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

In re:	:	**MDL Docket No. 4:03CV1507-WRW**
	:	**4:04CV01169**
PREMPRO PRODUCTS LIABILITY LITIGATION	:	
	:	
DONNA SCROGGIN	:	**PLAINTIFF**
v.	:	
WYETH, et. al.	:	**DEFENDANTS**

ORDER[1]

Pending are Defendants' Motion for Judgment as a Matter of Law, or for New Trial, or Remittitur of Punitive Damages Awards (Doc. Nos. 637, 642). Plaintiff has responded and Defendants have replied.[2] The parties presented oral arguments on May 9, 2008.

I. BACKGROUND

Following a trial of nearly three weeks, the jury, on February 25, 2008, found that Plaintiff proved by the greater weight of the evidence that Wyeth and Upjohn inadequately warned about a known or knowable risk of Premarin, Prempro, and Provera, and Defendants' failure to warn resulted in Plaintiff's breast cancer.[3] The jury awarded compensatory damages of $2,700,000.00.[4]

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[1]United States Magistrate Judge Henry L. Jones, Jr. is also assigned to this case and entered some of the orders referenced in this Order.

[2]Doc. Nos. 651, 652, 654, 655.

[3]Doc. No. 552.

[4]*Id.*

The punitive damages phase of the trial commenced on March 3, 2008, and lasted three days. On March 6, 2008, the jury found Defendants liable for punitive damages; Wyeth in the sum of $19,360,000.00 and Upjohn in the sum of $7,760,000.00.[5]

Following the entry of the judgment,[6] Defendants filed Motions for Judgment as a Matter of Law or for a New Trial on both compensatory and punitive damages. As to compensatory damage issues, the motions were denied on April 10, 2008, and the parties were directed to focus their attention on the issue of punitive damages.[7]

II. STANDARD OF REVIEW

A motion for judgment as a matter of law following a jury verdict -- a.k.a. motion for judgment notwithstanding the verdict ("JNOV") -- is governed by Federal Rule of Civil Procedure 50. Judgment as a matter of law is appropriate when the evidence, viewed in the light most favorable to the verdict, was such that no reasonable juror could have returned a verdict for the nonmoving party.[8] "Judgment as a matter of law is proper when the record contains no proof beyond speculation to support the verdict."[9] A court should review all of the evidence in the record, including any evidence unfavorable to the non-moving party that "the jury is required to believe."[10]

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[5]Doc. No. 616.

[6]Doc. Nos. 629, 636 (correcting the post-judgment interest rate).

[7]Doc. No. 647.

[8]*Minnesota Supply Co. v. Raymond Corp*, 472 F.3d 524, 536 (8th Cir. 2006).

[9]*Larson by Larson v. Miller*, 76 F.3d 1446, 1452 (8th Cir. 1996).

[10]9B CHARLES A. WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 2529 (3d ed. 2008) (citing *Reeves v. Sanderson Plumbing Products*, 530 U.S. 133 (2000)).

When considering a Motion for JNOV, a court may reconsider evidence that was erroneously admitted, strike the evidence, and then make the determination as to whether, based on the properly admitted evidence, there was sufficient evidence to support the verdict.[11]

Additionally, a trial judge who grants a JNOV should rule conditionally on an alternative motion for new trial.[12]

III. DISCUSSION

A. Dr. Parisian's Punitive Damages Stage Testimony

Plaintiff designated Dr. Parisian as her "regulatory expert," and asserted that Dr. Parisian would establish that the duty to test is part of the ordinary care required of pharmaceutical companies.[13] To support her opinions, Dr. Parisian was to rely on her observations over the years as a former FDA medical officer and her understanding of the regulations referenced in her expert report, her deposition and the supplemental briefs."[14]

Defendants repeatedly argued that Dr. Parisian's punitive damages phase testimony should be stricken. Because a court may "satisfy its gatekeeper role" under *Daubert* on a post-

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[11]*Weisgram v. Marley Co.*, 528 U.S. 440, 455-456 (2000) (Finding no abuse of discretion when the appellate court found expert testimony inadmissible and instructed that judgment be entered as a matter of law, since, without the erroneously admitted testimony, there was insufficient evidence to support the jury verdict. The Supreme Court rejected Plaintiff's assertion "that allowing courts of appeals to direct the entry of judgment for defendants will punish plaintiffs who could have shored up their cases by other means had they known their expert testimony would be found inadmissible." The Court recognized that "although [Plaintiff] was on notice every step of the way that [Defendant] was challenging his experts, he made no attempt to add or substitute other evidence.").

[12]*Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 253-54 (1940).

[13]Doc. No. 175.

[14]Doc. No. 389.

trial motion,[15] I will now consider Defendants' Motions to Strike. Incidentally, any assertion by Plaintiff that Defendants did not properly reserve their objections to Dr. Parisian's testimony is without merit. Defendants submitted motions to exclude,[16] lodged numerous objections during the punitive damages stage, and requested, both orally[17] and in writing,[18] that Dr. Parisian's punitive damages testimony be stricken or excluded. On an occasion or two, Defendants may have failed to reassert a specific objection contemporaneously, but their specific points had been made and were well-known to me and Plaintiff's counsel.

1. Pre-Trial Limitations on Testimony

Following several rounds of briefing and a hearing, an Order outlining permissible testimony from Dr. Parisian was entered:

> A purely factual recitation of the history of Provera, and its progression as a drug to be used in conjunction with estrogen to treat menopausal symptoms is relevant to show the environment in which Upjohn operated. Use of the specific advertising or promotional pieces is not necessary to make this point. Plaintiff has conceded that Dr. Parisian will not give an opinion on Upjohn's intent or whether Upjohn's advertisement influenced either Plaintiff or any treating physician.
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> Also Dr. Parisian's testimony is relevant, because she is attempting to show that off-label promotion, without testing, is a violation of pharmaceutical company's duty to use ordinary care . . . Plaintiff's attempt to use Dr. Parisian to establish that the duty to test is part of the ordinary care required from pharmaceutical companies, is relevant to the claims in this case. . .
>
> Dr. Parisian has recited her experience in the FDA and the history of Provera, but she has not set out what standards or "standards of the industry" she relies on. As Judge Wilson requested [in his] November 1, 2007 Order, Plaintiff must provide some citation to authority, whether it is legislative or historical, that Dr. Parisian relies on. I have not been able to find such a reference after reviewing her report in the record.

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[15]*Goebel v. Denver and Rio Grande Western R.R. Co.*, 215 F.3d 1083, 1087 (10th Cir. 2000).

[16]Doc. Nos. 66, 101, 577, 594.

[17]See March 3, 2008, Tr. at 2714; March 3, 2008, Tr. at 2740-41; March 5, 2008, Tr. at 2835; March 6, 2008, Tr. at 2974.

[18]Doc. Nos. 605, 607, 610, 611, 643.

> If Plaintiff can provide a specific reference to the standards relied upon by Dr. Parisian, I will reconsider this ruling and address the remaining issues raised in Upjohn's motion.[19]

In response, Plaintiff submitted supplemental briefing, and this order was entered:

> While I agree that Dr. Parisian's citations leave a bit to be desired, I believe she has met the *Daubert* threshold. Defendants' remaining criticism of Dr. Parisian's testimony and report can be addressed during cross-examination.
>
> Dr. Parisian can give her opinions on the reasonableness of a pharmaceutical company's actions based on her observations over the years and her understanding of the regulations referenced in her expert report, her deposition, and the supplemental briefs. Dr. Parisian will not be permitted to talk about or refer to what an "ethical" or "responsible" pharmaceutical company does or would do.[20]

2. Trial Testimony on Regulations

Although she is Plaintiff's "regulatory expert," Dr. Parisian mentioned only three FDA regulations during the punitive damages stage of trial. At the beginning of the punitive damages stage, Plaintiff asked Dr. Parisian whether she had "run across documents that would violate rules that the FDA has regarding how information is to be handled," and she responded, "Yes, sir."[21] Next, Dr. Parisian cited three C.F.R. statutes -- two of which Defendants claim were cited erroneously[22] -- and summarized the regulations:

> you're supposed to have adequate instructions for use, adequate warnings . . . truthful advertisement, reprints, [and] information that you would provide to your physician . . . marketing information is supposed to be truthful . . . and you're not allowed to have labeling that's false, not fair and balanced.[23]

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[19]Doc. No. 340 (The Order was entered by Judge Jones).

[20]Doc. No. 389.

[21]March 3, 2008, Tr. at 2678.

[22]See Doc. No. 643 ("But section 201.105 has to do with veterinary drugs, and section 203 with the reimportation and wholesale distribution of prescription drugs.").

[23]March 3, 2008, Tr. at 2679.

Following this cursory review of FDA regulations, Dr. Parisian and Plaintiff's counsel commenced addressing specific exhibits.

a. December 1975 Dear Doctor Letter (Plaintiff's Ex. 22) and January 1976 Response from FDA (Plaintiff's Ex. 24)

Plaintiff questioned Dr. Parisian about the December 1975 Wyeth "Dear Doctor" letter and the FDA's January 1976 summary of a meeting between Wyeth and the FDA, which discussed this letter.[24] In briefing,[25] Plaintiff asserted that these documents were necessary to "show Wyeth's policy to dismiss and distract, even outright deny, that Premarin causes cancer."[26]

After Dr. Parisian read lengthy passages from the exhibits, Plaintiff's counsel asked "Now, from your expert standpoint, what do those two letters . . . say with regard to Wyeth's knowledge of how to handle scientific data that pertains to their products?"[27] Defendants objected that the question called for speculation and was beyond the scope of Dr. Parisian's report. At the sidebar, I overruled the objection after Plaintiff asserted that Dr. Parisian could "certainly opine about what information FDA requires," how Wyeth responded, and "whether or not that's appropriate under the FDA guidelines."[28] Next, Plaintiff asked Dr. Parisian whether Wyeth "display[ed] a similar attitude as it relates to breast cancer."[29] Again Defendants objected, and it was overruled. Dr. Parisian testified that rather than "doing scientific studies

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[24]*Id.* at 2681-2685; Plaintiff's Exs. 22 and 24.

[25]Before the punitive damages stage commenced, the parties filed several motions and responses regarding witness, exhibits, *etc*.

[26]Doc. No. 588.

[27]March 3, 2008, Tr. at 2683.

[28]*Id.* at 2684.

