

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

LYNNE CROSS and CHARLES CROSS,

Plaintiffs,

v.

CASE NO.: 8:06-cv-429-T-23AEP

WYETH PHARMACEUTICALS, INC.,
et al.,

Defendants.

ORDER

The plaintiffs move (Doc. 78) to exclude (1) “all expert testimony that combination hormone therapy does not cause breast cancer” and (2) the proposed testimony of Dr. Arnold Blaustein. The defendants respond (Doc. 90) in opposition. Additionally, the defendants move (Docs. 110, 105, 130) (1) to exclude the proposed testimony of Dr. Michael Wertheimer; (2) to exclude the proposed testimony of Drs. Suzanne Parisian, Cheryl Blume, and Donald Austin; and (3) to exclude both “argument and testimony that the defendants failed to test”.¹ The plaintiffs respond (Docs. 172, 147, 154) in opposition.

¹ The defendants request (Docs. 135, 186) oral argument as well as an order compelling the “live testimony” of Dr. Wertheimer at a hearing on the pending motions. However, neither oral argument nor live testimony is necessary given the thorough briefing and ample supporting material in the record.

Discussion

1. Review Under Rule 702 and Daubert²

Rule 702, Federal Rules of Evidence, permits the admission of expert testimony if:

(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the method[] by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

Cook ex rel. Estate of Tessier v. Sheriff of Monroe County, Fla., 402 F.3d 1092, 1107 (11th Cir. 2005) (quoting United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004)); Diocese of St. Petersburg, Inc. v. Safety Nat. Cas. Corp., 2009 WL 2602451 (M.D. Fla. 2009) (McCoun, Mag. J.) (citing McCorvey v. Baxter Healthcare Corp., 298 F.3d 1253, 1257 (11th Cir. 2002)). The proponent of the testimony must “demonstrate that the witness is qualified to testify competently, that his opinions are based on [a] sound method[], and that his testimony will be helpful to the trier of fact.” Tessier, 402 F.3d at 1107. The proponent need not prove that the opinion is correct, but the proponent must prove by a preponderance of the evidence that the testimony is reliable. Allison v. McGhan Med. Corp., 184 F.3d 1999, 1312 (11th Cir. 1999). “Exactly how reliability is evaluated may vary from case to case, but what remains constant is the requirement that the trial judge evaluate the reliability of the testimony before allowing

² 509 U.S. 579 (1993).

its admission at trial.” Frazier, 387 F.3d at 1261.³ Helpful expert testimony “concerns matters . . . beyond the understanding of the average lay person.” Frazier, 387 F.3d at 1262.

2. Plaintiffs’ Motion to Exclude Both Dr. Blaustein’s and Other Expert Testimony About Hormone Therapy’s “Causing” Breast Cancer

In moving to exclude expert testimony that “combination hormone therapy,” i.e. estrogen plus progestin, is not a “cause” of breast cancer, the plaintiffs argue (1) that “[t]here should be no dispute . . . over whether combination hormone therapy causes breast cancer generally”; (2) that “[t]here is no legitimate scientific basis for disputing the causative link”; (3) that Dr. Blaustein’s proposed testimony fails to satisfy Rule 702, Federal Rules of Evidence, and Daubert; (4) that Dr. Blaustein is unqualified because Dr. Blaustein’s opinion derives from his clinical experience and not from research or from a peer-reviewed study; (5) that Dr. Blaustein’s opinion derives from neither scientific research nor empirical data and amounts to “unsubstantiated speculation” and “junk science”. In response, the defendants argue (1) that the plaintiffs’ argument is “properly raised by a motion for partial summary judgment on the issue of general causation”; (2) that the plaintiffs improperly focus on Dr. Blaustein’s conclusion rather than his method; (3) that the “proper procedure for challenging the correctness of an expert’s admissible conclusions is cross-examination”; (4) that the plaintiffs conflate “the concepts of risk and causation”; (5) that “there is no consensus in the medical and scientific community that [hormone therapy] generally causes breast cancer”; and

³ “The district court has broad discretion in determining whether to admit or exclude expert testimony, and its decision will be disturbed on appeal only if it is manifestly erroneous.” Evans v. Mathis Funeral Home, Inc., 996 F.2d 266, 268 (11th Cir. 1993).

(6) that Dr. Blaustein intends to testify that, based on his experience, his review of Lynne Cross's medical records, and his review of medical literature, hormone therapy is a "risk factor" for breast cancer rather than a "cause" of breast cancer.

