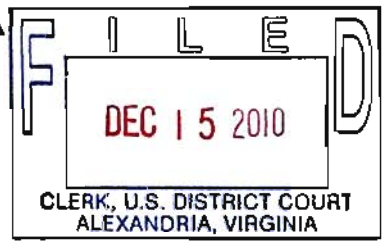
IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division



GEORGIA TORKIE-TORK,	)	
Plaintiff,	)	
	)	
v.	)	**No. 1:04cv945**
	)	
WYETH,	)	
Defendant.	)	

MEMORANDUM OPINION

In this removed diversity products liability matter, plaintiff claims defendant's hormone therapy product, Prempro, caused or aggravated her breast cancer. Because numerous suits of this nature were filed in many jurisdictions, the Judicial Panel on Multidistrict Litigation convened multidistrict litigation ("MDL") proceedings in the Eastern District of Arkansas, and this matter was transferred to that district for participation in the MDL proceedings, including general discovery. *See Torkie-Tork v. Wyeth*, No. 1:04cv945 (E.D. Va. Nov. 1, 2004) (Conditional Transfer Order). At the conclusion of MDL proceedings, the matter was returned to this district for all further proceedings, including case-specific discovery, summary judgment, and if necessary, a trial. *See Torkie-Tork v. Wyeth*, MDL No. 1507 (E.D. Ark. Apr. 8, 2010) (Conditional Remand Order). After disposition of various summary judgment motions,[1] two claims

[1] At the summary judgment stage, plaintiff conceded that under Virginia law, summary judgment was appropriate for Wyeth on the claims for strict liability for failure to warn, strict liability for design defect, negligent misrepresentation, and breach of express warranty. *See Torkie-Tork v. Wyeth*, No. 1:04cv945, — F. Supp. 2d —, 2010 U.S. Dist. LEXIS 106819 (E.D. Va. Oct. 4, 2010) (Memorandum Opinion) ("*Wyeth I*"). Wyeth also sought, and was granted, summary judgment on plaintiff's fraud claims. *See id.* (granting Wyeth summary judgment on the claim for fraudulent misrepresentation, but not for the claims of fraudulent concealment and negligent design defect); *Torkie-Tork v. Wyeth*, No. 1:04cv945, — F. Supp. 2d —, 2010 U.S. Dist. LEXIS 117592 (E.D. Va. Nov. 4, 2010)

remained for trial: (i) the claim that Wyeth negligently failed to provide an adequate warning of the breast cancer risks associated with Prempro, and (ii) the claim that Wyeth negligently designed Prempro with respect to the risk of breast cancer.

Among the myriad motions filed prior to trial was Wyeth's motion *in limine* to exclude any evidence concerning Wyeth's "fail[ure] to test . . . Prempro." Def. Mot. *in Limine* No. 12. This motion was denied; although plaintiff apparently was not asserting a separate claim for negligent failure to conduct additional studies of Prempro, it was unclear prior to trial whether evidence relevant to this issue might also be relevant to plaintiff's negligent failure to warn claim. Yet in the course of the trial, it became increasingly clear that plaintiff's counsel was eliciting testimony and presenting documents for the purpose of establishing and suggesting to the jury that Wyeth had negligently failed to conduct studies of Prempro, in addition to those required by the FDA, to assess more accurately any link between Prempro and breast cancer. Indeed, it became clear at this point in the trial that plaintiff intended to argue to the jury that Wyeth had a duty to conduct additional studies and that the failure to do so was part of the negligent failure to warn claim. For its part, Wyeth consistently argued that under Virginia law, a manufacturer had no duty to conduct studies or tests in these circumstances. Given the conflicting legal positions, the potential for jury confusion was manifest. Accordingly, to avoid jury confusion, it became necessary to resolve the question whether, under Virginia law, Wyeth has a duty to conduct additional tests or studies. This question was briefed and argued, and a bench ruling issued making clear that Virginia law, in the circumstances at bar, imposes no duty on a manufacturer to

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(Memorandum Opinion) ("*Wyeth II*") (granting Wyeth summary judgment on the remaining portion of the fraud claim, namely fraudulent concealment).

conduct additional studies or tests of its products. The jury was instructed accordingly, and this Memorandum Opinion elucidates this ruling.[2]

I.

Plaintiff Georgia Torkie-Tork is a citizen of Virginia. Defendant Wyeth is a Delaware corporation with its principal place of business in New Jersey. During times relevant to this litigation, Wyeth was one of the world's largest pharmaceutical companies[3] and the maker of Prempro, a hormone replacement therapy drug approved by the Food and Drug Administration ("FDA") for treatment of menopausal symptoms. Prempro is a combination hormone therapy drug consisting primarily of the hormones estrogen and progestin ("E+P").

