UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

LEAH ROYCE HINES,

Plaintiff,

v. Civil Action No. 2:04-0690

WYETH, d/b/a Wyeth, Inc.;
WYETH PHARMACEUTICALS, INC.;
and PHARMACIA & UPJOHN COMPANY,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is (1) defendants' motion for partial summary judgment on plaintiff's breach of implied warranty claims, and (2) defendants' motion for partial summary judgment on plaintiff's design defect claims, both filed March 28, 2011.

I. Background

This is a pharmaceutical products liability action in which plaintiff Leah Royce Hines alleges that she developed breast cancer as a result of ingesting hormone replacement therapy ("HRT") medications. The facts recited below are largely undisputed. To the extent that a dispute exists, the facts are construed in the light most favorable to the plaintiff.

HRT, as the term is used here, consists of two medications: estrogen and progestin. Estrogen is used to treat

menopausal symptoms such as hot flashes, night sweats, and vaginal atrophy. Studies published in the late 1970s and early 1980s suggested that prolonged estrogen use could lead to increased risks of endometrial cancer (that is, uterine cancer). Later scientific articles indicated that using progestin together with estrogen could lower this risk significantly, while other publications found that combining the two drugs increased breast cancer risks. Based on the findings of this former set of articles, physicians in the 1980s began prescribing progestin in combination with estrogen to treat menopausal symptoms.

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

In the late 1980s, plaintiff's physician began prescribing HRT drugs to treat her menopausal symptoms. Her main symptoms were excessive perspiration, mood disturbances, hot flashes, and vaginal dryness. She testified that the drugs were effective in relieving her symptoms.

During the time period that plaintiff took HRT drugs, the products' labeling contained breast cancer warnings, which plaintiff asserts were inadequate. Plaintiff does not remember reading this labeling or receiving any printed information from her prescribers regarding Premarin, Prempro, and Provera. She instead relied on her doctor to independently weigh the risks and benefits of any medication before prescribing it to her.

Plaintiff was diagnosed with breast cancer in August 1999. She thereafter instituted this action on July 7, 2004, invoking the court's diversity jurisdiction.[1] Her complaint asserts claims against defendants for negligence, strict liability (design defect and failure to warn), and breach of implied warranties.

Defendants have moved for partial summary on plaintiff's implied warranty claims, asserting that (1) the undisputed facts show that defendants' HRT drugs were fit for their "ordinary purpose" of alleviating menopausal symptoms; (2) plaintiff had a general rather than "particular purpose" for her

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

use of hormone therapy; and (3) plaintiff cannot show reliance. (Defs.' Mot. Summ. J. on Warranty ("Warranty MSJ") at 1). Defendants also moved for partial summary judgment on plaintiff's design defect claims, contending that (1) plaintiff cannot prove specific causation, and (2) plaintiff has not proposed true alternative designs of Premarin-plus-Provera, but instead different products altogether. (Def.'s Mot. Summ. J. on Design Defect ("Design Defect MSJ") at 1).

II. Motions for Partial Summary Judgment

A. Governing Standard

A party is entitled to summary judgment "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Material facts are those necessary to establish the elements of a party's cause of action. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

A genuine issue of material fact exists if, in viewing the record and all reasonable inferences drawn therefrom in a light most favorable to the non-moving party, a reasonable fact-finder could return a verdict for the non-movant. Id. The

moving party has the burden of showing -- "that is, pointing out to the district court -- that there is an absence of evidence to support the nonmoving party's case." Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). If the movant satisfies this burden, then the non-movant must set forth specific facts as would be admissible in evidence that demonstrate the existence of a genuine issue of fact for trial. Id. at 322-23. A party is entitled to summary judgment if the record as a whole could not lead a rational trier of fact to find in favor of the non-movant. Williams v. Griffin, 952 F.2d 820, 823 (4th Cir. 1991).