[29]*Id.*

and addressing the risks [of endometrial cancer, Wyeth] took another route in terms of trying to deal with the problem," and based on the documents she reviewed, there was a similar pattern with breast cancer.[30]

But, Dr. Parisian's testimony did not align with Plaintiff's assurances at the sidebar. Instead Dr. Parisian summarized the document:

> The letter shows that there has been a scientific discussion at the advisory panel meeting and the FDA anticipated that the company, since they are the primary provider of this product, would have pursued a scientific course or some kind of response about a clinical trial doing some kind of study. And that's why the FDA referred to this as a passive position. The company instead chose to tell physicians that it was simplistic and that there was no relation to their product and rather downplayed the risk in terms of addressing it as a responsible manufacturer.[31]

The testimony was simply a regurgitation of an exhibit, absent any expert analysis or opinion. Also missing was any reference to FDA requirements. Despite the assurances of Plaintiff's counsel, Dr. Parisian mentioned neither guidelines nor requirements in her assessment of these two exhibits. Regarding Plaintiff's Exhibits 22 and 24, the record is devoid of any testimony that Wyeth's actions violated FDA regulations or any other defined standard.[32] Instead, Dr. Parisian simply read and summarized the documents, as any layperson could have done. The promised expert testimony simply was not delivered, so I should have struck this testimony at the time.

b. Prempak Study Memo (Plaintiff's Ex. 95)

Next, Dr. Parisian addressed Wyeth's internal minutes of discussions about Prempak and its Prempak Study. Again, she and Plaintiff's counsel took turns reading the document into the

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[30] *Id.* at 2685.

[31] *Id.* at 2684.

[32] Notably, Dr. Parisian could hardly testify that Wyeth's action violated FDA regulations, because this position would have been contrary to the exhibit. The exhibit reads: "This letter is borderline in terms of violating the Food, Drug and Cosmetic Act." The FDA disagreed with Wyeth's actions, but believed only that Wyeth's actions had come close to crossing the line.

record. And, again, Dr. Parisian provided no testimony as a "regulatory expert." As best I can tell, the only reason this document was introduced was to point out that someone at Wyeth wanted to "peek at the data" of the ongoing study. There was no testimony that this would violate any regulations -- Dr. Parisian did not testify that this was inappropriate behavior -- she stated only that you "have to be careful peeking at the data" so as not to introduce bias.[33] I should not have permitted this evidence.

c. *Seasons* Magazine Proposal (Plaintiff's Ex. 154)

Plaintiff claimed Wyeth's proposal to the FDA regarding *Seasons* magazine established that "Wyeth pushed unapproved long term benefits of E and E+P" but did not study the potential risks of long-term use.[34] According to Plaintiff, the document "show[ed] Wyeth dismissed and distracted ERT/HRT breast cancer risk and overshadowed any risk of breast cancer with significant long term benefits."[35] Once again, Dr. Parisian read into evidence excerpts from the exhibit and summarized -- but her summary required no expertise.

When asked about the letter's meaning "from the FDA's standpoint," Dr. Parisian responded that all manufacturers are supposed to have fair and balanced labeling that's not misleading."[36] Dr. Parisian also testified that when pharmaceutical companies distribute information, it should be clear that the pharmaceutical company is the source of the information, rather than a doctor or pharmacist.[37] Essentially, her testimony mirrored the language in the document. Plaintiff's argument for introducing the document -- to show that "Wyeth pushed

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[33]March 3, 2008, Tr. at 2688.

[34]Doc. No. 588.

[35]*Id.*

[36]March 3, 2008, Tr. at 2693 (emphasis added).

[37]*Id.* at 2693.

unapproved long term benefits of E and E+P," but did not study the potential risks of long-term use -- was not established by Dr. Parisian. I should have struck the testimony and exhibit, because Dr. Parisian provided no expert analysis.

d. 1993 Premarin Marketing Plan (Plaintiff's Ex. 1565)

According to Plaintiff, the 1993 Premarin marketing plan "show[ed] Wyeth's awareness of long term use of its drugs by many consumers yet Wyeth never chose to study E or E+P long term to evaluate the risks . . . which goes squarely to notice, duty to test, and subsequent failure to warn."[38] Defendants suspected that Plaintiff actually intended to use the document to discuss marketing,[39] which is what happened. Dr. Parisian testified that the marketing plan exemplified when a pharmaceutical company's "marketing takes the first seat as opposed to the science."[40] Dr. Parisian's testimony about the document is devoid of any reference to the FDA or reliance on her expertise as an regulatory expert -- she provided an editorial about pharmaceutical companies putting sales and marketing before science, but gave no testimony from her position as a regulatory expert. The exhibit should have been excluded.

e. Essner's Prempro Launch Speeches (Plaintiff's Exs. 6776 and 6558)

Plaintiff contended that Bob Essner's April 4, 1995 and April 2, 1995 Prempro "launch" speeches showed "Wyeth's corporate policy to support and push E+P benefits long term without every [sic] studying E+P long term" and how Wyeth treated Prempro "from a risk and benefit perspective."[41]

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[38]Doc. No. 588.

[39]Doc. No. 2703-2704.

[40]March 3, 2008, Tr. at 2704.

[41]Doc. No. 588.

Basically, Dr. Parisian again read selected excerpts from the documents, but provided no analysis which would require regulatory expertise -- or any expertise. There was no mention of FDA regulations, nor any opinion based on her experience as an FDA medical officer. Plaintiff's primary critique of Essner's speeches was that they do not mention short-term use, breast cancer risk, or studies[42] -- this was not connected with FDA regulations.

Plaintiff also asked Dr. Parisian about Wyeth's "position with regard to how the product will be treated from a marketing standpoint."[43] In response, Dr. Parisian simply read the exhibit. Had she provided an actual opinion on this topic, it would have been beyond Dr. Parisian's expertise as a regulatory expert. I should have struck the testimony and exhibit.

f. Burson-Marsteller Account Overview (Plaintiff's Ex. 8019-A)

According to Plaintiff, the June 6, 1994 "Burson-Marsteller Premarin & Wyeth-Ayerst Women's Health: Account Overview" exemplified "Wyeth's policy of dismiss and distract of the concerns about the risk of HRT and breast cancer . . . [and] absolutely show[ed] Wyeth was on notice of breast cancer risks but did not study E+P and breast cancer and as a result did not warn of the risk."[44]

Dr. Parisian testified that if a company knew there was a link between its product and breast cancer, neutralizing that information would not be fair and balanced. She continued, "[I]t's the duty of the manufacturer to ensure that the product is safe for that indication and for those women who are using the product."[45]

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[42]March 3, 2008, Tr. at 2707.

[43]*Id.* at 2708.

[44]Doc. No. 588.

[45]March 3, 2008, Tr. at 2712-2713.

Following this testimony, I requested a sidebar, and voiced concern that Dr. Parisian was testifying outside the scope permitted by the pretrial orders. Plaintiff responded:

> [A]s to everything that I've put on thus far, I believe that I've linked it to the FDA regulations. And the concern that's been pointed out by Wyeth even in this most recent document was FDA regulatory concerns. And she went through and described, you know, what would be improper about the approach to neutralizing that evidence. So I don't think I've put in anything that doesn't fit within her area of expertise.[46]

Defendants responded that Dr. Parisian had "gone beyond both her report and her designation for this case and the limits of [pre-trial] ruling[s] regarding her testimony."[47] Plaintiff replied, "Your Honor, this is my only witness. I don't have any other witnesses. You struck Dr. Hollon."[48] Plaintiff's reason for eliciting testimony from Dr. Parisian that was outside of her report was not well founded. If a court strikes one expert, a party may not use another expert to give the same testimony if it is beyond the expert's expertise and designation. I should have struck this testimony.

g. George Mills Email on Breast Cancer Issues (Plaintiff's Ex. 7423)

Plaintiff introduced George Mills's (a Wyeth employee) February 25, 2000 email, which set out his idea for handling breast cancer issues. In the pretrial briefs, Plaintiff asserted that this exhibit "show[ed] Wyeth's policy of dismiss and distract of the concerns about the risks of HRT and breast cancer," and that Wyeth was on notice of a breast cancer risk, but neither studied nor warned of the risk.[49]

Plaintiff's counsel mentioned that he'd previously read the exhibit to the jury, and asked Dr. Parisian if it would "ever be appropriate . . . to withhold information about breast cancer risk

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[46]*Id.* at 2713.

[47]*Id.* at 2714.

[48]*Id.*

[49]Doc. No. 588.

from users of the product . . . ."[50] I am unsure as to why a regulatory expert would be needed to explain this document to the jury. The jury was equally capable of assessing the document and making the conclusions offered by Dr. Parisian. In pre-trial motions, Wyeth objected on various grounds,[51] and although a specific objection was not interposed during the punitive stage, I should have excluded this exhibit, which was clearly inadmissible via Dr. Parisian (Wyeth repeatedly objected that her testimony was not connected to FDA regulations).

h. February 28, 2000 Budget Proposal (Plaintiff's Ex. 8151)

According to Plaintiff, the February 28, 2000 budget proposal "show[ed] Wyeth's policy of funding to dismiss and distract the risk of breast cancer of E+P while expounding on the long-term benefits of E+P . . . ."[52] Counsel read a section of the exhibit: "In addition, media attention on two recent publications have raised consumer awareness about the relative risk of breast cancer . . . Additional funds are needed to minimize the impact on growth or programs which focus on the role of estrogen in disease prevention and help put the small potential risk of breast cancer in perspective."[53] Plaintiff's counsel asked Dr. Parisian, "Would it be appropriate to fund to this degree a campaign that seeks to cut down any media suggestion that there's a breast cancer risk."[54] Dr. Parisian responded, "No. It would not be appropriate from a public health point of view in terms of women's safety."[55] But where was the "regulatory" testimony promised from Dr. Parisian? Wyeth did not lodge a specific objection at this point, but had

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[50]March 3, 2008, Tr. at 2720.

[51]Doc. No. 566.

[52]Doc. No. 588.

[53]March 3, 2008, Tr. at 2721-2722.

[54]*Id.* at 2722.

[55]*Id.*

objected to the exhibit in a pre-trial motion.[56] I should not have permitted the exhibit to be admitted through Dr. Parisian, because she did not connect it with any FDA regulations.

i. Dr. Karla Kerlikowske Study

This is an August 14, 2007 article titled "Declines in Invasive Breast Cancer in Use of Postmenopausal Hormone Therapy in a Screening Mammography Population," by Dr. Karla Kerlikowske, which was published in the Journal of the National Cancer Institute.[57] After Dr. Parisian indicated that she had seen the document before, Plaintiff asked "can you tell us what Dr. Kerlikowske said regarding the potential risk" of breast cancer.[58] Dr. Parisian read the following to the jury:

> Based on an estimated 211,300 breast cancer cases in 2003, 75 percent of these diagnosed in postmenopausal women, 85 percent of them are ER positive, and an annual decline of 13 percent in ER-positive disease. The impact of declining use of postmenopausal hormone therapy could account for an estimated 17,500 fewer ER-positive invasive breast cancer cases annually among women aged 50 to 69 years.[59]

This testimony on "excess breast cancers" was the subject of numerous oral and written motions. At the close of Dr. Parisian's punitive damages phase testimony, Defendants argued that this "learned treatise" was not properly authenticated by Dr. Parisian.[60] Plaintiff argued that the article was authenticated by Dr. Austin -- an epidemiologist and Plaintiff's "general causation

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[56]Doc. No. 566.

