IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
HOT SPRINGS DIVISION

In re:	:	**MDL Docket No. 4:03CV1507-WRW**
	:	**6:05CV06074**
PREMPRO PRODUCTS LIABILITY LITIGATION	:	
	:	
	:	
SHIRLEY DAVIDSON	:	**PLAINTIFF**
	:	
v.	:	
	:	
WYETH, INC., et al.	:	**DEFENDANTS**

ORDER

Pending is Defendants' Motion for Summary Judgment (Doc. No. 116). Plaintiff has responded,[1] Defendants have replied,[2] and Plaintiff filed a sur-reply.[3]

I. BACKGROUND

Defendants contend they are entitled to summary judgment because Plaintiff is unable to establish general causation, since her general causation expert, Dr. Austin, was precluded from testifying that short-term use of Prempro causes breast cancer.[4]

In response to Defendants' motion, Plaintiff argues: (1) Dr. Colditz can establish general causation through his promotion theory; (2) studies support short-term causation; and (3) the order excluding testimony was an advisory opinion.

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[1]Doc. No. 119.

[2]Doc. No. 121.

[3]Doc. No. 123.

[4]*See* Doc. Nos. 112, 118.

II. DISCUSSION

A. *Daubert* Standard

A summary of the relevant *Daubert* standard, set out thoroughly in the January 19, 2011 Order, is necessary here. Again, the central inquiry under Rule 702 is whether the proffered expert's testimony is sufficiently reliable,[5] and the burden of establishing reliability rests on the proponent of the expert testimony.[6] The testimony must be based on scientific, technical, or other specialized knowledge,[7] and, "knowledge" requires more than a subjective belief or an unsupported speculation; it requires an appropriate level of validation.[8]

Rule 702 has 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.[9] Second, it must be the product of reliable principles and methods.[10] Third, the expert must have applied those principles and methods reliably to the facts of the case.[11]

B. Dr. Colditz

Wyeth filed a Motion to Exclude any expert testimony regarding short-term use. In response, Plaintiff proffered only Dr. Donald Austin and his report on short-term use. Judge

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

[6]*Barrett*, 606 F.3d at 980 (quoting *Marmo v. Tyson Fresh Meats, Inc*., 457 F.3d 748, 757 (8th Cir. 2006)).

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

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

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

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

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

Volpe granted Defendants' Motion to Exclude on January 19, 2011, and I affirmed his ruling three days later.[12]

Because Dr. Austin's testimony was excluded after two *Daubert* hearings and much briefing, Plaintiff now argues, in response to Defendants' Motion for Summary Judgment, that Dr. Colditz's "promotion" theory is enough to chin the pole on general causation. I disagree.

In a December, 2006, deposition, Dr. Colditz testified:

> When we look at the evidence from across the studies, it's clear that the promotion effect can start to be detected in six to twelve months. It can be spread out to numerous years beyond that. It's really going to depend on where the abnormal cells are in the pathway to cancer. They haven't got the cancer, they get exposed to E plus P, and they get promoted to move on down the cascade to invasive breast cancer.[13]

Defendants responded that Dr. Colditz's deposition testimony is an "unsupported assertion" and "that the only epidemiological studies that Plaintiff relied on for the short-term use issue were those identified by Dr. Austin in his declaration and *Daubert* hearing testimony."[14] Defendants also point out that there is no short-term use causation report from Dr. Colditz, nor is there a "citation to the 'studies' to which the quotation . . . refers."[15]

I re-read Dr. Colditz's report, which he described as an analysis of a risk versus benefits assessment of HRT use. The report notes that "[s]hort term [use] is considered therapy lasting less than 24 months. Long term is considered to be 24 months of use or longer. The distinction of course is not a bright line. A significant relation between duration of use and risk can be

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[12]Doc. Nos. 112, 118.

[13]Doc. No. 119-11.

[14]Doc. No. 121.

[15]*Id.*

either protective or harmful, a decrease or increase in risk with each year of use."[16] However, Dr. Colditz cited no studies to support this delineation.