Beginning in or about 1996, plaintiff began experiencing severe menopausal symptoms. To address these symptoms, plaintiff obtained and filled prescriptions for Prempro from three physicians at various times, although the evidence is in dispute as to when she first began taking Prempro and the length of time for which she took it.

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[2] Although not pertinent to the question addressed here, it is worth briefly noting developments in the case since the issuance of the bench ruling addressed here. Following completion of plaintiff's case in chief, Wyeth was granted judgment as a matter of law on plaintiff's design defect claim pursuant to Rule 50(a), Fed. R. Civ. P. *See Torkie-Tork v. Wyeth*, No. 1:04cv945 (E.D. Va. Nov. 30, 2010) (Order). A ruling on Wyeth's motion for judgment as a matter of law on plaintiff's punitive damages claim was initially deferred but ultimately granted at the conclusion of Wyeth's case in chief. *See Torkie-Tork v. Wyeth*, No. 1:04cv945 (E.D. Va. Dec. 2, 2010) (Order). Additionally, at the conclusion of Wyeth's case in chief, plaintiff won judgment as a matter of law on Wyeth's claim for contributory negligence. *Id.* Jury deliberations commenced on December 2, 2010, and the following day, the jury returned a unanimous verdict in favor of Wyeth, ruling that plaintiff had not proven, by the greater weight of the evidence, "that the warnings Wyeth provided to her prescribing doctor(s) were inadequate." *See Torkie-Tork v. Wyeth*, No. 1:04cv945 (E.D. Va. Dec. 3, 2010) (Jury Verdict). Given this finding, the jury neither reached nor decided questions of proximate causation or damages.

[3] Pfizer Inc. purchased Wyeth at some point since the filing of this action.

Plaintiff claimed she began taking the drug sometime in 1998, but the pharmacy records produced show prescriptions only as early as May 1999. In any event, the parties agree that she ceased using Prempro in June 2002. Thus, plaintiff contends she took Prempro continuously for four years, whereas Wyeth points out that pharmacy records show only about two and a half years of use.[4]

Plaintiff contends that three doctors prescribed her Prempro at various times. Only two of the asserted prescribing doctors testified at trial and neither specifically recalled prescribing Prempro to plaintiff. One of these doctors, William Hurwitz, employed plaintiff as a receptionist. During the pertinent period, Hurwitz specialized, not in gynecology, but in pain management medicine.[5] He also testified that it was his general practice to read and to rely on the warning labels for any drug before prescribing it to a patient, and that had he prescribed Prempro for plaintiff, which he does not specifically remember doing, he would first have read Prempro's warning label. Plaintiff's second testifying physician, Dr. Joel Schulman, is an internal medicine practitioner specializing in pulmonary medicine. Schulman testified that he served as plaintiff's internist and did not recall prescribing Prempro for plaintiff. Although he testified that it was possible he renewed an existing Prempro prescription for plaintiff, Schulman characterized that scenario as "highly unlikely," adding that it was his "general rule . . . not to prescribe [Prempro] initially" because he preferred for patients to rely on

[4] Plaintiff contends that many of her pharmacy records were destroyed in the ordinary course of business by the pharmacies and thus do not reflect her full prescription history.

[5] Hurwitz lost his license to practice medicine based on events that culminated in felony convictions for unlawful distribution and dispensing of controlled substances. Tr. 11/18/10 PM, at 219:16-220:12.

a gynecologist to determine whether hormone therapy is prudent in the patient's particular circumstances. Tr. 11/18/10 AM, at 61:17-25, 73:4-11.

The warning label for Prempro contained several statements regarding breast cancer, including the following:

> The majority of studies . . . have not shown [a breast cancer] association in women who have ever used estrogen replacement therapy. The effect of added progestins on the risk of breast cancer is unknown, although a moderately increased risk in taking combination estrogen/progestin therapy has been reported. Other studies have not shown this relationship.

See Wyeth I, 2010 U.S. Dist. LEXIS 106819 at *3-7 (discussing the Prempro label).[6] The parties' experts differed sharply on whether the Prempro warning label accurately and adequately disclosed the breast cancer risks associated with taking Prempro.[7]

The use of Prempro proved effective for the treatment of plaintiff's symptoms, and she continued using the drug until June 2002, at which time an abnormality was noted on her mammogram.[8] At the direction of Dr. Ronald Orleans, plaintiff's gynecologist, she immediately discontinued her use of Prempro, and a follow-up

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[6] In fact, at the time plaintiff was prescribed Prempro, the words "breast cancer" appeared in the Prempro entry of the Physician's Desk Reference at least 16 times.