[57]Karla Kerlikowske, et al., *Declines in Invasive Breast Cancer and Use of Postmenopausal Hormone Therapy in a Screening Mammography Population*, 100 J. OF THE NAT'L CANCER INST. 599 (2008).

[58]March 3, 2008, Tr. at 2722.

[59]March 3, 2008, Tr. at 2722.

[60]March 5, 2008, Tr. at 2837-2838

expert" -- during the compensatory damages phase of trial.[61] While the article may have been authenticated by Dr. Austin, Plaintiff did not establish that Dr. Parisian was qualified to interpret it.[62] The evidence from this learned treatise is epidemiologically based and relates to causation; both are outside the scope of Dr. Parisian's qualifications -- again, FDA regulations were her designated forte.[63]

"A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty. That would not be responsible science."[64] According to the Advisory Committee notes to Federal Rule of Evidence 803(18), a learned treatise may be admitted as substantive evidence only when "an expert is on the stand and available to explain and assist in the application of the treatise . . . ."[65] As a regulatory expert, Dr. Parisian could not "explain and assist in the application" of the Kerlikowske article to this case. Additionally, Dr. Parisian gave no indication that she relied on the article in forming her regulatory opinions. Accordingly, Dr. Parisian should not have been permitted to read portions of the Kerlikowske article into evidence, and her testimony regarding the Kerlikowske article should have been excluded.

j. CME "Myths and Misperceptions" Handout (Plaintiff's Ex. 427)

This exhibit is a CME course handout titled "Myths and Misperceptions, Breast Cancer and HRT" from September, 1998. Dr. Parisian testified that the FDA would have no ability to

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[61]Doc. No. 652.

[62]During a sidebar, I responded that Defendants' objections made me very uncomfortable and made me think I had made pretty clear error. I concluded "I'm going to overrule your motion at this time. I've got it under advisement still." See March 5, 2008, Tr. at 2838.

[63]An expert must establish the trustworthiness of a treatise as viewed by professionals in that field.

[64]*Dura Automotive Systems of Indiana v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002).

[65]FED. R. EVID. 803(18).

restrict these types of CME activities. Since the FDA could not restrict these activities, there was no evidence that Wyeth's actions violated FDA regulations. Accordingly, Dr. Parisian's interpretation of the exhibit was unnecessary.

Furthermore, when Plaintiff used this exhibit, Wyeth objected to "lack of foundation" because the exhibit was "not a Wyeth document."[66] The objection was sustained, but Plaintiff continued to use the document. Allowing further testimony after I sustained the objection was error. It appears that I had my mind in neutral at this point. The testimony regarding this document should not have been admitted.

k. March 4, 1999 Grants Authorizations (Plaintiff's Ex. 5733)

Through Dr. Parisian, Plaintiff introduced Wyeth's finance committee's March 4, 1999 authorization for awards and grants, but all Plaintiff's counsel did with the exhibit was read a few of the names of the organizations on the list.[67] There was no connection between this exhibit and FDA regulations. In fact, the "FDA doesn't have regulations about unrestricted grants."[68] I should have excluded this testimony by Dr. Parisian.

l. Ghostwriting

Dr. Parisian testified that the FDA would not be aware of ghostwriting,[69] and she provided no testimony linking FDA regulations and ghostwriting. Accordingly, I should not have permitted Dr. Parisian to testify on this topic.

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[66]March 3, 2008, Tr. at 2726.

[67]*Id.* at 2728.

[68]Feb. 20, 2008, Tr. at 2345.

[69]March 3, 2008, Tr. at 2729.

m. 1970 Upjohn "Dear Doctor" Letter (Plaintiff's Ex. 5785)

This November 19, 1970 Upjohn "Dear Doctor" letter informed physicians that Upjohn's oral contraceptive, Provest, had been shown to be connected with the "appearance of mammary nodules in beagle dogs exposed to multiples of the human dose of the progestational component for a prolonged period of time."[70] Upjohn relayed to physicians that "[a]ll available clinical data suggest no reason to predict human extrapolation of this finding nor is there any way of disproving that this can occur in the human."[71] Using this exhibit, Dr. Parisian testified only that Upjohn could have arrived at a different conclusion based on the data, and Upjohn could have done its own study to determine the validity.[72] This is more argument than expert testimony. Furthermore, there was no testimony that Upjohn's decision not to conduct a study to refute the beagle dog findings violated any FDA regulations or breached any duty Upjohn might have to test. Dr. Parisian's assessment of this document lacked any regulatory expertise, and I should have excluded the testimony.

n. July 21, 1992 HRT Scientific Review: Executive Session Summary (Plaintiff's Exs. 11011 and 11012)

Through Dr. Parisian, Plaintiff introduced an Upjohn internal memorandum and attachment that described the company's desire to get indications for HRT uses and its strategy going forward. Dr. Parisian simply read a few sections from the document. Since she provided no testimony regarding FDA regulations,[73] the testimony should have been excluded.

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[70]Plaintiff's Ex. 5785.

[71]*Id.*

[72]March 3, 2008, Tr. at 2731-2732.

[73]March 3, 2008, Tr. at 2736-2739.

3. Necessity of Expert to Distill of Voluminous Documents

In pre-trial briefs and hearings, Plaintiff argued that an expert like Dr. Parisian was necessary to review and summarize documents and "give the jury the tools they need to look at those documents, [and] understand them in the context of a regulatory background."[74] Plaintiff asserted that "Dr. Parisian's testimony and use of internal company document [would] educate the jury, not merely duplicate counsel's closing argument."[75] Plaintiff pointed out that in other bellwether trials I ruled that this was acceptable for trial.[76] In this case, the Court[77] ruled: "A purely factual recitation of the history of Provera, and its progression as a drug to be used in conjunction with estrogen to treat menopausal symptoms is relevant to show the environment in which [Defendants] operated."[78] The purpose for allowing such testimony was efficiency, and the summary of the documents was to be "purely factual."

Repeatedly, Plaintiff has argued that "[d]istilling voluminous documents is proper" for an expert -- but I do not believe the 22 or so documents introduced through Dr. Parisian during the punitive damages stage can be considered "voluminous." But more importantly, and contrary to Plaintiff's position during the *Daubert* hearing, and during he punitive damages stage, Dr. Parisian, generally, did not "give the jury the tools they need to look at those documents, [to] understand them in the context of a regulatory background"[79] -- she simply read the documents to the jury.

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[74]Nov. 5, 2007, Tr. at 113.

[75]Doc. No. 175.

[76]Nov. 5, 2007, Tr. at 113 and Doc. No. 175.

[77]I say "the Court," because this Order was entered by Judge Jones.

[78]Doc. No. 340.

[79]Nov. 5, 2007, Tr. at 113.

I cannot accept Plaintiff's position that Dr. Parisian "didn't just read a document," but "tie[d] pieces of the puzzle together."[80] To the contrary, Dr. Parisian usually read selected portions of documents in evidence, without further comment. I did not anticipate that documents would be admitted via Dr. Parisian so that she could simply engage in recitation of those exhibits; jurors are capable of reading documents. Ironically, on cross-examination, Dr. Parisian, on at least one occasion, took the position that the document "speaks for itself."[81]

If an expert does nothing more than read exhibits, is there really any point in her testifying as an expert? As was seen during the punitive damages stage, the use of the "regulatory expert" to deal with large volumes of documents is subject to abuse. The expert did not explain the documents, provide summaries, or tie them in to her proposed regulatory testimony. Dr. Parisian did not provide analysis, opinion, or expertise.

4. Applying FDA Regulations to the Facts

In response to Defendants' Motion to Exclude Dr. Parisian's testimony regarding FDA regulations -- filed before Dr. Parisian testified during the punitives phase -- Plaintiff asserted that Dr. Parisian "will testify further, what those [FDA] regulations require <u>in a particular set of facts and circumstances</u>. Dr. Parisian will also testify that the regulations were violated under this set of facts."[82] She did neither. As discussed in detail above, Dr. Parisian often did nothing, or little, more than read exhibits.

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[80]May 9, 2008, Tr. at 41.

[81]March 3, 2008, Tr. at 2794.

[82]Doc. No. 589 (emphasis in original).

5. Summary

Federal Rule of Evidence 702 permits expert testimony to assist a jury in understanding technical or scientific evidence. Dr. Parisian was designated to testify on regulations and the standards and practice in the industry based on her experience. Yet, Dr. Parisian's punitive damages stage testimony was hardly expert in nature. The question and answer sessions merely paid lip service to Dr. Parisian testifying from an expert standpoint.

The Advisory Committee notes to Federal Rule of Evidence 702 read: "If the witness is relying . . . primarily on experience, then the witness must explain how that experience is a sufficient basis for the opinion and how that experience is reliably accurate to the facts." In pretrial hearings, Judge Jones and I both expressed concern regarding whether Dr. Parisian met this requirement (as evidenced by the repeated requests for citations and explanations[83]). After hearing Dr. Parisian's testimony in the punitive damages phase and reviewing it post-trial, I realize that our concerns were warranted.

Dr. Parisian's punitive damages stage testimony reveals "how vital it is that judges not be deceived by the assertions of experts who offer credentials rather than analysis."[84] "An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process."[85] Expert opinion must be just that -- expert opinion drawn from a special expertise. Opinion given through the mouth of an expert does not necessarily make it expert opinion.

During the punitive damages stage of the trial, Dr. Parisian's testimony tracked Plaintiff's legal arguments, and there was very little significant analysis. On numerous occasions, Dr. Parisian declared "this isn't fair and balanced," but she provided no explanation. Dr. Parisian,

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[83]Doc. Nos. 340, 389, and Nov. 14, 2008 email Correspondence from the Court.

[84]*Minasian v. Standard Chartered Bank, PLC*, 109 F.3d 1212, 1216 (7th Cir. 1997) (citations omitted).

[85]*Id.*

no doubt has special knowledge and skill regarding FDA operations and regulations, but she did not apply this knowledge and skill to her testimony.