A court must neither resolve disputed facts nor weigh the evidence, Russell v. Microdyne Corp., 65 F.3d 1229, 1239 (4th Cir. 1995), nor make determinations of credibility. Sosebee v. Murphy, 797 F.2d 179, 182 (4th Cir. 1986). Rather, the party opposing the motion is entitled to have his or her version of the facts accepted as true and, moreover, to have all internal conflicts resolved in his or her favor. Charbonnages de France v. Smith, 597 F.2d 406, 414 (4th Cir. 1979). Inferences that are "drawn from the underlying facts . . . must be viewed in the light most favorable to the party opposing the motion." United States v. Diebold, Inc., 369 U.S. 654, 655 (1962).

B. Implied Warranties

West Virginia law provides for two types of implied warranties: (1) the implied warranty of merchantability, and (2) the implied warranty of fitness for a particular purpose. See W. Va. Code §§ 46-2-314, 46-2-315. Plaintiff contends that defendants breached both of these implied warranties.

1. Implied Warranty of Merchantability

Section 46-2-314 of the West Virginia Code, which is adopted from the Uniform Commercial Code ("U.C.C.") § 2-314, states that "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." W. Va. Code § 46-2-314(1). For goods to be "merchantable," they must be, among other things, "fit for the ordinary purposes for which such goods are used," id. § 46-2-314(2)(c), and "adequately contained, packaged, and labeled as the agreement may require," id. § 46-2-314(2)(e).

Defendants claim that their HRT products were merchantable inasmuch as they proved "fit" for their "ordinary purpose" of alleviating plaintiff's menopausal symptoms. (Warranty MSJ Mem. at 1). Plaintiff responds that the HRT drugs were not merchantable because defendants' drug labeling "failed

to adequately warn either Mrs. [Hines] or her doctors" of the risk of breast cancer. (Pl.'s Opp. at 6-10). Attempting to undercut this theory of liability altogether, defendants argue that while the adequacy of their drug labeling may be pertinent to a product liability claim for failure to warn, it is irrelevant for the purposes of an implied warranty claim. (Warranty MSJ Reply at 2-3).

It appears that the West Virginia Supreme Court of Appeals has had no occasion to discuss the implied warranty of merchantability as it relates to claims of inadequate labeling in products liability actions. Inasmuch as West Virginia Code § 46-2-314 mirrors U.C.C. § 2-314, the court finds guidance in case law from other states that have adopted the U.C.C.'s implied warranty provisions.

To begin, although defendants maintain that plaintiff's failure to warn theory is simply out of place in the implied warranty context (without citing any authority), the court's independent review of the case law reveals otherwise. See Bly v. Otis Elevator Co., 713 F.2d 1040, 1045 (4th Cir. 1983) (applying Virginia law and holding that "a manufacturer may breach its implied warranty of merchantability by failing to warn or instruct concerning dangerous propensities or characteristics of

a product even if that product is flawless in design and manufacture."); Hill v. Searle Labs., 884 F.2d 1064, 1070 n.10 (8th Cir. 1989) (noting that an "inadequate warning can be evidence of a breach of warranty on the part of a manufacturer"); Duford v. Sears, Roebuck & Co., 833 F.2d 407, 412 (1st Cir. 1987) (applying New Hampshire law and holding that plaintiffs can pursue claims for breach of implied warranty of merchantability based on a failure to warn theory); Stephens v. G.D. Searle & Co., 602 F. Supp. 379, 381 (E.D. Mich. 1985) (same; applying Michigan law); Bryant v. Adams, 448 S.E.2d 832, 843 (N.C. Ct. App. 1994) ("a failure to warn of dangerous propensities concerning a product may create an action of breach of implied warranty of merchantability . . . [by] render[ing] a product unmerchantable" under North Carolina's version of U.C.C. § 2-314); see also Barkley Clark & Christopher Smith, 1 The Law of Product Warranties § 5:5 (2010) (noting that, under U.C.C. § 2-314, "courts find goods to be unfit for their ordinary purposes when they can identify one of three general types of defects: manufacturing defects, design defects, and . . . failure to warn of its dangerous propensities.") (emphasis added).[2]