In this instance, the plaintiffs present both argument and evidence in support of a general "causal connection" between hormone therapy and breast cancer. However, as the defendants correctly argue, the causal connection between hormone therapy and breast cancer, i.e., whether hormone therapy (as the plaintiffs argue) "causes" breast cancer through "promotion" or whether hormone therapy (as the defendants argue) amounts to a "risk factor" for breast cancer, is a matter properly determined by the jury. Thus, the plaintiffs' argument on this point provides no basis for excluding Dr. Blaustein's proposed testimony.

Additionally, in requesting exclusion, the plaintiffs argue that Dr. Blaustein is unqualified because "[s]imply being a medical doctor does not qualify one to pontificate on scientific cause and effect in an area completely unrelated to th[e] doctor's practice". However, as Dr. Blaustein explains in his expert report,⁴ Dr. Blaustein possesses significant expertise in the relevant field of medicine. Dr. Blaustein serves as the co-director of the "second largest oncology clinic in South Florida" and has treated cancer patients (including breast cancer patients) for more than thirty years. Approximately twenty-five percent of Dr. Blaustein's patients (including both new and "follow-up" patients) suffer breast cancer.⁵ Thus, Dr. Blaustein is not simply a medical doctor. Dr.

⁴ (Doc. 90-10)

⁵ (Doc. 90-29)

Blaustein derives his expert knowledge from more than thirty years of experience in treating cancer patients and undoubtedly possesses the qualification necessary to opine (1) that, in his practice and experience, a doctor cannot tell a patient “the cause of her breast cancer” and (2) that no generally accepted scientific method permits a doctor to determine the precise cause of a woman’s breast cancer.

The plaintiffs argue that Dr. Blaustein’s proposed testimony is unreliable because Dr. Blaustein employs no scientific method in reaching his conclusion about Lynne Cross’s breast cancer and because Dr. Blaustein’s proposed testimony depends entirely upon “his unquantifiable and untestable clinical experience” (rather than independent research). In response, the defendants argue that Dr. Blaustein conducted no independent research because Dr. Blaustein presents no “theory” of breast cancer causation. Rather, Dr. Blaustein’s proposed testimony critiques and responds to the plaintiffs’ causation theory. In other words, Dr. Blaustein claims (1) that insufficient and inconsistent data support a causal connection between hormone therapy and breast cancer and (2) that proof that hormone therapy increases the risk of breast cancer is distinct from proof that hormone therapy causes breast cancer. Dr. Blaustein’s method consists of a review of Lynne Cross’s medical records and an application of Dr. Blaustein’s experience in treating cancer patients.

As the defendants argue, Dr. Blaustein’s method is consistent with the method of a cancer specialist treating a cancer patient. The method that Dr. Blaustein employs in formulating his expert opinion satisfies both Rule 702 and Daubert. Dr. Blaustein’s testimony appears helpful based on his expertise and his experience in the treatment of

breast cancer. Thus, contrary to the plaintiffs' assertion that Dr. Blaustein offers "nothing more than mere unsupported assertions," Dr. Blaustein's proposed testimony appears helpful, reliable, and supported by Dr. Blaustein's extensive education and experience in the relevant field of medicine.

*3. The Defendants' Motion to Exclude the Proposed
Testimony of Dr. Wertheimer*

In moving to exclude the proposed testimony of Dr. Wertheimer, the defendants argue (1) that "no doctor can determine the specific causes of an individual woman's breast cancer"; (2) that Dr. Wertheimer concedes "that he never tells his patients what caused their breast cancer"; (3) that Dr. Wertheimer's "differential diagnosis," although an accepted and reliable method of determining the cause of certain diseases, is flawed and unreliable because "no method[] exists that would allow a physician to reliably establish the cause of an individual's breast cancer"; and (4) that Dr. Wertheimer neither published a peer-reviewed article about his causation opinion nor authored any relevant written material on the subject. In response, the plaintiffs argue (1) that "no court has limited or excluded Dr. Wertheimer's testimony"; (2) that Dr. Wertheimer's practice "regularly involves evaluating both the cause of breast cancer and whether [hormone therapy] is responsible for individual cases"; (3) that "differential diagnosis" is "one of the most recognized and accepted scientific methodologies"; (4) that, with "exacting reliability," Dr. Wertheimer applied "differential diagnosis" to Lynne Cross's case; and (5) that Dr. Wertheimer's method "is grounded in sound medicine and is regularly practiced by physicians treating breast cancer patients."