When Dr. Parisian actually elaborated on documents, her testimony did "no more than counsel for plaintiff [did] in argument, *i.e.*, propound a particular interpretation of [defendant]'s conduct."[86] Having an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony. Because Dr. Parisian's testimony -- or reading -- invaded areas that required no expert assistance, it was inappropriate "expert" testimony.[87]

Since Dr. Parisian testified as to the bottom line without any explanation, failed to provide expert analysis, testified beyond limitations established by pretrial orders, testified in areas beyond her expertise, and invaded areas that required no expert testimony, most of Dr. Parisian's punitive damages testimony should have been excluded.

B. Sufficiency of Evidence During Punitive Damages Stage

Excluding the testimony I erroneously allowed in through Dr. Parisian, Plaintiff did not produce sufficient evidence to create an admissible issue under the clear and convincing standard required for punitive damages.

The Arkansas Supreme Court has approached punitive damages with caution: "If punitive damages are improperly awarded, the defendant suffers far more than a plaintiff does if the jury incorrectly fails to give him a windfall."[88] In Arkansas, "an award of punitive damages is justified only where the evidence indicates that the defendant acted wantonly in causing the

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[86] *In re Rezulin*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) ("[E]xperts should not be permitted to 'supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence.'").

[87] *Id*. at 541.

[88] *Nat'l Bank of Commerce v. McNeill Trucking Co., Inc.*, 828 S.W.2d 584, 589 (Ark. 1992) (Dudley, J., concurring).

injury or with such a conscious indifference to the consequences that malice may be inferred."[89] To justify an award of punitive damages, "it must appear that the negligent party knew, or had reason to believe, that his act of negligence was about to inflict injury, and that he continued in his course with a conscious indifference to the consequences, from which malice may be inferred."[90] Arkansas law requires an "element of willfulness or such reckless conduct on the part of the defendant as is equivalent thereto."[91] "Gross dereliction of duty does not warrant punitive damages."[92]

In the punitive damages stage, Plaintiff's burden was to establish, by clear and convincing evidence, that Defendants knew or should have known that their negligent failure to warn (which, based on the compensatory damages phase testimony, included a duty to test) of the risks associated with ERT/HRT use and breast cancer would result in injury, and that Defendants continued the conduct with wantonness or reckless disregard from which malice can be inferred.

During opening statements of the punitive damages stage, Plaintiff's counsel argued the evidence would establish that:

> Wyeth and Upjohn failed to follow up on the red flags that showed that this product was causing breast cancer, they failed to get the proper answers by going out and studying the drugs, and they failed to give the doctors and the women accurate information. And then finally, they failed to market the product appropriately.[93]

Yet, the evidence Plaintiff presented was an extension of the liability arguments that amounted to no more than negligence. The record, absent erroneously admitted information,

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[89]*Union Pacific R.R. Co. v. Barber*, 149 S.W.3d 325, 343 (Ark. 2004) (citing cases).

[90]*Id.*

[91]*Id.*

[92]*Orsini v. Larry Moyer Trucking, Inc.*, 833 S.W.2d 366, 368 (Ark. 1992); see also *Alpha Zeta Chapter of Pi Kappa Alpha Fraternity by Damron v. Sullivan*, 740 S.W.2d 127, 132 (Ark. 1987) ("Negligence alone, however gross, is not enough to sustain punitive damages.").

[93]March 3, 2008, Tr. at 2649.

reflects insufficient evidence of wantonness, willfulness, or reckless disregard from which malice could be inferred.

1. Summary of Punitive Damages Evidence Against Wyeth.

Plaintiff's argument for punitive damages can be summarized as follows: In 1976 Wyeth was aware of the Hoover Study, which suggested a link between estrogen use and breast cancer. The endometrial cancer crisis also occurred around this time, and Wyeth should have seen it as a wake-up call to commence looking into the relationship between estrogen use and breast cancer. Wyeth knew that physicians were prescribing estrogen and progestin together, and it should have realized that if E-alone causes cancer in one reproductive organ, the addition of progestin could cause cancer in similar organs. Wyeth "knew" adding progestin to estrogen could increase the risk of breast cancer.

Wyeth knew more study was needed, but took a passive role in conducting studies. When Wyeth considered initiating the Prempak Study, Wyeth was concerned that the study might not be successful and could be "embarrassing." Wyeth never completed the Prempak Study.

Wyeth responded to studies associating ERT and HRT use with breast cancer by downplaying the studies and promoting the benefits of ERT and HRT. Specifically, Wyeth used public relations firms, "friendly organizations to which it gave millions of dollars, friends who spoke favorably about its products, marketing, press manipulation or even ghostwriting" to counter studies (and media) reporting a link between HRT and breast cancer.[94]

[94]Doc. No. 652.

a. Wyeth Knew About Studies Linking Breast Cancer and Estrogen

Plaintiff argued that in 1976 Wyeth was aware that the Hoover Study[95] suggested a link between estrogen use and breast cancer, but "did nothing" in response.[96] This argument is contrary to the evidence in the record. Wyeth acknowledged the Hoover Study and determined that the suggestion of a link between estrogen use and breast cancer "required further evaluation and monitoring, which is what [Wyeth] did."[97] Additionally, Wyeth took the position that it "need[ed] to know all there is to know, both good and bad, about all available studies having a bearing" on the connection between estrogen use and breast cancer.[98] Wyeth recognized that it may need to "shift their efforts to the development of a protocol for a study on mammary cancer."[99]

Three months later, in June of 1976, Wyeth noted that "there have been and are numerous epidemiological studies on the clinical effects of long term estrogen therapy," but concluded that the "studies on estrogen-breast cancer relationships . . . show[ed] no significant increase in the relative risk."[100] Wyeth concluded that "[t]he fact that no recent significant increase in breast cancer has been reported can be taken as an indirect indication that estrogens do not cause an

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[95]Dr. Hoover wrote a letter to Wyeth that reads:

> Enclosed is a confidential copy of a manuscript which will be published . . . This study forms the basis for my . . . statement that I had evidence which I interpreted as indicating that menopausal estrogens may be a risk factor for breast cancer as well as for endometrial cancer. As you can see, the findings for breast cancer are certainly not as clear-cut as those for endometrial cancer . . . I believe it does indicate that there may be a problem, that certainly needs more intensive study.

Plaintiff's Ex. 31.

[96]Doc. No. 652.

[97]Feb. 7, 2008, Tr. at 504.

[98]Plaintiff's Ex. 26.

[99]*Id.*

[100]Plaintiff's Ex. 28.

increase in breast cancer" and that "[e]strogen use does not appear to bring about an increased risk of breast cancer."[101]

In sum, Wyeth's response to the 1976 study suggesting a link between estrogen use and breast cancer -- recognition of a possible connection and follow-up research -- illustrated neither a passive response nor reckless indifference that would infer malice.

b. Endometrial Crisis Should Have Been A Wake-Up Call

In post-trial briefing, Plaintiff asserted that the "endometrial cancer crisis should have been a wake-up call to Wyeth. If E-alone cause[d] cancer in one reproductive organ, the addition of a new hormone, progestin, could cause cancer in another such organ."[102] I do not recall any expert testifying that, because Wyeth was aware that hormones may cause cancer below the waist, it should have known that hormones could cause cancer above the waist. Without scientifically supported evidence, this statement is nothing more than argument. Even if Plaintiff's position was supported by some evidence, the record reflects that Wyeth reviewed the available science and considered the issue.[103]

c. Wyeth Knew That Adding Progestin Could Increase Risk

In its post-trial brief, Plaintiff argued that "Wyeth knew that the addition of a progestin could increase the incidence of breast cancer";[104] but the brief lacked a citation to evidence that Wyeth "knew" progestins could increase the incidence of breast cancer. Based on the record, what Wyeth "knew" was that "[t]he possible role of progesterone in the etiology of breast cancer

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[101]Plaintiff's Ex. 28 (emphasis in original).

[102]Doc. No. 652.

[103]Plaintiff's Exs. 28, 117, and 1057.

[104]Doc. No. 652.

is another area that need[ed] clarification."[105] Additionally, the fact that as late as the mid-1990s the medical community believed that adding a progestin to an estrogen would protect against breast cancer, in the same way it protected the uterus, rebuts Plaintiff's unsupported assertion that Wyeth "knew" just the opposite.[106] Accordingly, Plaintiff's argument that Wyeth knew the addition of a progestin could increase the incidence of breast cancer was unsupported by any significant evidence.

d. Wyeth Knew More Study Was Needed, But Took a Passive Role

Plaintiff asserted that in 1977, Wyeth knew that "more study was needed on the combination product."[107] Dr. Parisian testified that Wyeth took a "passive role" in response to the endometrial cancer crisis.[108] She also testified that Wyeth had a passive attitude in its response to breast cancer: "Instead of doing scientific studies addressing the risks, they took another route in terms of trying to deal with the problem."[109] Notably, Wyeth objected that Dr. Parisian was "not competent to talk about Wyeth's attitude,"[110] and I overruled the objection. On reflection, this was error.

Plaintiff relied on Plaintiff's Exhibits 22 and 24 for this testimony. However, above I determined that since Dr. Parisian did not connect her testimony on these documents to FDA regulations, the testimony and exhibits should not have been admitted. That being so, there is no evidence to support Plaintiff's position.

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[105]Plaintiff's Ex. 28.

[106]Feb. 6, 2008, Tr. at 458-459; Feb. 8, 2008, Tr. at 850-852; Feb. 15, 2008 Tr. at 1811-1812.

[107]Doc. No. 652.

[108]March 3, 2008, Tr. at 2685.

[109]*Id.*

[110]*Id.* at 2684-2685.

e. The Prempak Study

Wyeth began studies of the estrogen and progestin combination in the early 1980s.[111] Specifically, in 1983, Wyeth initiated the Prempak Study. Plaintiff's critique of the Prempak Study was minimal -- she introduced speculative evidence regarding "embarrassment," pointed out that someone wanted to peek at the data, and emphasized that the study was not completed. I will address each of these in turn.

i. Study Results Could be Embarrassing

A September 22, 1983, Wyeth internal correspondence titled "PREM-PAK: Desired Labeling and Indications" reads, in part:

> An underlying consideration concerning our overall approach to the FDA concerning PREM-PAK has been the importance of avoiding the problems which could arise if the FDA were to take the position that PREM-PAK is equivalent to a combination drug product of the type requiring demonstration that the combination does more than its components in regard to each indication for the combination product. To attempt such demonstration would be very costly, would take many years, and might in the end not prove successful. In fact, the results of the studies that would be needed could turn out to be embarrassing.[112]

Plaintiff asserted that this exhibit "goes to the heart of this issue of whether or not [Wyeth] had reckless disregard."[113] However, Dr. Parisian's testimony about the exhibit, given during the compensatory damages stage, was limited:

> Q: And what could be embarrassing, from your standpoint as an FDA reviewer, if they did studies?
> A: Well, it would be embarrassing, perhaps, if the results weren't positive and you didn't get approved.[114]

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[111]Feb. 6, 2008, Tr. at 441-442.