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[2] Courts have permitted failure to warn theories under both § 2-314(2)(c) (requiring fitness for ordinary purposes) and § 2-314(2)(e) (requiring adequate labeling), without according primacy to either subsection. See Clark & Smith, supra, The Law

In assessing whether West Virginia's high court would permit an implied warranty claim predicated on a failure to warn/inadequate labeling theory, the court is guided by the First Circuit's decision in Mello v. K-Mart Corporation, 792 F.2d 1228 (1st Cir. 1986). There the trial judge instructed the jury to consider the adequacy of the defendant manufacturer's warnings in determining whether the defendant's product, a hydraulic jack, was "merchantable" within the meaning of § 2-314. Appealing a jury verdict for the defendant, the plaintiff claimed that the trial judge's implied warranty instruction was erroneous. As do the defendants here, the plaintiff in Mello argued that the manufacturers' warnings were irrelevant to the question of whether the product was "fit for the ordinary purposes for which such goods are used" under § 2-314. Applying Tennessee law, the

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of Prod. Warranties § 5:5. However, "a plaintiff who alleges breach of warranty of merchantability is not obligated to identify which factors under § 2-314(2) are breached." Bond v. Nibco, Inc., 623 A.2d 731, 737 (Md. Ct. Spec. App. 1993) (Motz, J.); see also Sundberg v. Keller Ladder, 189 F. Supp. 2d 671, 676 (E.D. Mich. 2002) ("The plaintiff is under no obligation to specify his perceived defect when suing under a warranty theory"). This conclusion is supported by Official Comment 6 to § 2-314, which clarifies that "[s]ubsection (2) does not purport to exhaust the meaning of 'merchantable' nor to negate any of its attributes not specifically mentioned in the text of the statute, but arising by usage of trade or through case law . . . the intention is to leave open other possible attributes of merchantability." W. Va. Code § 46-2-314 cmt. 6.

First Circuit rejected this contention and found no error in the trial judge's instruction. The court's analysis is worth quoting at length:

> The parties have not cited, and our research has failed to disclose, any Tennessee authorities squarely addressing this question in the context of a claim for breach of warranty. However, it seems likely that, if confronted with the issue, the Tennessee courts would adopt the view that the presence of warnings or instructions is relevant to a determination whether a product is fit for its ordinary purpose.
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> The Tennessee courts have held that, in a claim based on strict liability, "[r]elevant to the determination of whether a product is defective and unreasonably dangerous is the presence or absence of a statement accompanying the product which in some way informs the user of the danger." . . . Courts and commentators that have considered the question have concluded that the elements of a claim based on strict liability and a claim based on breach of implied warranty "are essentially the same." Gumbs v. International Harvester, Inc., 718 F.2d 88, 94-95 (3d Cir. 1983) (applying Virgin Islands law) (collecting authorities).
>
> Because the two causes of action are essentially congruent, we see no reason why the warnings or instructions which accompanied the jack would not also be relevant to a determination whether K-Mart broke the implied warranty of merchantability on the jack.

Id. at 1234-35 (some citations omitted); see also 1 David Owen, et al., Madden & Owen on Products Liability § 4:5 (3d ed. 2011) ("Generally, proof that a product is 'defective' under strict liability in tort will establish that a product is not merchantable, and vice versa."); 63 Am. Jur. 2d Products Liability § 522 ("Strict liability and implied warranty are

parallel theories of recovery . . . Apart from the availability of certain contract defenses in a breach of warranty case, there is little difference between the two theories of liability once it has been established that a defect exists in the product that gives rise to the action for damages.") (footnotes omitted).[3]

Under West Virginia's strict products liability doctrine, a plaintiff may pursue a failure to warn theory of recovery. See Ilosky v. Michelin Tire Corp., 307 S.E.2d 603, 609 (W. Va. 1983) (recognizing that a product may be deemed "defective" for strict liability purposes if it lacks an adequate warning). Because courts have recognized that claims for strict liability and breach of the implied warranty of merchantability are essentially coextensive in products liability actions, the court anticipates that the West Virginia Supreme Court would

