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 defendants' motion to exclude the causation testimony of Dr. William Burns (Doc. No 254), filed May 27, 2011.[1]

I. Background

This is a pharmaceutical products liability action in which plaintiff Leah Royce Hines alleges that she developed breast cancer as a result of ingesting hormone replacement therapy ("HRT") drugs manufactured by defendants. HRT here

[1] At a pretrial conference on June 17, 2011, the court conferred with counsel regarding the necessity of an evidentiary hearing on the various Daubert motions currently pending before the court. (See Doc. No. 343). The parties made clear that such a hearing was not necessary. Defendants have, however, requested oral argument on the motions. Inasmuch as the parties' briefs and supporting exhibits adequately present the issues ripe for adjudication, the court finds that oral argument would not aid the decisional process and accordingly denies defendants' request for oral argument as to the present motion.

consists of two medications, estrogen and progestin ("E+P"), that are commonly prescribed in combination to treat menopausal symptoms.

This action concerns three HRT drugs: Premarin, Prempro, and Provera. Defendant Wyeth, LLC ("Wyeth") manufactured Premarin, an estrogen drug, and Prempro, a combination estrogen and progestin drug. Defendant Pharmacia & Upjohn Company ("Upjohn") manufactured and distributed Provera, a progestin drug. The generic name for Provera is medroxyprogesterone acetate ("MPA").

Plaintiff's physician prescribed HRT drugs to treat her menopausal symptoms from approximately July 1994 to April 1999. She was diagnosed with breast cancer in July 1999, and thereafter instituted this action on July 7, 2004, invoking the court's diversity jurisdiction.[2] Her complaint asserts claims against defendants for negligence, strict liability (design defect and failure to warn), and breach of implied warranty.

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[2] The case was transferred to multidistrict litigation in the United States District Court for the Eastern District of Arkansas on October 26, 2004. Over five years later, on April 13, 2010, it was remanded to this court for the completion of discovery, pretrial activity, and trial.

Defendants seek to exclude the causation testimony of one of plaintiff's surgeons, Dr. William Burns.

## II. Governing Standard

The admission of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's decision in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Under Rule 702 and Daubert, expert testimony must satisfy a two-prong test: (1) the testimony must concern "scientific, technical, or other specialized knowledge"; and (2) it must "aid the jury or other trier of fact to understand or resolve a fact at issue." Westberry v. Gislaved Gummi AB, 178 F.3d 257, 260 (4th Cir. 1999) (citing Daubert, 509 U.S. at 592); Fed. R. Evid. 702. "The first prong of this inquiry necessitates an examination of whether the reasoning or methodology underlying the expert's proffered opinion is reliable -- that is, whether it is supported by adequate validation to render it trustworthy." Westberry, 178 F.3d at 260. "The second prong of the inquiry requires an analysis of whether the opinion is relevant to the facts at issue." Id. Thus, an expert's testimony is admissible under Rule 702 if it "rests on a reliable foundation and is relevant." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141

(1999).

As to the reliability prong, the Court in Daubert announced a non-exhaustive list of factors to guide the trial judge's inquiry, including "(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing Daubert, 509 U.S. at 592-94).

As to the relevancy prong, "the expert's proffered scientific testimony must be sufficiently tied to the facts of the case that it will be of assistance to the factfinder in resolving a disputed fact." Bourne ex rel. Bourne v. E.I. Dupont de Nemours & Co., 189 F. Supp. 2d 482, 495 (S.D. W. Va. 2002). "That is, there must be a 'valid scientific connection to the pertinent inquiry' before the testimony is admissible." Id. (quoting Daubert, 509 U.S. at 591-92).

Our court of appeals has summarized the overarching duties of a trial court in resolving Daubert motions as follows:

> **A district court considering the admissibility of expert testimony exercises a gate keeping function to assess whether the proffered evidence is sufficiently reliable and relevant . . . The inquiry to be undertaken by the district court is "a flexible one" focusing on the "principles and methodology" employed by the expert, not on the conclusions reached. Daubert, 509 U.S. at 594-95 . . . In making its initial determination of whether proffered testimony is sufficiently reliable, the court has broad latitude to consider whatever factors bearing on validity that the court finds to be useful . . . The court, however, should be conscious of two guiding, and sometimes competing, principles. On the one hand, the court should be mindful that Rule 702 was intended to liberalize the introduction of relevant expert evidence. . . . [T]he court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct . . . As with all other admissible evidence, expert testimony is subject to being tested by "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." Daubert, 509 U.S. at 596 . . . On the other hand, the court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to "be both powerful and quite misleading." Id. at 595 . . . [G]iven the potential persuasiveness of expert testimony, proffered evidence that has a greater potential to mislead than to enlighten should be excluded.**