“Differential diagnosis ‘is accomplished by determining the possible causes for the patient’s symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.’” Guinn v. AstraZeneca Pharm. LP, 602 F.3d 1245, 1253 & n.6 (11th Cir. 2010) (per curiam) (quoting Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999)); see In re Prempro Prod. Liab. Litig., 586 F.3d 547, 566-67 (8th Cir. 2009) (Wollman, J.). A reliable differential diagnosis need not eliminate each possible alternative cause, but the differential diagnosis must “at least consider other factors that could have been the sole cause of the plaintiff’s injury.” 602 F.3d at 1253. The expert must sufficiently explain why other conceivable causes are susceptible to exclusion. 602 F.3d at 1253.

As explained previously, the causal connection between hormone therapy and breast cancer is a matter properly determined by the jury. Similar to Dr. Blaustein, Dr. Wertheimer possesses decades of experience in diagnosing and treating breast cancer patients.⁶ Until 2010, Dr. Wertheimer directed the Cambridge Breast Center and served as the associate chief of surgery at Cambridge Hospital. Dr. Wertheimer is the director of the breast center and the chief of breast surgery at Beth Israel Deaconess Medical Center, a Harvard Medical School teaching hospital. Having spent most of his professional career “caring for women with breast cancer and other forms of breast disease,” Dr. Wertheimer undoubtedly qualifies based on his education and experience to testify as an expert on the issues presented in this action.

⁶ (Doc. 173-1)

In conducting and reporting his differential diagnosis, Dr. Wertheimer (1) reviews Lynne Cross's medical records, insurance records, medical bills, and deposition testimony; (2) reviews medical literature, "case-specific" expert reports, and "generic" expert reports; (3) asserts that the differential diagnosis method "has been peer reviewed and published"; (4) considers Lynne Cross's personal history, radiographic and biopsy results, and breast cancer risk factors, e.g., family history, reproductive history, age of menarche, number of children, age at first pregnancy, use of breast feeding, use of birth control, breast density, breast surgery, obesity, alcohol consumption, and post-menopausal hormone therapy; (5) reviews "current and pertinent medical literature regarding [hormone] therapy and its causal relation to breast cancer"; (6) explains that breast cancer with estrogen or progesterone receptors is "hormone[-]dependent," which means that the cancer requires hormones to grow; (7) identifies the possible sources (endogenous and exogenous) of female hormones necessary to develop and grow hormone-dependent cancer; (8) considers evidence of Lynne Cross's level of endogenous estrogen and breast density; (9) identifies "ionizing radiation," excessive alcohol consumption and exogenous ovarian hormones (hormone replacement therapy) as "known causes of breast cancer"; (10) finds that, based on her menopausal symptoms and the effectiveness of hormone replacement therapy, Lynne Cross was a "low hormone producing woman"; and (11) eliminates both radiation and alcohol consumption as causes of Lynne Cross's breast cancer.⁷ Ultimately, Dr. Wertheimer opines that Lynne Cross's use of hormone therapy was "a substantial

⁷ (Doc. 173-1)

contributing factor in her development of hormone-dependent breast cancer” and that “but for” Lynne Cross’s use of hormone therapy, Cross “would not have developed a hormone[-]dependent breast cancer.”

In this instance and in accord with applicable precedent, Dr. Wertheimer’s application of differential diagnosis appears admissible under Rule 702 and Daubert. Dr. Wertheimer’s differential diagnosis depends on his theory (which he describes as generally accepted and which the plaintiffs espouse) that hormone therapy causes breast cancer by promotion of “hormone-dependent” cancer. Dr. Wertheimer identifies other “known causes” of breast cancer and sufficiently eliminates the other “known causes” and as the cause of Lynne Cross’s breast cancer. Dr. Wertheimer comprehensively reviews Lynne Cross’s personal and medical history, including risk factors such as breast density, alcohol consumption, and obesity. Because Dr. Wertheimer determines that Lynne Cross suffered “hormone-dependent” breast cancer and that (before suffering breast cancer) Lynne Cross was a “low hormone producing woman,” Dr. Wertheimer concludes that exogenous hormones became a substantial contributing factor in Lynne Cross’s developing breast cancer. Accordingly, to the extent that the defendants believe that Dr. Wertheimer’s conclusion is incorrect, the defendants may challenge the opinion on cross-examination.