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[3] Some courts have merged the doctrines in products liability actions because they are so intertwined. See, e.g., Hearn v. R.J. Reynolds Tobacco Co., 279 F. Supp. 2d 1096, 1103 (D. Ariz. 2003) ("in Arizona, when a complaint alleges product liability claims under theories of both breach of implied warranties and strict liability, those theories merge."). Other courts have noted that the requirements of the two doctrines are "not identical," but that "'[a]s a practical matter, the distinction between the defect concepts in tort law and in implied warranty theory may have little or no effect in most cases,' depending on the nature of the proof and the way in which issues of fact were litigated." Fritz v. White Consol. Indus., 762 N.Y.S.2d 711, 714 (N.Y. App. Div. 2003) (quoting Denny v. Ford Motor Co., 662 N.E.2d 730, 738 (N.Y. 1995)).

permit a plaintiff to pursue an implied warranty of merchantability claim based on a failure to warn theory.[4] The court thus proceeds to analyze plaintiff's breach of implied warranty claim.

"For the duty to warn to exist, the use of the product must be foreseeable to the manufacturer or seller." Syl. Pt. 3, Ilosky, 307 S.E.2d at 603. The treatment of menopausal symptoms was, of course, a foreseeable use of the HRT drugs, as even defendants acknowledge that this was the "ordinary purpose" of their medications. (See infra Part II.B.2). So the court's focus turns to the adequacy of defendants' drug labeling. Given that this issue has arisen at the summary judgment stage, it is important to note that the "determination of whether a defendant's efforts to warn of a product's dangers are adequate is a jury question." Id. at Syl. Pt. 4.

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[4] The court notes that plaintiff has also asserted a strict liability failure to warn claim which, like her implied warranty claim, is predicated on defendants' allegedly inadequate labeling. (See First. Am. Compl. ¶¶ 36-42). Defendants have not moved for summary judgment as to this claim.

While the overlap between plaintiff's strict liability and implied warranty claims could potentially lead to jury confusion at trial, this issue can be addressed at trial. The court is satisfied, at the summary judgment stage, that both claims may proceed as a matter of law.

Plaintiff points out that studies available during the period that she ingested HRT drugs (1987-1999) -- in particular the 1989 "Bergkvist study" -- revealed a "significant" risk of breast cancer associated with combination estrogen and progestin therapy. (See Pl.'s Opp., Ex. 17). Despite the availability of these studies, plaintiff asserts, Upjohn's 1994 Provera labeling did not mention the risk of breast cancer in humans. (See Pl.'s Opp., Ex. 18, 1994 Provera Physicians' Desk Reference ("PDR") (noting occurrence of breast malignancies in "beagle dogs," but that "significance with respect to humans has not been established")). Wyeth's Premarin labeling from 1994 noted a "possible increased incidence of breast cancer in those women on estrogen therapy taking higher doses for prolonged periods of time," but goes on to state that the "majority of studies . . . have not shown an association with the usual doses used for estrogen replacement therapy." (Pl.'s Opp., Ex. 19, 1994 Premarin PDR). Wyeth's 1996 Prempro labeling stated that some studies reported a "moderately increased risk of breast cancer" in women taking low doses of combination therapy for prolonged periods. (Pl.'s Opp., Ex. 5, 1996 Prempro PDR). As with the Premarin labeling, however, the Prempro warning says that "the majority of studies" have shown no such association. (Id.). The

Prempro labeling also noted that "[t]he effect of added progestin on the risk of breast cancer is unknown, although a moderately increased risk in those taking combination estrogen/progestin therapy has been reported. Other studies have not shown this relationship." (Id.).