**Westberry, 178 F.3d at 261 (some citations and footnotes omitted). Ultimately, "[t]he proponent of the [expert] testimony must establish its admissibility by a preponderance of proof." Cooper, 259 F.3d at 199.**

## III. Motion to Exclude

### A. Background

Dr. Burns is a board certified general surgeon who served as one of plaintiff's treating physicians. (Pl.'s Opp., Ex. 3, Dr. Burns Dep. at 27). He first saw plaintiff in August of 1998 and continued to treat her until 2005. (Pl.'s Opp. at 3). During that time, Dr. Burns performed diagnostic breast biopsies on plaintiff; diagnosed her with Grade II infiltrating ductal carcinoma with major tubular component and ductal carcinoma in situ in plaintiff's left breast; and performed a double mastectomy and removed lymph nodes for pathology testing to ensure that there had been no metastatic spread of the cancer. (Id.).

Plaintiff seeks to admit Dr. Burns' testimony to demonstrate, among other things, specific causation. (Pl.'s Opp. at 2). According to plaintiff, Dr. Burns "concluded to a reasonable degree of medical certainty that E+P caused [her] breast cancer" after performing a differential diagnosis based on his review of plaintiff's medical record. (Id. at 3). Claiming that Dr. Burns adhered to a reliable methodology in reaching his conclusion, plaintiff maintains that his expert testimony is

relevant to, and will aid the jury in, resolving whether her use of HRT drugs caused her to develop breast cancer.

Defendants have asserted a number of contentions in opposing Dr. Burns' causation testimony. Defendants argue that Dr. Burns' causation opinion does not rest on a reliable foundation, inasmuch as he did not conduct a reliable differential diagnosis of plaintiff to determine the cause of her breast cancer. Defendants further contend that Dr. Burns' causation testimony is irrelevant because it is not stated to a reasonable degree of probability. (Mem. Supp. Defs.' Mot. to Exclude at 8). Specifically, defendants maintain that Dr. Burns testified only that HRT possibly caused plaintiff's breast cancer, an opinion that is "too tentative to be admissible." (Id.). The court assesses these contentions in turn.

B. Reliability of Dr. Burns' Causation Testimony

Plaintiff claims that Dr. Burns reached his specific causation opinion by way of a methodology called differential diagnosis. (Pl.'s Opp. at 2). Defendants respond that Dr. Burns did not conduct a reliable differential diagnosis of plaintiff to

**determine the cause of her breast cancer.[3] (Defs.' Reply 9-10). The court finds that Dr. Burns' causation testimony does not pass the Daubert reliability threshold.**

**The Fourth Circuit has explained that differential diagnosis "is a standard scientific technique of identifying the cause of a medical problem . . . 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." Westberry, 178 F.3d at 262. "A reliable differential diagnosis provides a valid foundation for an expert opinion under Rule 702." Cooper, 259 F.3d at 200 (emphasis in original). To satisfy the Daubert reliability standard, an expert conducting a differential diagnosis must adequately "rule in" and "rule out" alternative causes. See Tamraz v. Lincoln Elec. Co., 620 F.3d 665, 674 (6th Cir. 2010); In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717 (3d Cir. 1994). This entails compiling a "list of possible causes that are generally**

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[3] **Defendants also maintain that the use of differential diagnosis to determine the cause of an individual's breast cancer is per se unreliable. However, the court has already rejected this contention in a memorandum opinion and order previously entered in this action. See Hines v. Wyeth, No. 04-690, slip op. at 9-11 (S.D. W. Va. July 8, 2011) (Doc. No. 393).**

capable of causing the illness or disease at issue, and then systematically and scientifically ruling out specific causes until a final, suspected cause remains." Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1342 (11th Cir. 2010).

The following exchange constitutes the entirety of Dr. Burns' deposition testimony concerning differential diagnosis:

> Q. Did you ever do a differential diagnosis at the time you were treating [plaintiff] to determine what the cause of her breast cancer was?
>
> * * * *
>
> A. Yeah. When I did her history and physical exam, I asked her when she first started having periods, menarche, which hers was late. And how many pregnancies she had, multiple, seven. And when she had menopause, and that was at age 48. And I asked her if she ever took hormone replacement therapy, and she said yes, for 22 years, but she had recently stopped it. I asked her if anybody in her family had breast cancer. At that point, she said no.