Additionally, Dr. Colditz does not include breast cancer as an injury related to short-term use of HRT in the chart found on page three of his report -- "Increase in breast cancer" is listed only in the "Long term" category.[17] In the section of the report where Dr. Colditz specifically addresses breast cancer, he cites nine articles. Four of the articles do not assess "short-term use"; two articles only breakdown use at the five year mark; two were studies that Dr. Austin said were not reliable for analyzing short-term use; and one article analyzed the Million Women Study ("MWS").

Dr. Colditz's deposition testimony appears to be relying on biological plausibility. While it may be relevant in the whole scheme of things, it does not establish causation. Even Dr. Austin admitted this -- "It's not a measure of causality, it is a criterion for determining how much evidence, how much to weigh the evidence in favor or not."[18] Again, the burden is on Plaintiff to establish that the expert testimony is sufficiently reliable; she has not met her burden.

C. Studies Support General Causation

Plaintiff asserts that "studies support that Prempro can cause breast cancer after short-term use." However, Plaintiff cites the same studies that Dr. Austin used (unreliably, I again note) to support his testimony on short-term use -- testimony that was deemed inadmissible.

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[16]*Rush v. Wyeth*, No. 4:05-cv-00497-BRW (E.D. Ark.), Doc. No. 218-9.

[17]*Id.*

[18]*In re Prempro*, No. 4:03-CV-01507-WRW (E.D. Ark.), Doc. No. 2547.

D. Advisory Opinion[19]

Plaintiff contends that the January 11, 2011 Order was an advisory opinion, since "the specific facts of this case" have been "ignored."[20]

First, this is a "short-term" use case, and Defendants' motion sought the exclusion of short-term use testimony in this case. Second, Plaintiff agreed that Dr. Austin's short-term use expert report was the report she was relying on for general causation. Third, counsel represented Plaintiff at two separate hearings on this issue. Finally, the reference to "ignor[ing] the specific facts" of this case is unpersuasive, since Dr. Austin's short-term use opinion is not case specific -- rather the same report is used in all cases. The only specific facts that needed to be considered in determining whether the Order would apply to this case are whether Plaintiff took Prempro, for how long, and her type of cancer. Accordingly, the short-term use issue was ripe in this case, and the Order excluding Dr. Austin's testimony is not merely advisory.

E. Duration of Use

Plaintiff took Prempro for less than two years,[21] and in her response, Plaintiff did not address this issue -- the response mentioned only Pamela Kuhn's duration of use.

Regardless, Plaintiff was unable to cite any studies that reliably show that Prempro use of around three years or fewer causes ductal breast cancer. In fact, the studies showed the opposite -- that the placebo group did not pass the Prempro group for incidences of breast cancer until "after about three years in prior users,"[22] and "in the third year and beyond."[23] Even the Calle

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[19]An advisory opinion is "[a] nonbinding statement by a court of its interpretation of the law on a matter submitted for that purpose." Black's Law Dictionary 1201 (9th ed. 2009).

[20]Doc. No. 119.

[21]*Id*.

[22]*In re Prempro*, No. 4:03-CV-01507-WRW, Doc. No. 2480-59 -- Garnet L. Anderson, et al, *Prior Hormone Therapy and Breast Cancer Risk in the Women's Health Initiative*

Study, which was relied on by Dr. Austin, noted that in a "sensitivity analysis" the risk between Prempro users and placebo did not "beg[i]n to diverge" until year three.[24] Since Plaintiff's use was less than two years, she is unable to distinguish her case from these findings (and it appears to me that Plaintiff conceded this point by not addressing it in her response).

F. New study

On February 1, 2011, Plaintiff submitted an additional article, which she claims shows that "the Court's and Wyeth's reliance on the WHI is misplaced."[25] According to Plaintiff, this new article[26] "establishes firmly that the WHI was unable to adequately measure the breast cancer risk of E+P."[27] The article indicates that "[a] new finding of this study, which has been little investigated previously, is that the interval between menopause and starting hormonal therapy has a substantial effect on breast cancer risk."[28] It is worth noting that this new assessment involved data from the MWS, and again, the reliability concern for the MWS on the short-term use issue is

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Randomized Trial of Estrogen plus Progestin¸ 55 Maturitas at 104 (2006).