[112]Plaintiff's Ex. 69.

[113]March 3, 2008, Tr. at 2649.

[114]Feb. 12, 2008, Tr. at 1286.

Plaintiff argued that this exhibit established that Wyeth was aware that a study might reveal that breast cancer could result when progestin is added to estrogen;[115] however, she provided no evidence to support this position. During trial, Wyeth explained that the exhibit:

> is talking about the FDA combination drug policy, which typically when you combine two products together into a combination, the first product has a certain degree of benefit or efficacy and the second product has a certain degree of benefit or efficacy. The expectation is that the combination would have a greater benefit, more efficacy, faster efficacy, better efficacy. In this instance, we were not putting the MPA or the progestin component to estrogen to make it more efficacious, to give it better effect, to relieve vasomotor symptoms faster or better, to improve bone better. It was there to protect the endometrium only.
>
> So what Dr. Perdue is saying is that if FDA or anyone were to expect that this particular combination would have better efficacy, it wouldn't, and so if one were to have that expectation, the results of the study might be embarrassing because it didn't provide greater efficacy. That was never the intent and was not the expectation.[116]

When considering the exhibit in context and based on the evidence as a whole, Plaintiff's position appears to be speculation. This evidence that Plaintiff claimed went "to the heart of this issue of whether or not [Wyeth] had reckless disregard," provided no support for her position on punitive damages.

ii. Someone Suggested Peeking at the Data

The Prempak Study's goal was to show that adding progestin to an estrogen would reduce the risk of endometrial hyperplasia.[117] Wyeth's summary of minutes -- from a meeting held in mid to late 1987[118] -- discussing the progress of the Prempak Study reads:

> Objective was to demonstrate that the presence of a progestogen did not add to the detriment of the product . . . Hope [the hyperplasia] is showing up in estrogen alone

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[115]May 9, 2008, Tr. at 44.

[116]Feb. 7, 2008, Tr. at 641.

[117]March 3, 2008, Tr. at 2687.

[118]The document is not dated, but the following is included: "No meeting on this project has been held in the last 12 months (May 1986)." Plaintiff's Ex. 95.

> group. If not, can [sic] kiss the product good-bye . . . Somebody should peek at the data when you reach a certain point. [Wyeth] hides the randomization code.[119]

Regarding testing, Plaintiff's counsel suggested that "it looks like [Wyeth] was doing the right thing, but somebody else within this system wanted to peek at the data."[120] As for peeking at the data, as noted above, Dr. Parisian testified only that "[w]e have to be careful peeking at the data because you can introduce bias . . . ."[121] She did not contend that "peeking at the data" was inappropriate or a violation of any regulations; she suggested only that you must be careful. Additionally, there was no testimony that Wyeth either peeked at the data or introduced bias.

iii. The Prempak Study Was Not Completed

Plaintiff pointed out that the Prempak Study was not completed. In 1988, the Prempak Study ended because of on-going difficulty obtaining participants.[122] No reckless disregard can be inferred from the fact that the study was never completed.

f. Refusal to Provide Drugs to ECOG (Plaintiff's Exs. 251 and 265)

During the compensatory damages stage, Plaintiff presented two internal Wyeth memos, dated December 8, 1993 and February 9, 1994, regarding Wyeth's refusal to supply Premarin in support of a proposed study by the Eastern Cooperative Oncology Group.[123] According to the documents, Wyeth would not provide drugs for the ECOG study "consistent with company policy."[124] While discussing the December 8, 1993 memo, Plaintiff's counsel argued that Wyeth's "company policy" in 1993 was "not to provide drugs to people that were doing studies

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[119]Plaintiff's Ex. 95.

[120]March 3, 2008, Tr. at 2688.

[121]*Id.*

[122]Feb. 15, 2008, Tr. at 1864.

[123]Plaintiff's Exs. 251 and 265.

[124]Plaintiff's Ex. 251.

on breast cancer."[125] The witness "absolutely disagree[d]" with this statement.[126] Using the February 9, 1994 memo, Plaintiff's counsel again attempted to get the witness to agree that Wyeth had a policy of not supporting breast cancer studies; again, the witness disagreed.[127] The witness later testified that Wyeth's "company policy" at the time was to not study ERT or HRT in patients who had previously been diagnosed with breast cancer, because this was a "contraindication"[128] for the products.[129]

In its post-trial brief, Plaintiff asserted that since Wyeth provided no document laying out "company policy," a jury has the right to infer that the policy was to not give drugs to breast cancer studies.[130] Plaintiff had the burden of proof, and the testimony was that Wyeth's "company policy" in 1993 was to not support the study because it involved a contraindication. Plaintiff presented no evidence to contradict Wyeth's explanation of the "company policy." Accordingly, the ECOG evidence provided no support for Plaintiff's claim that Wyeth took a passive role in conducting studies.

g. Prempro Pivotal Trial

In 1988, Wyeth submitted a draft to the FDA for what would become the Prempro Pivotal Trial.[131] The Prempro Pivotal Trial "monitored for safety risks, including breast cancer . . . ."[132]

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[125]Feb. 7, 2008, Tr. at 552.

[126]*Id.* at 553.

[127]*Id.* at 554.

[128]According to the Merriam-Webster on-line dictionary, in medicine, a contraindication is a condition or factor "that makes a particular treatment or procedure inadvisable." Available at: http://www.merriam-webster.com/dictionary/contraindication

[129]Feb. 7, 2008, Tr. at 625.

[130]May 9, 2008, Tr. at 45.

[131]Feb. 7, 2008, Tr. at 642. This study was a one-year, randomized controlled trial designed to "assess the impact on endometrial hyperplasia of the combination product." Feb. 7,

Plaintiff conceded that the Prempro Pivotal Trial studied for breast cancer, but argued that it was not long enough.[133] While this may be true, I do not believe this is evidence from which reckless disregard can be inferred.

h. Reaction to Adverse Studies and Media

According to Plaintiff, Wyeth's reactions to studies that suggested a link between breast cancer and hormone replacement therapy demonstrated Wyeth's conscious indifference. Plaintiff pointed out that Wyeth used public relations firms, "friendly organizations to which it gave millions of dollars," marketing, press manipulation, and ghostwriting to counter studies (and press reporting on the studies) that suggested a link between HRT and breast cancer.[134]

i. Public Relations Firms

Burson-Marsteller is a public relations firm that has worked for Wyeth since the 1980s.[135] Plaintiff devoted considerable time discussing numerous marketing and public relations suggestions that Burson-Marsteller submitted to Wyeth over the years.

According to Plaintiff, Burson-Marsteller's June 6, 1994 "Premarin & Wyeth-Ayerst Women's Health: Account Overview"[136] showed Wyeth's strategy of "pre-empting negative

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2008, Tr. at 644.

[132]*Id.* at 644.

[133]Feb. 7, 2008, Tr. at 590.

[134]Doc. No. 652.

[135]March 5, 2008, Tr. at 2897-2898.

[136]Plaintiff's Ex. 8019-A.

press [and] offer[ing] the media balanced information."[137] According to the document, this approach "[n]eutralized [the] impact of negative news linking ERT to range of health issues."[138] Dr. Parisian testified that if it were true that there was a link between the product and breast cancer, this approach would not be "fair and balanced . . . [and] it's the duty of the manufacturer to ensure the product is safe for that indication . . . ."[139] This exhibit referenced activities that occurred from 1989-1991, but, according to another Burson-Marsteller proposal, as late as 1995, there was "no definitive evidence associating breast cancer with estrogen . . . [and] the majority of epidemiological studies [showed] no association between the usual low doses used for ERT and breast cancer."[140]

In 1997, Burson-Marsteller suggested that "[i]n the world of ERT and breast cancer, misperceptions and confusion dominate the emotional issues surrounding breast cancer,"[141] and they wanted "to impact existing attitudes about breast cancer by promoting reality and debunking myths surrounding the issues," to get users or potential users away from the "misperceptions linking HRT and breast cancer."[142] The goal was to provide women with "the correct information on the relationship between breast cancer and HRT . . . ."[143] Dr. Parisian testified that Burson-Marsteller's proposal "wanted to create the desired perception of HRT and breast cancer was not known [sic], but I'm supposedly getting so many benefits that I will not

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[137]Plaintiff's Ex. 8019-A; March 3, 2008, Tr. at 2928.

[138]Plaintiff's Ex. 8019-A.

[139]March 3, 2008, Tr. at 2711-2712.

[140]Plaintiff's Ex. 5677.

[141]*Id.*

[142]*Id.*

[143]*Id.*

fear breast cancer anymore."[144] She said that the proposal "would not be acceptable" to the FDA because it was not "fair and balanced."[145]

In the proposal, Burson-Marsteller designated the Nurses' Health Study as one of "four primary barriers distorting reality" between breast cancer and HRT.[146] According to Dr. Parisian, if this was how Wyeth viewed the Nurses' Health Study, it should have updated its labeling and marketing to physicians or done a study to determine if there was a link between breast cancer and HRT.[147] Again, however, Dr. Parisian did not bottom her opinion upon FDA regulations -- her designated area of expertise.

Plaintiff also introduced an August 22, 1997 Burson-Marsteller proposal titled "Premarin Pre-emptive Plan."[148] Plaintiff's counsel pointed out that the plan wanted to "redefine Premarin's risk profile, [sic] breast cancer, demonstrate that Premarin is not a carcinogen."[149] Yet, there was no testimony explaining what this meant, or why it might be malicious.

Plaintiff presented a July 25, 1994 letter from Burson-Marsteller to Wyeth titled "Breast Cancer & ERT: Risk in Perspective Campaign -- Preliminary Recommendations."[150] However, the testimony relating to this document was not relevant to a punitive damages issue (I'm still puzzled as to why it was introduced).[151]

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[144]March 3, 2008, Tr. at 2715.

[145]*Id.*

[146]Plaintiff's Ex. 5677.

[147]March 3, 2008, Tr. at 2716-2717.

[148]Plaintiff's Ex. 1448.

[149]March 5, 2008, Tr. at 2829.

[150]Plaintiff's Ex. 1030.

[151]See March 5, 2008, Tr. at 2816-2820.