(Pl.'s Opp., Ex. 3, Dr. Burns Dep. at 86). Dr. Burns later testified that late menarche, multiple pregnancies, and early menopause are all risk factors for breast cancer. (See id. at 91-92).

At most, this deposition testimony shows that, in Dr. Burns' opinion, plaintiff had several baseline risk factors for breast cancer. Yet in reaching his tentative conclusion (discussed supra) that HRT drugs "contributed to the growth of

**[plaintiff's] tumor," (id. at 95), Dr. Burns does not explain how or why he ruled out these non-HRT risk factors. Moreover, later portions of his testimony indicate that he did not reliably rule in alternative causes. When asked if he was "aware of anything else [other than HRT] that would have contributed to the growth of the tumor," Dr. Burns simply responded "No." (Id. at 96). A review of the record in this case, however, reveals that there were several plausible, alternative causes of plaintiff's breast cancer, including endogenous estrogen (i.e., estrogen naturally produced by the body) and plaintiff's dense breasts. Indeed, as discussed in a prior memorandum opinion and order entered in this action, plaintiff's specific causation expert, Dr. Michael Wertheimer, devotes a substantial part of his report assessing and excluding these alternative causes. See Hines v. Wyeth, No. 04-690, slip op. at 19-23 (S.D. W. Va. July 8, 2011) (Doc. No. 393). Dr. Burns provides no such analysis. It appearing that Dr. Burns did not "systematically and scientifically" rule in and rule out specific causes until a final cause remained, the court concludes that Dr. Burns' differential diagnosis does not satisfy the Daubert reliability standard.**

**C. Relevance of Dr. Burns' Testimony**

**Defendants also challenge the relevance of Dr. Burns'**

causation testimony. Defendants maintain that Dr. Burns failed to testify in his deposition to a reasonable degree of medical probability that plaintiff's use of HRT drugs caused her breast cancer. Inasmuch as the law of West Virginia is clear that "indeterminate expert testimony on causation that is based solely on possibility . . . is not sufficient to allow a reasonable juror to find causation," Tolley v. ACF Indus., Inc., 575 S.E.2d 158, 168 (W. Va. 2002), defendants assert that Dr. Burns' causation testimony would not aid the jury in resolving a material issue and is therefore irrelevant under Daubert.

Dr. Burns first discussed his causation opinion in response to an inquiry from defendants' counsel concerning his (Dr. Burns') conversations with plaintiff's counsel before plaintiff initiated this action:

> Q. Did you tell [plaintiff's counsel] what the cause of her breast cancer was?
>
> A. What my opinion was?
>
> Q. Yeah.
>
> A. Yes.
>
> Q. And what did you tell him?
>
> A. I told him that she had breast cancer that could have been exacerbated or had causative effect due to hormone replacement therapy.

(Pl.'s Opp., Ex. 3, Dr. Burns Dep. at 12-13). Dr. Burns' opinion

on the causal relationship next arose in a lengthy exchange with defendants' counsel, interrupted by several objections by counsel for plaintiff:

> Q. Okay. And you agree that medical test[ing] cannot specifically say, hey, because you took -- your tumor's ER positive and PR positive, that it had to come from [HRT]. You agree with that; right?
>
> * * * *
>
> A. If it's ER/PR positive, and you're taking that medication, I personally can't see how it couldn't be -- have some effect on the tumor. Whether it's a causative effect or an additive effect, I'm not sure.
>
> Q. Okay. Well, let's focus on that; all right? So do you have an opinion within a reasonable degree of medical certainty that [HRT] causes the initial tumor? Can you say that?
>
> A. I don't have scientific data to determine that, and I have not seen any literature that says specifically that it's causative. . . .
>
> * * * *
>
> Q. Do you have an opinion within a reasonable degree of medical certainty that the use of [HRT] causes breast cancer?
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> * * * *
>
> A. I think women that take hormone replacement therapy have an increased incidence of development of breast cancer to their peers. So I think with a reasonable degree of medical certainty, then I would think that there is a causative and additive, both, what degree -- I'm not sure -- effect on breast cancer by [HRT]. . . .
>
> Q. Okay. Let's break that down a little bit. . . . Do you believe that the use of Premarin and Provera causes breast cancer? That is, that it initiates the