*4. Defendants’ Motion to Exclude the Proposed Testimony
of Drs. Parisian, Blume, and Austin*

The defendants move (Doc. 105) to exclude the proposed testimony of Drs. Parisian, Blume, and Austin, expert witnesses designated by the plaintiffs to testify about “what a ‘reasonable’ pharmaceutical company should have done . . . to test their

hormone therapy [] medications.” The defendants argue that the proposed testimony merits exclusion because (1) no expert can identify an industry custom, practice, or standard; (2) no “FDA testing regulation” governs the defendants conduct or “provides an objective standard for Dr. Blume’s and Dr. Parisian’s testing opinions”; (3) the plaintiffs’ “true motive” in calling each witness is to use the witnesses as “document delivery devices”; (4) other courts excluded the testimony of doctors Parisian and Blume; and (5) the doctors’ “advocacy-based opinions” are unhelpful and unreliable.

In response, the plaintiffs argue (1) that, even though the doctors offer an “ultimate opinion” on an “ultimate issue,” the proposed testimony is admissible to assist the jury in determining an ultimate issue,⁸ (2) that Drs. Parisian and Blume will assist the jury in understanding “the protocols for prescription drug labeling,” the protocol for evaluating “safety signals of a risk problem,” “pharmacovigilance procedure[],” design of human clinical trials, and the procedure for implementing changes to drug labels; (3) that the defendants’ motion is moot as the motion pertains to Dr. Austin, because the plaintiffs intend to call Dr. Austin as a “generic causation expert”; and (4) that Drs. Parisian and Blume are qualified by experience to testify about the applicable industry standard. According to the plaintiffs, Drs. Parisian and Blume (who each possess

⁸ Although a testifying expert may not offer a legal conclusion, Federal Rule of Evidence 704(a) provides, in relevant part, that ‘testimony in the form of an opinion or inference otherwise admissible is not objectionable because it embraces an ultimate issue to be decided by the trier of fact.’ See 13 WEINSTEIN’S FEDERAL EVIDENCE MANUAL § 13.04 (stating, for example, that “an expert’s testimony that a company’s financial filings were ‘reasonable,’ although arguably stating a legal conclusion, was not worded in the statutory language and would have been useful to a jury trying to resolve complex questions under the securities laws.”).

extensive experience in the field of pharmaceutical products and FDA regulation)⁹ rely on their professional experience and on FDA regulations. Additionally, in forming an opinion, each relies on (1) FDA guidance pertaining to hormone therapy products and research, (2) PhRMA Code standards written by members of the pharmaceutical industry and outlining reasonable practices, and (3) Wyeth's "internally recognized safety standards."

Even though Drs. Parisian and Blume opine on an ultimate issue, each doctor's opinion appears admissible. However, the custom and practice of drug testing in the pharmaceutical industry is irrelevant to the determination of whether the defendants adequately warned Lynne Cross and her doctor of the risk of breast cancer. In other words, testimony about the research that a "reasonable" pharmaceutical company would have performed on a hormone therapy product is irrelevant to the adequacy of the warning, i.e., the defectiveness or fitness of the product. Accordingly, the testimony of Drs. Parisian and Blume merits exclusion from the liability phase of this bifurcated action.

Conclusion

Accordingly, the plaintiffs' motion (Doc. 78) to exclude "all expert testimony that combination hormone therapy does not cause breast cancer" and to exclude the proposed testimony of Dr. Arnold Blaustein is **DENIED**. The defendants' motion (Doc. 110) to exclude the proposed testimony of Dr. Michael Wertheimer is **DENIED**. The defendants' motion (Doc. 105) to exclude the testimony of Drs. Suzanne Parisian,

⁹ (Docs. 147-16, 147-17, 147-18)

Cheryl Blume, and Donald Austin is **GRANTED IN PART** and **DENIED IN PART**. The testimony of Drs. Parisian and Blume is excluded from the liability phase of this action. The motion is denied as to the testimony of Donald Austin to the extent that the plaintiffs offer Austin's testimony not as proof a "custom and practice" but as proof of the plaintiff's "general causation" theory. The motion (Doc. 130) to exclude argument and testimony about the "failure to test" is **GRANTED** as to the liability phase of this action. The request (Doc. 135) for oral argument is **DENIED**, and the motion (Doc. 186) to compel the live testimony of Dr. Wertheimer is **DENIED AS MOOT**.

ORDERED in Tampa, Florida, on August 10, 2011.



STEVEN D. MERRYDAY
UNITED STATES DISTRICT JUDGE