Plaintiff introduced Wyeth's 1991 "Premarin crisis preparedness plan."[152] According to the testimony, the document was a "mock exercise" for how "Wyeth could respond to issues."[153] There appears to be nothing per se wrong when a company prepares to respond to negative press.

Essentially, Plaintiff used the Burson-Marsteller documents to suggest that Wyeth's responses to negative media are inappropriate. But the evidence in the record established that Wyeth believed the "media sensationalize[d] negative events,"[154] and that the science conflicted with the media reports. Employing a public relations firm to counter the media is not, in itself, evidence of reckless disregard by the company; rather, it may be a business model employed by most corporations. According to the documents, Wyeth's goal was to put the "risk in perspective" and assure that the media provided "balanced" reports on the science regarding the link between HRT and breast cancer. This seems to be in line with Dr. Parisian's repeated phrase that the FDA requires information to be "fair and balanced." Plaintiff's point is that Wyeth countered the media, rather than embracing it and conducting studies. If true, on this record, it is evidence of, at most, negligence -- not clear and convincing evidence of reckless indifference by Wyeth.

ii. Donations to Friendly Organizations

According to Wyeth's finance committee's March 4, 1999 authorization, Wyeth authorized $18,114,725 for awards and grants as part of the annual budget.[155] The exhibit also listed each of the organizations receiving the awards and grants. Plaintiff emphasized the quantity and scope of Wyeth's donations, but Dr. Parisian conceded that Wyeth's support of

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[152]Plaintiff's Exs. 1187, 1188, 1190. See March 5, 2008, Tr. at 2898-2903, 2924-2925.

[153]March 5, 2008, Tr. at 2924.

[154]Plaintiff's Ex. 8019-A.

[155]Plaintiff's Ex. 5733.

ACOG, NAMS, and other medical associations was appropriate.[156] So, this exhibit provides no evidence of reckless indifference. And, as discussed above, I should not have permitted the exhibit to be introduced through Dr. Parisian.

iii. *Seasons* Magazine (Plaintiff's Ex. 154)

Wyeth's *Seasons* magazine was intended for "women taking Premarin with incentives to continue taking Premarin."[157] Plaintiff claimed that Wyeth used *Seasons* magazine to downplay the breast cancer risk while promoting the benefits of HRT.[158] According to Plaintiff, this evidence also goes to Wyeth's state of mind.[159]

In a February 25, 1991 letter, the FDA responded to Wyeth's *Season* magazine proposal, which Wyeth "plan[ned] to use in a direct-to-consumer program . . . ."[160] The "draft [was] submitted to the FDA in advance of and requesting permission to publish it."[161] The FDA believed that the proposed draft was "misleading in that the sponsorship [was] not clearly stated. It intentionally misleads the reader into thinking that her physician [was] somehow responsible for providing it to her."[162] The FDA also pointed out that there were "a number of other potentially false and misleading points in the submitted material."[163]

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[156]Feb. 13, 2008, Tr. at 1534-1535.

[157]Plaintiff's Ex. 154.

[158]Doc. No. 588.

[159]May 9, 2008, Tr. at 32.

[160]Plaintiff's Ex. 154.

[161]March 3, 2008, Tr. at 2749.

[162]March 3, 2008, Tr. at 2690.

[163]Plaintiff's Ex. 154.

According to Dr. Parisian, if "Wyeth wanted to do something like [the *Seasons* magazine ad campaign], they would have to clearly indicate that they are the source, and they are trying to sell their own products to the woman."[164] Wyeth responded to the FDA on February 25, 1991:

> It was not our intent to imply to consumers that Seasons [sic] magazine is a commercially available magazine being provided by her physician or pharmacist. We have, therefore, revised all components of the program to clearly state that the program and magazine are produced and distributed by Wyeth-Ayerst.[165]

Wyeth revised the *Seasons* magazine draft and resubmitted it to the FDA.[166] On August 19, 1991, the FDA informed Wyeth that it had "further discussed the revised [*Seasons* magazine] campaign," and had "no objections to [Wyeth] proceeding with this campaign."[167] In the ten years that Wyeth published *Seasons* magazine, the FDA never complained about an issue of *Seasons* magazine "as it was published to the public."[168]

Dr. Parisian only testimony on this exhibit was that when pharmaceutical companies distribute information, it should be clear that the pharmaceutical company was the source of the information, rather than a doctor or pharmacist.[169] The document did not provide proof of reckless indifference. Additionally, the April 16, 1991 letter from Wyeth to the FDA[170] reveals Wyeth's state of mind -- there's no need to speculate. Wyeth revised the draft to conform with

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[164]March 3, 2008, Tr. at 2693.

[165]Wyeth's Ex. 368.

[166]March 3, 2008, Tr. at 2750.

[167]Wyeth's Ex. 700; March 3, 2008, Tr. at 2750.

[168]March 3, 2008, Tr. at 2750-2751.

[169]*Id.* at 2692.

[170]Wyeth's Ex. 368.

the FDA's request, and "endeavored to clearly state throughout these pieces that the program and magazine are published and provided by Wyeth-Ayerst Laboratories, makers of Premarin."[171]

If this exhibit suggests malice or reckless disregard, the suggestion is weaker than a $2.00 suitcase -- it is not enough standing alone or with the other admissible evidence to create a submissible issue on punitive damages. Furthermore, I unable to discern or divine how this omission (failing to show who wrote the articles) relates to a failure to warn allegation. Regardless, as discussed in Section III(A)(2)(c) of this Order, I should have struck the exhibit and Dr. Parisian's testimony about the exhibit.

iv. Press Manipulation

In early 1990, Wyeth discovered that Dr. Graham Colditz was going to present a study relating Premarin and increases in the risk of breast cancer. Plaintiff introduced evidence that Wyeth's proposed strategy in response to the study was to "[b]e reactive on the cancer issue. Be prepared to take a responsive stance towards media covering the cancer story with accurate, full and balanced information on the issues presented in proper context."[172] Wyeth also considered "plans for publishing breast cancer study."[173] Neither of these actions, without more, support any inference of reckless disregard by Wyeth.

Plaintiff contended that the February 28, 2000 "Premarin -- Additional Marketing Budget" "show[ed] Wyeth's policy of funding to dismiss and distract the risk of breast cancer of E+P while expounding on the long term benefits of E+P . . . ."[174] Additional funds were needed because the current budget did

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[171]*Id.*

[172]Plaintiff's Ex. 1265.

[173]*Id.*

[174]Doc. No. 588.

> not adequately support the additional tactics needed to drive growth, particularly in light of the introduction of four new competitors . . . In addition, media attention on two recent publications have [sic] raised consumer awareness about the relative risk of breast cancer . . . Additional funds are needed to minimize the impact on growth or programs which focus on the role of estrogen in disease prevention and help put the small potential risk of breast cancer in perspective.[175]

This document does not bolster Plaintiff's claim for punitive damages. The fact that Wyeth increased the Premarin budget in an effort to "put the small potential risk of breast cancer in perspective" does not support a claim that Wyeth acted with reckless indifference. While "putting the risk of breast cancer in perspective" rather than doing an independent study may support a claim for negligence, it does not rise to the level required for punitive damages.

The record is replete with evidence that Wyeth wanted the media to present "balanced" information.[176] No malice or reckless indifference can be inferred from a company's desire to attempt to assure the media presents "balanced" information, especially when there is on-going debate on an issue.

v. Ghostwriting

Plaintiff focused heavily on the fact that Wyeth, through DesignWrite, collaborated with authors to have articles written about HRT in a process called "ghostwriting." In closing argument, Plaintiff asserted that ghostwriting is "exactly the type of conduct that necessitates punitive damages."[177] However, there is no evidence that this practice is inappropriate or that Wyeth supported articles that it knew were false or misrepresented the science. Rather, the articles supported Wyeth's position on the state of the science. Additionally, there was evidence

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[175]Plaintiff's Ex. 8151.

[176]Plaintiff's Ex. 1265; Feb. 7, 2008, Tr. at 619, 625; Feb. 12, 2008, Tr. at 1294, 1305; Feb. 20, 2008, Tr. at 2323, 2340; March 3, 2008, Tr. at 2711; March 5, 2008, Tr. at 2928, 2932, 2935, 2956-2957.

[177]March 6, 2008, Tr. at 3025.

that ghostwriting was a common practice in the industry.[178] In fact, Dr. Parisian conceded that she had done ghostwriting on behalf of Johnson & Johnson.[179]

Regardless of the bad inference Plaintiff placed on ghostwriting, it is apparently the norm in the industry,[180] and without evidence that Wyeth lied or misrepresented the science it chose to support, this evidence does not establish malicious behavior that would permit punitive damages. Additionally, this testimony was introduced through Dr. Parisian, but has no link to FDA regulations -- Dr. Parisian's area of expertise. And, if the inference of reckless disregard is raised, it is very weak. There is not enough to support submission to the jury taken alone or considered with all the other admissible evidence.

vi. Essner Launch Speech (Plaintiff's Exs. 6558, 6776)

Plaintiff contended that Bob Essner's (a Wyeth executive) April 4, 1995 Prempro "launch speech"[181] to the Wyeth sales team and his April 2, 1995 Prempro "launch speech"[182] showed "Wyeth's corporate policy to support and push E+P benefits long term without ever studying E+P long term" and how Wyeth dealt with "Prempro from a risk and benefit perspective."[183] During post-trial briefing, Plaintiff asserted that the launch speeches showed how "Wyeth illegally tried to hook postmenopausal women on E+P for the rest of their lives."[184] However,

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[178]Feb. 20, 2008, Tr. at 2343.

[179]Feb. 13, 2008, Tr. at 1533-1534.

[180]"[H]iring third-party professional writers and asking authors to sign those and asking those authors to be responsible for their content is very common practice." Feb. 20, 2008, Tr. at 2343.

[181]Plaintiff's Ex. 6776.

[182]Plaintiff's Ex. 6558.

[183]Doc. No. 588.

[184]Doc. No. 652.

when the Essner launch speeches are reviewed in context, they provides little support for Plaintiff's claims for punitive damages.