As evidence of the inadequacy of defendants' breast cancer warnings, plaintiff relies on the testimony and report of her "labeling expert," Dr. Suzanne Parisian. Dr. Parisian testified in another HRT case that Wyeth's Prempro labeling from 1997 "was not adequate and it is not accurate in terms of a physician trying to read this label to determine if E plus P increases the risk of breast cancer." (Pl.'s Opp., Ex. 16, Trial Tr. of Dr. Parisian's Testimony in Singleton v. Wyeth, No. 02285 (Pa. Ct. Com. Pl. Jan. 27, 2010), at 113). Dr. Parisian went on to list information that an adequate warning would have contained that did not appear in Wyeth's labeling. (Id. at 117-126). Plaintiff also cites Dr. Parisian's expert report, in which she critiqued Upjohn's Provera labeling as follows:

> From 1975 through 2002 the Provera package insert published in the PDR, and the present product label (revised April 2004) made no reference to the increased risk of breast cancer in humans associated with use of the drug in [combination hormone therapy]. No past or current label warns of whether the addition of a progestin to estrogen in hormone therapy increases, or may increase, the risk of breast cancer in women.

(Pl.'s Opp., Ex. 20, Expert Witness Rep. & Decl. of Dr. Parisian, at ¶ 150). Defendants do not rebut or even address this evidence.

Viewing the record in the light most favorable to the plaintiff, the court concludes that genuine issues of material fact exist as to the adequacy of defendants' drug labeling. Summary judgment on plaintiff's implied warranty of merchantability claim is accordingly denied.

2. Implied Warranty of Fitness for a Particular Purpose

Section 46-2-315 of the West Virginia Code provides as follows:

> Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.

W. Va. Code § 46-2-315. The West Virginia Supreme Court has held that § 46-2-315 gives rise to an implied warranty when three elements are met: "(1) the seller at the time of the contracting had reason to know the particular purpose for which the goods were required; (2) the buyer relied upon the seller to select suitable goods; and (3) the goods were unfit for the particular

purpose intended." Syl. Pt. 2, Jones, Inc. v. W.A. Wiedebusch Plumbing & Heating Co., 201 S.E.2d 448 (W. Va. 1973).

Defendants contend that plaintiff's implied warranty of fitness claim fails because plaintiff cannot show a "particular purpose" about which both the buyer and the seller knew. Plaintiff responds that she took defendants' HRT drugs for the particular purpose of treating her menopausal symptoms, that she and her doctors were aware of this purpose, and that defendants' drugs were unfit for this purpose.

Official Comment 2 to § 46-2-215 distinguishes between the implied warranty of merchantability and the implied warranty of fitness as follows:

> A "particular purpose" differs from the ordinary purpose for which the goods are used in that it envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability and go to uses which are customarily made of the goods in question. For example, shoes are generally used for the purpose of walking upon ordinary ground, but a seller may know that a particular pair was selected to be used for climbing mountains.

W. Va. Code § 46-2-215 cmt. 2. And so, § 46-2-215 requires a particular purpose that differs from the ordinary purpose for which the goods are generally used. See Wilson v. Brown & Williamson Tobacco Corp., 968 F. Supp. 296, 302 (S.D. W. Va.

1997) (dismissing implied warranty of fitness claim brought under W. Va. Code § 46-2-315 based upon plaintiff's failure to allege that his use of product differed from the "ordinary purpose" for which the product was intended to be used). While plaintiff contends that she took defendants' HRT drugs for the particular purpose of treating her menopausal symptoms, the record reveals that the treatment of menopausal symptoms was the ordinary, rather than particular, purpose for which the drugs were used. Inasmuch as plaintiff has offered no evidence showing a particular purpose of the HRT drugs, her claim under § 46-2-215 fails as a matter of law.

C. Design Defect

Defendants move for partial summary judgment as to plaintiff's design defect claims "[t]o the extent Plaintiff relies upon the contention that Premarin-plus-Provera was defectively designed in that safer alternatives were available." (Design Defect MSJ Mem. at 1). Plaintiff emphasizes that proof of a "safer alternative" is not required to establish a design defect claim under West Virginia law and maintains that she has, in any event, offered evidence of a "safer alternative" sufficient to preclude defendants' request for partial summary judgment. (Pl.'s Opp. at 1-2).