[7] *Wyeth I*, in resolving summary judgment on plaintiff's fraud claims, addressed the accuracy of the Prempro warning label, concluding that no statement in the warning label was false in light of the existing science. 2010 U.S. Dist. LEXIS 106819 at *18-32. In particular, a statistical analysis of the relevant universe of scientific studies identified by both parties—with appropriate consideration of the studies' confidence intervals—confirmed that the Prempro label was not false in stating that the "majority of studies . . . have not shown [a breast cancer] association" for ever-use of estrogen replacement therapy. *Id.* at *19-25.

[8] A 1999 compression mammogram revealed a spot in plaintiff's left breast in the exact place where, in 2002, cancer was detected. Although the spot was not determined to be cancerous in 1999, plaintiff was advised to have annual mammograms thereafter. She did not thereafter undergo all annual mammograms prior to 2002, missing "one or two" mammograms because she claimed it was difficult fitting them into her work schedule. Tr. 11/23/10 PM, at 282:6-10; Tr. 11/24/10, at 67:17-68:20.

sonogram and needle biopsy were performed. Based on the results of these procedures, plaintiff was diagnosed with hormone receptor positive breast cancer on June 18, 2002. Thereafter on June 27, 2002, she underwent a partial mastectomy to remove the cancerous tissue. A pathology report signed on July 3, 2002 confirmed that the cancer was hormone receptor positive, meaning that the cancer was of a type that can be fueled by hormones such as those contained in Prempro. A surgical procedure on July 24, 2002 confirmed that the June 27, 2002 mastectomy had removed all cancerous tissue. The cancer has not recurred.

After plaintiff ceased taking Prempro, the Women's Health Initiative ("WHI") released results from a large-scale clinical trial of hormone therapy drugs indicating a 1.24 relative risk of breast cancer for those taking Prempro.[9] After publication of the WHI results, sales of Prempro dropped dramatically. The trial record reflects that Prempro continues to be sold, although with a new warning label. Wyeth's consistent contention has been that prior to the WHI study's release, scientific studies had been inconclusive regarding Prempro's breast cancer risk. At trial, plaintiff has contended that instead of allowing the breast cancer association to remain inconclusive until the WHI study was completed, Wyeth should have conducted further studies of Prempro on its own to ascertain the nature of the risk and to warn doctors accordingly.[10]

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[9] A relative risk of 1.24 means that, in general, women who take combination hormone therapy drugs like Prempro are 1.24 times as likely to be diagnosed with breast cancer as women who did not take such a drug. For example, if the general risk of breast cancer in a population is, as plaintiff's expert witness testified, 30 out of 1,000—meaning that without anyone taking Prempro, one would expect 30 women out of every 1,000 to develop breast cancer—then the introduction of Prempro would increase the risk to approximately 37 out of 1,000. Tr. 11/23/10 PM, at 190:23-191:1.

[10] It is worth noting that for purposes of winning FDA approval for Prempro, Wyeth conducted certain required studies. The FDA, in approving Prempro and its warning

II.

Analysis properly begins with the Supreme Court of Virginia's clearly-expressed view that products liability actions may take one of three forms. In this respect, the Supreme Court of Virginia noted specifically in *Morgen Industries, Inc. v. Vaughan*, 252 Va. 60, 65 (1996), that a product may be "unreasonabl[y] dangerous" for the purposes of a products liability action "if it is [i] defective in assembly or manufacture, [ii] unreasonably dangerous in design, or [iii] unaccompanied by adequate warnings concerning its hazardous properties." *Id.* at 65. At least one court has concluded that because there are only three recognized, independent bases for products liability actions in Virginia, a separate failure to test claim cannot stand. *See Sykes v. Bayer Pharms. Corp.*, 548 F. Supp. 2d 208, 215 (E.D. Va. 2008) (denying a failure to test claim, reasoning that because Virginia courts recognize only three types of products liability claims, "[b]y implication, any other type of product-liability claim cannot succeed.").

But this point does not alone suffice to dispose of the question whether under Virginia law Wyeth had a duty to conduct additional studies of Prempro beyond those required by the FDA such that its failure to do so amounted to a negligent failure to warn.