First, Plaintiff pointed out that nowhere in these launch speeches does Mr. Essner mention short-term use, breast cancer risk, or studies;[185] but, Plaintiff presented no evidence as to why these speeches would require reference to these specific topics. Additionally, according to the testimony, the sales organization "spent the next five days learning about the safety and efficacy of the product."[186]

Second, Plaintiff argued that Mr. Essner instructed the sales force to "thumb its nose at the FDA" and "improperly, if not illegally promote lifetime use for all women."[187] This conclusion is not supported by the evidence. Mr. Essner's comments were:

> [Dr. Healy] made the prediction that in the very near future there is going to be a revolutionary increase in the use of hormones to prevent and treat a variety of conditions in older women . . . [Dr. Healy said] that women starting on HRT at menopause and staying on it for the rest of their lives will become the rule, and that this will have a dramatic and positive effect on women's health . . . We have an opportunity to start the HRT revolution that Dr. Healy predicted. We can make real the full promise of HRT to create in the near future a world where the majority of women will start HRT at menopause and continue on it for the rest of their lives. A world where women will get the full medical benefit of replacing the estrogen lost after menopause and the full protective effect of MPA."[188]

Mr. Essner was quoting Bernadine Healy, the former head of NIH, and her opinion that all women should be on HRT. Additionally, nowhere in the speech does he tell the sales force to promote Prempro in this manner; rather, he's suggesting that things look good for Prempro in view of Dr. Healy's predictions on the future of HRT.

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[185]March 3, 2008, Tr. at 2707.

[186]March 5, 2008, Tr. at 2888.

[187]Doc. No. 652.

[188]Plaintiff's Ex. 6558.

Plaintiff also pointed out that Mr. Essner referenced Carrie Smith-Cox's (from Wyeth's marketing department) comments that "for Prempro and Premphase there are no boundaries, no limits."[189] The unrequited testimony regarding the meaning of "no boundaries, no limits" is that Mr. Essner wanted to get the sales force "fired up" about going all-out to promote Prempro;[190] the phrase was about the sales force's "selling effort."[191]

But, as discussed earlier in detail, I should have struck these two exhibits and Dr. Parisian's testimony about the exhibits.

vii. IARC Document (Plaintiff's Ex. 146)

Plaintiff contended that Wyeth wanted to "ensure that IARC [did] not develop a position on a definitive relationship between breast cancer and estrogen replacement therapy . . . ."[192] Plaintiff argued that this is "not appropriate,"[193] but Plaintiff provided no testimony to support this position -- only argument of counsel. In fact, the only point Plaintiff made with this exhibit (that wasn't in opening statement or closing argument -- which are not evidence) was that it referred to estrogen therapy alone.

There is no testimony that Wyeth's forming a task force to "provide the necessary information to IARC"[194] to support Wyeth's position that there was no definitive relationship between estrogen therapy and breast cancer is improper. If Wyeth believed that there was no "definitive association" between estrogen replacement therapy and breast cancer, why wouldn't

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[189]March 3, 2008, Tr. at 2707.

[190]March 5, 2008, Tr. at 2887.

[191]Plaintiff's Ex. 6776.

[192]Plaintiff's Ex. 146 (emphasis in original).

[193]March 3, 2008, Tr. at 2650.

[194]Feb. 7, 2008, Tr. at 547-548.

it attempt to gather science and convince IARC that there was no "definitive association" between the two?

2. Summary of Punitive Damages Evidence Against Upjohn

Plaintiff contended that Upjohn was liable for punitive damages because it conducted no studies and proposed no warnings to the FDA regarding the possible connection between Provera use and breast cancer. Plaintiff's position was:

As early as 1963, Upjohn should have been aware of the breast cancer risk related to Premarin, based on an abstract that was released. In 1966, the FDA rejected Upjohn's supplemental new drug application for "revised labeling to include the adjunctive use of [Provera] in hypoestrogenic states."[195] According to Plaintiff, when the FDA informed Upjohn that the "supplemental application [was] incomplete" because it "failed to include adequate clinical data . . .,"[196] Upjohn was on notice of its duty to test the relationship between Provera and breast cancer. In 1970, Upjohn knew that animal toxicology studies, involving a product that was different from Provera, but that contained medroxyprogesterone, reported that the subjects developed mammary nodules. But rather than test, Upjohn informed doctors that "[a]ll available clinical data suggest no reason to predict human extrapolation of this finding nor is there any way of disproving that this can occur in the human."[197] In the 1980s and 1990s, Upjohn promoted Provera as "the other half of estrogen replacement therapy," and the FDA scolded Upjohn when some advertisements attempted to promote Provera for indications (prevention of endometrial hyperplasia, osteoporosis) for which it was not approved. During this

[195]Plaintiff's Ex. 10388.

[196]*Id.*

[197]Plaintiff's Ex. 5785.

entire time, Upjohn never conducted its own study addressing the breast cancer in connection with HRT.[198]

a. 1963 Upjohn Memo (Plaintiff's Ex. 10388)

Plaintiff asserted that "Upjohn knew of the potential breast cancer risk at least by 1963,"[199] and should have started studying the drug. In June, 1963, Upjohn analyzed an abstract titled "Provera-induced hypercalcemia in women with advanced breast cancer."[200] But this document does not support Plaintiff's suggested inference. The uncontradicted testimony is that the report suggested progestin may have raised calcium levels in women who already had breast cancer.[201]

b. "The Other Half of Estrogen Replacement Therapy"

During the punitives stage, Plaintiff's punitive damages evidence against Upjohn focused primarily on correspondence between the FDA and Upjohn regarding advertising campaigns for Provera. Plaintiff argued that this evidence established a duty to test -- *e.g.*, "If a drug company advertises its products to be used in combination with another product, the company has a duty to study the two drugs in operation together."[202] The evidence was:

- **January 5, 1984 FDA Letter** -- The FDA requested "immediate cancellation" of an advertisement that "impl[ied] the use of Provera with estrogen replacement therapy except in those situations as described in [the] approved package insert."[203] The FDA also informed Upjohn that it recognized that the concurrent

[198]March 3, 2008, Tr. at 2738-2739; March 5, 2008, Tr. at 2813.

[199]Doc. No. 651.

[200]Plaintiff's Ex. 10910.

[201]Feb. 19, 2008, Tr. at 2199-2201 and 2226.

[202]Doc. No. 651.

[203]Plaintiff's Ex. 10154.

use of estrogen and progestin was becoming a more common practice, but that Upjohn needed to update its package insert before promoting Provera for such a use.[204]

- **September 10, 1985 FDA Letter** -- The FDA wanted ads titled "The other half of estrogen replacement therapy" removed from circulation, because the ads "present[ed] Provera as being safe and effective for the treatment and reversal of endometrial hyperplasia which [was] not an approved indication . . . ."[205] Plaintiff argued that this exhibit establishes that in 1985 Upjohn was aware that its product was being used with estrogen and was under a duty to test.
- **July 10, 1986 Letter** -- Upjohn informed the FDA that it planned to submit a proposal for a "convenience pack" for concomitant estrogen and progestin administration.[206] The FDA informed Upjohn that "there [was] not yet an indication for such combinations and the potential risks [were] not yet resolved."[207]
- **January 15, 1988 FDA Letter** -- Upjohn wanted Provera approved to oppose the endometrial effects of estrogen in menopausal women receiving estrogen replacement therapy. The FDA informed Upjohn that it "failed to provide substantial evidence consisting of adequate well-controlled studies . . ." that

[204] *Id.*

[205] Plaintiff's Exs. 10178 and 10155 (same document).

[206] Plaintiff's Ex. 10342.

[207] *Id.*

Provera will have this effect.[208] Dr. Parisian testified only that the FDA believed that there was insufficient evidence to support the indication Upjohn wanted.

- **October 30, 1990 FDA Letter**[209] -- This exhibit was admitted into evidence, but Plaintiff never discussed it with a witness.
- **October 31, 1990 FDA Letter**[210] -- The FDA informed Upjohn that it should voluntarily withdraw a promotional piece that suggested that combination estrogen and progestin therapy is indicated to reduce the risk of postmenopausal osteoporosis, because Provera was not indicated for that use.
- **November 13, 1990 FDA Letter** -- The FDA rejected Upjohn's proposed ads based on the ads' "emphasis . . . on 'menopausal therapy' rather than on an approved product indication."[211] On November 9, 1990, Upjohn informed the FDA that "the relevant promotion pieces and reprints [were] no longer being distributed by sales representatives."[212]
- **December 9, 1991 FDA Letter**[213] -- In response to a proposed advertisement from Upjohn, the FDA reminded Upjohn that Provera was not "indicated for use in postmenopausal replacement therapy for the prevention of endometrial hyperplasia."[214]

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[208]Plaintiff's Ex. 10166.

[209]Plaintiff's Ex. 10180.

[210]Plaintiff's Ex. 10179.

[211]Plaintiff's Ex. 3401.

[212]Upjohn's Ex. 928.

[213]Plaintiff's Ex. 10189.

[214]Plaintiff's Ex. 10189.

- **December 13, 1991 FDA Letter** -- The FDA informed Upjohn that referring to a postmenopausal patient as a candidate for using Provera is "potentially misleading to the reading regarding the indication for use of the product."[215]

Plaintiff asserted several purposes for this evidence. In pre-trial responses to Upjohn's objections to the exhibits, Plaintiff argued that the exhibits showed Upjohn's policy of promoting "Provera to be used in combination with Premarin without an indication or approval to do so."[216] According to Plaintiff, the advertisements "demonstrate[d] Upjohn's failure to study and to warn, and tie[] directly to FDA violations."[217] Plaintiff repeatedly argued that Upjohn calling Provera "the other half of estrogen [replacement] therapy" after being reprimanded by FDA amounted to conscious disregard on the part of Upjohn to follow the rules of the FDA.[218] And, again during the hearing on Defendants' Motions for JNOV, Plaintiff argued that the FDA "repeatedly admonished" Upjohn for advertisements promoting Provera as "the other half of hormone therapy" [sic].[219] But, in its opposition to Defendant's Motion for JNOV, Plaintiff argued that the advertisements "simply triggered Upjohn's duty to study."[220] Regardless of the intended purpose of the evidence, the evidence was merely an extension of the liability phase. At best, this evidence went to a duty to test, which was a compensatory damages stage issue.

If Plaintiff's final position is that the exhibits established a duty to test, then the exhibits are no help in determining punitive damages. First, as stated, this is a compensatory damages

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[215]Plaintiff's Ex. 10189.

[216]Doc. No. 588.

[217]Doc. No. 588.

[218]Feb. 19, 2008, Tr. at 2216; Feb. 14, 2008, Tr. at 1604-1605.

[219]May 9, 2008, Tr. at 55.

[220]Doc. No. 651.

stage issue. Second, Plaintiff conceded that "Upjohn was doing studies during this time frame of the endometrial effects of the combination drugs,"[221] but argued that Upjohn was not conducting the "right" studies.