[23]*Id* at Doc. No. 2462-37 -- Rowan T. Chlebowski, M.D., et al., *Influence of Estrogen Plus Progestin on Breast Cancer and Mammography in Healthy Postmenopausal Women*, 289 J. Am. Med. 24, 3247 (2003).

[24]*Id* at Doc. No. 2480-85 -- Eugenia Calle, Ph.D., et al, *Postmenopausal Hormone Use and Breast Cancer Associations Differ by Hormone Regiment and Histological Subtype*, 115 Cancer at 936 (2009).

[25]Doc. No. 123.

[26]Doc. No. 123-1 -- Valerie Beral, et al., *Breast Cancer Risk in Relation to the Interval Between Menopause and Starting Hormone Therapy*, J. Nat'l Cancer Institute (2011).

[27]Doc. No. 123.

[28]Doc. No. 123-1.

that it did not break down estrogen and progestin types[29] and it conducted a separate assessment of Prempro at only the five year mark.

While Plaintiff's new study may bolster her position that the time gap between menopause and initiation of HRT use may relate to the risk of breast cancer, the study does not resolve the core issue: Plaintiff's experts failed to reliably provide any scientific studies that supported the position that Prempro use of around three years or fewer showed an increased risk in breast cancer. At this point, Plaintiff's burden is to establish her expert's testimony is reliable; she has not done so.

G. Plaintiff's February 4, 2011 Letter

In further support of her position that the January 19, 2011 *Daubert* Order is incorrect, Plaintiff submitted Judge Fuste's post-trial Order, which she claims "directly conflicts with this Court's opinion on the 'short-term use' issue . . . ."[30] Plaintiff point out that Judge Fuste had the opportunity to review all the same briefing, found that "plaintiffs' evidence is not junk science and passes muster under *Daubert*."[31] This interpretation of Judge Fuste's orders, seems to me, to be a bit exaggerated, and overlooks some essential points.

First, the joint *Daubert* hearing with Judge Fuste did not involve live testimony (because I did not think it was necessary at the time -- however, Dr. Austin's reliability issues were exposed when he testified at the second *Daubert* hearing before Judge Volpe). Second, Judge Fuste had limited time to address the issue because his trial was scheduled to commence a week after the

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[29]In one of his papers, even Dr. Colditz recognized an issue with the MWS -- "not broken out for type of hormone used." *See* Colditz, G.A., *Estrogen, estrogen plus progestin therapy, and risk of breast cancer*. Clinical Cancer Research 11 909s-17s (2005).

[30]Doc. No. 125.

[31]*Id.*

Daubert hearing. Third, because of the time constraints, Judge Fuste allowed Defendants to *voir dire* Dr. Austin during trial, and, at that time, he determined that Dr. Austin was qualified as an epidemiologist. Fourth, Judge Fuste ruled out Dr. Austin's short-term use report, limited his testimony to "what he said before," and required Wyeth to deal with their short-term use objections "in the context of trial."[32] Finally, when Judge Fuste became aware of all the problems with Dr. Austin's testimony, his case was in an entirely different procedural posture than this case -- the jury had already rendered a verdict.

Plaintiff contends that the *Daubert* Order in this case "ignores the difference between a study's ability to detect a risk and its ability to quantify that risk, particularly under rare circumstances."[33] Assuming Plaintiff is correct -- that WHI did not reliably "quantify" the short-term use risk -- she still failed to present expert testimony that reliably concluded that short-term use establishes an increased risk of ductal breast cancer; that remains Plaintiff's burden.

CONCLUSION

To establish proximate causation in this short-term use case, Plaintiff must provide expert testimony. Plaintiff named Dr. Austin as her short-term use expert, and his testimony was excluded. Accordingly, Defendants' Motion for Summary Judgment (Doc. No. 116) is GRANTED. All other pending motions are DENIED as MOOT.

IT IS SO ORDERED this 14th day of February, 2011.

/s/Billy Roy Wilson
UNITED STATES DISTRICT JUDGE

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[32]Judge Fuste excluded Dr. Austin's short-term use report because it was a "late submission." *Rivera-Adams, et al. v. Wyeth*, No. 3:03-CV-01713 (D. Puerto Rico), Doc. No. 186.

[33]Doc. No. 125.