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label in 1994, concluded that the drug was safe and effective for its intended use based on then-existing scientific studies. The jury was properly instructed that this finding by the FDA was not conclusive as to whether this warning was adequate. *See* Tr. 12/2/10, at 202:14-203:1; *see also Wyeth v. Levine*, — U.S. —, 129 S. Ct. 1187, 1204 (2009); *Hill v. Searle Labs*, 884 F.2d 1064, 1068 (8th Cir. 1989)). Additionally, Wyeth also participated in post-FDA-approval studies. Specifically, Wyeth (i) supported the Women's Health Initiative by providing Prempro to all participants free of charge, and (ii) provided financial support for the Nurses' Health Study, a long-term, ongoing questionnaire-based study of women's health that collected data on, among other associations, the link between hormone replacement therapy and breast cancer. Nevertheless, solely for the purpose of resolving the present issue, this Memorandum Opinion proceeds on the assumption that plaintiff could, if permitted, adduce evidence that Wyeth had the resources to conduct further tests of Prempro to reveal the breast cancer risks with greater precision.

This question is resolved by the Supreme Court's further teaching in *Owens-Corning Fiberglas Corp. v. Watson*, 243 Va. 128 (1992). There, the Supreme Court of Virginia made unmistakably clear that a manufacturer's duty to warn of a product's dangers imposes no underlying duty to conduct additional studies or tests because a failure to warn claim rests on a *reason to know* standard rather than the broader *should have known* standard. *Id.* at 134-36. As Justice Hassell put it, speaking for a unanimous court, "[t]here is a significant legal difference between the phrases *reason to know* and *should know*"; the latter formulation may require a manufacturer to conduct additional studies while the former does not. *Id.* at 135.[11] Justice Hassell went on to make unmistakably clear that in a products liability action, including one for failure to warn, "the appropriate standard in Virginia is whether a manufacturer has a reason to know, not whether the manufacturer should know," of a product's dangerous properties. *Id.* at 136 (citing *Featherall v. Firestone*, 219 Va. 949, 962 (1979)). In reaching this result, the Supreme Court of Virginia struck a proper balance between the costs to manufacturers of additional studies and tests—costs which are subsequently passed onto consumers, often in the form of delays in releasing the product—and the benefits of bringing the drug to market expeditiously based on existing knowledge of the product's dangers.

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[11] The distinction between the two standards is clearly seen in other jurisdictions. For example, California recognizes both a strict liability failure to warn claim and a negligent failure to warn claim, with the critical distinction being that the negligence claim focuses on "what a reasonably prudent manufacturer would have known and warned about," while the strict liability claim centers on what dangers were "known or knowable" in light of then-existing science. *Carlin v. Superior Court*, 920 P.2d 1347, 1351 (Cal. 1996). While California and Virginia apparently employ the same knowledge standard in a negligent failure to warn claim, Virginia recognizes no strict liability claim for failure to warn. *See Harris v. T.I., Inc.*, 243 Va. 63, 71 (1992) (noting that strict liability is not recognized in Virginia).

Plaintiff seeks to avoid the plain meaning of the *Owens-Corning* opinion by arguing that the court's pronouncements are mere dicta. This argument is unpersuasive. To be sure, the *Owens-Corning* teaching was issued in an odd procedural context. The trial record in *Owens-Corning* indicated that the trial court instructed the jury to apply a should have known standard, and because neither party objected, the instruction became the "became the law of [the] case." *Id.* at 136. Nonetheless, notwithstanding the affirmance, the Supreme Court made clear that the instruction was in error and that a correct instruction should have been based on the reason to know standard. Nor was *Owens-Corning* the first Supreme Court decision to reach this conclusion; in the *Featherall* case, the Supreme Court of Virginia adopted the Restatement (Second) of Torts § 388 (1965) and its reason to know standard. *See Featherall*, 219 Va. at 962. Moreoever, the Supreme Court has relied on *Owens-Corning*'s discussion of the reason to know standard in various subsequent decisions. *See, e.g., Jones v. Ford Motor Co.*, 263 Va. 237, 253 (2002) (applying the reason to know standard in a negligent failure to warn case involving unintended acceleration in Ford vehicles).

In sum, there can be no serious doubt that the reason to know standard, as elucidated in the *Owens-Corning* opinion, applies here. Indeed, in the context of pharmaceutical drugs, as here, imposition of the reason to know standard is particularly sensible given the FDA already requires testing of any drug as a qualification for approval. Accordingly, evidence and testimony is not admissible for the purpose of establishing that Wyeth could have or should conducted additional tests of Prempro, and counsel must not be permitted to advance arguments in this regard. The only dangers for which Wyeth had a duty to warn adequately are those dangers which Wyeth knew or had

reason to know existed based on the science available at the time the product left Wyeth's hands. *Owens-Corning*, 243 Va. at 134-36.; *see also Morgen Indus.*, 252 Va. at 65 (discussing the elements of a failure to warn claim); *see also* n.7 *supra*.

The Clerk is directed to send a copy of this Memorandum Opinion to all counsel of record.

Alexandria, Virginia
December 15, 2010

/s/
T. S. Ellis, III
United States District Judge