To the extent that these exhibits are intended to establish Upjohn's alleged reckless indifference, the inference is not supported by the record. A review of the exhibits shows that the FDA's criticisms were quite specific. Never did the FDA criticize Upjohn's use of the phrase "the other half of estrogen replacement therapy"; rather, the FDA criticized the indications for use suggested by the advertisements. Specifically, the FDA scolded Upjohn for suggesting progestin prevented endometrial hyperplasia,[222] provided protection against osteoporosis,[223] and was safe and effective for treatment and reversal of endometrial hyperplasia.[224]

In summarizing these exhibits, Dr. Parisian testified that Upjohn was "ignoring the FDA" and "providing labeling that's misleading, that's false and misleading, with inadequate instruction for use."[225] This testimony is also essentially unsupported by the evidence. First, the documents involve advertising, not labeling. Second, there is no evidence establishing that Upjohn ignored the FDA. These letters were a dialogue between the FDA and Upjohn regarding appropriate advertising. The FDA informed Upjohn that an ad was "potentially misleading," and Upjohn changed the advertisements. Based on the sum of the testimony at trial, this is the normal course of business.

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[221]March 3, 2008, Tr. at 2734.

[222]Plaintiff's Ex. 10189.

[223]Plaintiff's Ex. 10179.

[224]Plaintiff's Exs. 10178 and 10155.

[225]March 3, 2008, Tr. at 2736.

Dr. Parisian elaborated that "Upjohn is not doing the clinical trials. If you want that indication, you need to do the clinical trials to support that indication and get approved . . . ."[226] But this doesn't establish malice, without evidence that Upjohn knew or should have known that ingesting progestin would cause breast cancer. At this time (mid 1980s) it was the standard of care in the medical community to prescribe Provera to prevent uterine bleeding and uterine cancer.[227] Although this was the standard of care, prevention of uterine cancer was not an approved indication.[228]

According to Dr. Parisian, if Upjohn "wanted that indication," it needed "to do a clinical study and submit an application to the FDA for approval."[229] Plaintiff asked "while we know that Upjohn was doing studies during this time frame of the endometrial effects of the combination, in all of the documents that you've reviewed, did Upjohn ever do any breast cancer studies during that time frame"; Dr. Parisian responded "No."[230] However, if Upjohn was relying on other breast cancer studies or data, this would not establish malice or reckless disregard.

Finally, if these exhibits were submitted under the negligence standard, they might pass muster for jury consideration, but not under the clear and convincing standard.

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[226]March 3, 2008, Tr. at 2736.

[227]*Id.* at 2790.

[228]*Id.* at 2791.

[229]*Id.* at 2733.

[230]*Id.*

c. Response to the Degge Group Findings

Plaintiff argued that Upjohn's response to the Degge Group findings "is the most telling proof of Upjohn's abject refusal to examine the breast cancer issue . . . ."[231] Following the release of the Bergkvist article,[232] Upjohn retained the Degge Group to conduct a review of the literature on the link between breast cancer and estrogen and progestin use.[233] Based on their review of the literature, the Degge Group determined that the "ultimate effect of progestins on the development of human breast cancer is still unclear . . . ."[234] The Degge Group also determined that additional study was needed, and listed numerous case control studies and cohort studies that were on-going.[235] This report was published in 1992.[236] Plaintiff argued that Upjohn did nothing in response to the Degge Group's report.[237] By "Upjohn did nothing," Plaintiff's point is that Upjohn failed to do an "in-house" study.[238] Dr. Parisian was asked "did Upjohn ever do one thing . . . to find out the effect of MPA in combination with estrogen on breast cancer," and she responded "No."[239]

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[231]Doc. No. 651.

[232]Dr. Parisian testified that the first study that she could recall showing an increased risk of breast cancer when progestins and estrogens are used -- as opposed to estrogen alone -- was the Bergkvist Study, which was published in 1989. However, Dr. Parisian admitted that Bergkvist was not statistically significant. Feb. 13, 2008, Tr. at 1449.

[233]Feb. 15, 2008, Tr. at 1455; Feb. 19, 2008, Tr. at 2167.

[234]Plaintiff's Ex. 10116.

[235]Feb. 19, 2008, Tr. at 2168; Plaintiff's Ex. 10116.

[236]Feb. 19, 2008, Tr. at 2167-2168.

[237]Doc. Nos. 166, 651.

[238]March 3, 2008, Tr. at 2738-2740; March 5, 2008, Tr. at 2986-2987, 2993.

[239]March 3, 2008, Tr. at 2738.

Plaintiff's focus on the fact that Upjohn did not do its own breast cancer studies is of no consequence. This is argument, unsupported by the evidence -- there is no evidence that Upjohn was required to conduct its own "in-house" study. Additionally, Dr. Parisian did not reference any FDA regulations that require a pharmaceutical company to conduct an "in-house" study. In fact, as the agreed-to jury instruction points out, Upjohn's duty was "to test or otherwise discover risk about which a manufacturer should warn."[240] The unrebutted evidence was that pharmaceutical companies can monitor and rely on the research of independent investigators, rather than conduct their own studies.[241] So, Plaintiff's argument regarding Upjohn's own, in-house study falls well-short of creating a jury issue under the clear and convincing standard.

3. Summary of Evidence During Punitive Damages Stage

In Arkansas, a punitive damages claim "is properly submitted to the jury . . . where the claim is supported by 'substantial evidence.'"[242] Since this case lacked substantial evidence, I should not have submitted the punitive damages issue to go to the jury. Plaintiff presented evidence of what, at first blush, might be considered unsavory practices (*e.g.*, ghostwriting, advertising, countering negative press, *etc.*), but it falls short of establishing a submissible jury issue.

Plaintiff's burden was to show, by clear and convincing evidence, that Defendants knew or should have known of the consequences of their actions, and in the face of this knowledge continued a course with such abhorrent indifference to the consequences that malice can be inferred. But the evidence in this case establishes, at most, negligence. Defendants were aware of an association between estrogen and endometrial cancer in the late 1970s. Defendants knew that physicians were starting to prescribe progestin with estrogen in an effort to protect the

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[240]Doc. No. 554 (emphasis added).

[241]Feb. 19, 2008, Tr. at 2214.

[242]*Morris v. Union Pacific R.R.*, 373 F.3d 896, 903 (8th Cir. 2004).

endometrium. In the late 1970s and early 1980s, the scientific community believed that prescribing progestin to women on estrogen reduced the risk of endometrial hyperplasia.[243] By 1983, ACOG and OB-GYNs endorsed this idea, and the position was held steadfastly throughout the 1980s, 1990s, and today.[244] Additionally, the medical community believed, throughout the 1980s and into the mid-1990s,[245] that progestin protected women taking estrogen from breast cancer.[246]

Plaintiff conceded that the breast cancer risk associated with estrogen plus progestin had not been accepted when she ingested the drugs, but argued that this "has no bearing on [Defendants'] failure to study."[247] While it may have no bearing on a failure to study, it goes to the heart of the punitive damages issue -- did Defendants know or should they have known?

Plaintiff asserted that had Defendants done the "right" studies, they would have uncovered the breast cancer risk long ago.[248] Again, this is compensatory phase argument; punitive damages require much more -- clear and convincing evidence of reckless disregard is a heavier burden. Plaintiff's attacks on the inadequacies of the studies relied on by Defendants provide little support for punitive damages. There was no evidence that Defendants knew the

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[243]Feb. 19, 2008, Tr. at 2136.

[244]March 3, 2008, Tr. at 2789.

[245]See Feb. 13, 2008, Tr. at 1461 (Dr. Parisian agreed that up until 1995, "there was still an operating assumption and belief that progestins would reduce the risk of breast cancer posed by estrogen alone . . . .").

[246]Feb. 19, 2008, Tr. at 2165, 2230. Dr. Gambrell published an article in 1983 that suggested a reduced risk of breast cancer in women who were on the combination of estrogen and progestins. Feb. 19, 2008, Tr. at 2210. Also, Dr. Dey testified that Wyeth conducted internal research, that it shared with the FDA, that "found that some of the components in Premarin protected against breast cancer." March 5, 2008, Tr. at 2896. This testimony was unimpeached.

[247]Doc. No. 651.

[248]*Id.*

studies they conducted or relied upon were inadequate to support their position on the breast cancer issue; and sufficient evidence of reckless disregard is missing.

Upjohn repeatedly attempted to get advertisements approved that suggested indications that had not been approved for Provera. Upjohn submitted the ads, the FDA reviewed the ads, and the FDA rejected them; this appears to be how the process works between the FDA and pharmaceutical companies. Evidence that the FDA scolded Upjohn four or five times, over 20 years, because its proposed advertisements were overly broad, does not establish reckless indifference -- this might be different had Upjohn acted contrary to the FDA's criticisms.

Wyeth used advertising to promote estrogen and progestin products. Wyeth also considered suggestion from a public relations firm on how to respond to studies that reflected poorly on its products and present the media with balanced report of the facts. These actions, standing alone or when considered with the other evidence in this case, do not establish reckless disregard.

Once again, to warrant punitive damages, Plaintiff's burden was to prove, by clear and convincing evidence, that: (1) Defendants knew or should have known, in light of the circumstances at the time, that not testing and warning would naturally and probably result in injury; and (2) Defendants continued to not test and warn with reckless disregard for the consequences from which malice can be inferred.[249] Plaintiff's evidence established neither.

CONCLUSION

Based on the findings of fact and conclusions of law above, Defendants' Motions to Strike Dr. Parisian's testimony from the punitive damages phase is GRANTED in PART, and

[249] *D'Arbonne Const. Co., Inc. v. Foster*, 123 S.W.3d 894 (Ark. 2003).

her testimony is STRUCK, as outlined above. Absent the improperly admitted testimony, there is insufficient evidence for a punitive damages award.

Because Plaintiff failed to present clear and convincing evidence warranting punitive damages, Defendants' Motions for Judgment as a Matter of Law (Doc. Nos. 637, 642) are GRANTED as to punitive damages, and the punitive damages awards are VACATED.

If Defendants' Motion for Judgment as a Matter of Law had not been granted, they, at least, would be entitled to a new trial on punitive damages. Accordingly, in the alternative, Defendants' Motion for New Trial is GRANTED.

Plaintiff's Motions for Taxation of Costs (Doc. No. 631) is DENIED without prejudice. The motion should forthwith be modified in consideration of this Order as well as the concessions Plaintiff made in her May 5, 2008 reply.[250]

Since I have a deep and abiding faith in randomly selected juries, I am always reluctant to set aside a jury finding. This jury was very attentive throughout. I admitted much evidence that should not have been admitted. The fault is mine alone.

IT IS SO ORDERED this 8th day of July, 2008.

/s/ Wm. R. Wilson, Jr.
UNITED STATES DISTRICT JUDGE

[250]Doc. No. 653.