter? When does a drug company have to send one? When may a drug company send one? When does the FDA send one? Is it considered part of the label?
>
> 5. What is a "Black Box" warning?
>
> 6. What is a Phase IV commitment? Could the FDA enforce any commitment it got from Wyeth?
>
> 7. What does it mean for a drug to be grandfathered

> in? What is DESI? Does that mean that no studies on the drug are required?
>
> 8. Did the FDA have the power to order a study on the combination of E and P prior to 1994 when the drugs were not approved for use in combination?
>
> 9. What is acceptable promotion of a drug under FDA rules and practices? What is not appropriate? What is permissible to tell doctors and what not?
>
> 10. What is the purpose of the different mandatory sections of a drug label? How are "warnings" different from "precautions" and "contraindications"?

(Pl.'s Mot. at 9). In addition to these topics, Dr. Parisian may offer commentary on any document or exhibit in evidence, provided that her testimony is limited to explaining the regulatory context in which the document or exhibit was created, defining any complex or specialized terminology therein, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge. For example, Dr. Parisian may testify to the adequacy of defendants' prescription drug labels, so long as her opinion is predicated upon her understanding of the relevant regulatory requirements and not her general opinion regarding how a responsible or ethical drug manufacturer should act. Finally, as explained in the July 8 memorandum opinion and order, Dr. Parisian may not simply construct a factual narrative based upon recorded evidence, nor may she offer testimony concerning the reasonableness of

defendants' testing procedures or the intent, motives, or knowledge of defendants or their employees.

1. Qualifications

The court finds that Dr. Parisian is qualified to offer testimony concerning the general regulatory requirements governing defendants and other pharmaceutical manufacturers. Dr. Parisian served as a Medical Officer at the FDA, and her experience there involved various aspects of the regulation of prescription drugs. (Pl.'s Mot. at 8). Moreover, her expert report demonstrates specialized knowledge of the regulatory standards applicable to drug manufacturers. Inasmuch as defendants do not challenge her qualifications, the court finds that Dr. Parisian is qualified to testify to the regulatory framework governing prescription drug manufacturers and its applicability to defendants.

2. Relevance

The court further finds that Dr. Parisian's testimony in this regard is relevant to this action. Plaintiff's causes of action against defendant are grounded in West Virginia common law and make no reference to the FDA or any governing regulations. Nevertheless, both parties intend to offer evidence of

defendants' compliance or noncompliance with relevant industry or government standards, including regulations promulgated by the FDA, to demonstrate the reasonableness of defendants' conduct and the safety of their prescription drugs. (Proposed Pretrial Order at 9-10). A lay juror, however, can hardly be expected to understand "the complex regulatory framework that informs the standard of care in the pharmaceutical industry." In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 191 (S.D.N.Y. 2009) (finding that Dr. Parisian's testimony concerning "general FDA regulatory requirements and procedures" would aid the jury). Accordingly, the court finds that Dr. Parisian's testimony concerning generally applicable FDA regulations is relevant to and will assist the trier of fact in resolving material issues.

3. Reliability

Finally, the court finds that Dr. Parisian's opinion is grounded upon an appropriate and reliable methodology. An expert witness is permitted to draw conclusions from a set of observations based on extensive and specialized experience. Kumho Tire Co. v. Carmichael, 526 U.S. 137, 156 (1999). Dr. Parisian's testimony concerning the governing regulatory framework is based upon her experience as an FDA Medical Officer. Moreover, her expert report demonstrates that she derived any

opinion concerning defendants' compliance with the relevant regulations in the same manner and applying the same methodology as would a Medical Officer. (See, e.g., Pl.'s Resp. to Defs.' Mot. to Suppress, Ex. 23a, Expert Report of Suzanne Parisian, M.D., at 3 (explaining that Dr. Parisian's duties with the FDA included, among other things, assessing prescription drug labels)). The court finds that plaintiff has satisfied her burden in demonstrating the admissibility of Dr. Parisian's testimony concerning the FDA, the regulations governing prescription drug manufacturers, and defendants' compliance therewith.

III. Conclusion

Pursuant to the foregoing analysis, it is ORDERED that plaintiff's motion be, and it hereby is, granted to the extent that it seeks an order clarifying the court's July 8 memorandum opinion and order, and denied in all other respects. It is further ORDERED that Dr. Parisian be, and she hereby is, permitted to testify as outlined above, subject to the limitations set forth in the July 8 memorandum opinion and order.

The Clerk is directed to forward copies of this written opinion and order to all counsel of record.

DATED: July 13, 2011

John T. Copenhaver, Jr.
United States District Judge