**cancer cells. Is that what you believe?**

*** * * ***

**A. I'm trying to see in my mind if there's a difference between causes and initiates, probably not. I'd say dual replacement therapy causes an increase in incidents of breast cancer.**

*** * * ***

**Q. All right. Well, I'll ask you again. Is it your opinion sitting here today that the use of [HRT] initiates the breast cancer?**

*** * * ***

**A. I think it's one of the multiple components potentially that could initiate cancer.**

(Id. at 34-38). Dr. Burns' opinion as to the causal relationship arose again later in the deposition on examination by plaintiff's counsel:

**Q. You mentioned earlier in the deposition that you had an opinion that her combination [HRT] contributed to the growth of her tumor from the time of her last mammogram to the time of her -- prior to diagnosis to the time of diagnosis; is that correct?**

**A. Yes.**

**Q. Are you aware of anything else that would have contributed to the growth of the tumor during that time?**

**A. No.**

**Q. You mentioned that you rely on the [2002 Women's Health Initiative ("WHI")] study to support your opinion about causation in this case . . . . Did you also rely on that study to say if the duration of use was five years or greater, you would think that the HRT**

**could be causal?**

**A. That's my opinion, yeah. I don't have any scientific data to prove that.**

*** * * ***

**Q. All right. Your opinion about the causal role of [HRT] and breast cancer in [plaintiff's] case, are you expressing that to a reasonable degree of medical certainty?**

**A. Yes.**

**(Id. at 95-98). Finally, counsel for defendants raised the topic one last time at the conclusion of Dr. Burns' deposition:**

**Q. And is it accepted in your profession now that the WHI and the other literature shows that combination [HRT] can cause breast cancer?**

*** * * ***

**A. It causes an increase incidence of breast cancer. I can't say it's a direct cause.**

**(Id. at 102).**

**Dr. Burns has offered a rather imprecise opinion. With respect to the general causal relationship between HRT drugs and breast cancer, Dr. Burns offered at least three opinions. He first testified that HRT drugs "have some effect on the tumor," be it "a causative effect or an additive effect." (Id. at 34). He then offered a more definitive opinion, asserting that "there is a causative and additive . . . effect on breast cancer by [HRT]" but adding, "what degree -- I'm not sure." (Id. at 35).**

**Shortly thereafter, he reverted to his original opinion, noting that HRT is "one of the multiple components potentially that could initiate cancer." (Id. at 38).**

**Of course, Dr. Burns is offered not for general causation purposes but for specific causation. And not unlike his testimony concerning the general causal relationship between HRT drugs and breast cancer, Dr. Burns' opinion concerning whether these drugs specifically caused plaintiff's breast cancer is less than clear. Dr. Burns first opined in effect that HRT drugs possibly caused her breast cancer. Early in the deposition, Dr. Burns testified that, in his opinion, plaintiff "had breast cancer that could have been exacerbated or had causative effect due to [HRT]." (Pl.'s Opp., Ex. 3, Dr. Burns Dep. at 12-13 (emphasis added)). Near the conclusion of the deposition, plaintiff's counsel summarized Dr. Burns' causation opinion in somewhat firmer terms:**

> **Q. You mentioned earlier in the deposition that you had an opinion that her combination [HRT] contributed to the growth of her tumor from the time of her last mammogram to the time of her -- prior to diagnosis to the time of diagnosis; is that correct?**
>
> **A. Yes.**
>
> **Q. Are you aware of anything else that would have contributed to the growth of the tumor during that time?**

A. No.

(Id. at 95-96 (emphasis added)).

Notwithstanding the apparent inconsistences in Dr. Burns' testimony, the court is not inclined at this juncture to find that his causation testimony is irrelevant as too speculative. Rather, in light of the earlier determination that Dr. Burns' differential diagnosis was inadequate under Daubert and Rule 702, the court excludes his causation testimony on reliability grounds alone.

## IV. Conclusion

For the foregoing reasons, the court ORDERS that defendants' motion to exclude the causation testimony of Dr. Burns be, and it hereby is, granted.[4]

[4] The court's ruling obviates the need to address defendants' alternative contentions that Dr. Burns' testimony should be excluded because plaintiff failed to disclose him as an expert witness as required by Federal Rule of Civil Procedure 26(a)(2)(A) and because he is not qualified to render causation testimony. Additionally, the court's finding that Dr. Burns' causation testimony is unreliable does not preclude Dr. Burns from testifying in his role as plaintiff's treating physician.

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

**DATED: July 14, 2011**

**John T. Copenhaver, Jr.**
**United States District Judge**