The parties' briefings talk past each other to a great extent, and consequently fall short in articulating the precise issues facing the court. One point is clear, however: defendants are not asking for summary judgment on plaintiff's entire design defect claim; they only request summary judgment to the extent that plaintiff's design defect theory rests on the availability of a "safer alternative." The court accordingly considers whether defendants are entitled to summary judgment as to this specific question.

West Virginia's strict products liability doctrine has its origin in Morningstar v. Black and Decker Manufacturing Co., 253 S.E.2d 666 (W. Va. 1979). Syllabus Point 4 of Morningstar provides as follows:

> **In this jurisdiction the general test for establishing strict liability in tort is whether the involved product is defective in the sense that it is not reasonably safe for its intended use. The standard of reasonable safeness is determined not by the particular manufacturer, but by what a reasonably prudent manufacturer's standards should have been at the time the product was made.**

Id., at Syl. Pt. 4. Generally speaking, "[o]nce it can be shown that the product was defective when it left the manufacturer and that the defect proximately caused the plaintiff's injury, a recovery is warranted." Id. at 680. "[A] defective product may fall into three broad, and not necessarily mutually exclusive, categories: design defectiveness; structural defectiveness; and

use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels." Id. at 682.

To be sure, the West Virginia Supreme Court has not stated one way or the other whether a design defect claim requires proof of a safer alternative design of the allegedly defective product. See Philip Combs & Andrew Cooke, Modern Products Liability Law in West Virginia, 113 W. Va. L. Rev. 417, 427 (2011) (noting lack of caselaw on the issue). Nevertheless, even if it is not required, offering evidence of a safer alternative is at least one method of showing that a product is "not reasonably safe for its intended use" for the purposes of a design defect claim.

In support of her alternative design theory, plaintiff identifies oral micronized progesterone ("OMP"), a non-synthetic or "natural" progestin drug.[5] OMP is considered "natural" because it is chemically identical to natural progesterone. Plaintiff asserts that the primary defect of defendants' HRT drugs is the synthetic progestin component (i.e., Provera and the progestin component of Prempro). This is because breast cancer risks

[5] Defendants note that, in discovery responses, plaintiff identified lower dosages of the HRT drugs, no hormone therapy at all, and topical hormonal products as safer alternative designs to defendants' HRT drugs. In moving for partial summary judgment, defendants point out a lack of record evidence supporting these theories of alternative design. Inasmuch as plaintiff's opposition brief does not respond to these arguments, the court deems the points conceded.

increase significantly when synthetic progestin is used in combination with estrogen. OMP, however, is not known to heighten breast cancer risks when combined with estrogen. And so plaintiff maintains that OMP is a safer alternative to synthetic progestin. As support for this theory, plaintiff offers evidence showing that (1) OMP has been widely available since the 1980s; (2) studies from the 1990s revealed that OMP posed less breast cancer risks than synthetic progestin; and (3) defendants were aware of these studies. (See Pl.'s Opp. at 12-20). Plaintiff also cites expert testimony and reports indicating that OMP is a safe alternative to synthetic progestin. (Id.).

Defendants first contend that plaintiff's alternative design theory fails because she has not shown "specific causation," or, in other words, that OMP would have avoided her injury. In essence, defendants argue that plaintiff must offer expert testimony showing not only that OMP reduces the risk of breast cancer generally, but also that OMP would have specifically prevented the plaintiff from developing breast cancer. Defendants cite no authority directly supporting this proposition. Indeed, in a recent HRT case involving Wyeth, Torkie-Tork v. Wyeth, 739 F. Supp. 2d 895 (E.D. Va. 2010) (Ellis, J.), the district court rejected the precise argument made by defendants here:

> **Wyeth argues that plaintiff has only identified "generic experts" to discuss diminished cancer risks from**

> plaintiff's alternative Prempro designs, rather than "case specific experts" who will show how the alternative designs would have avoided cancer in this plaintiff ...
>
> Wyeth's characterization of the experts as "generic" is misleading and unhelpful; plaintiff's expert reports indicate that alternative designs to Prempro would present little or no risk of breast cancer to anyone, which, of course, includes plaintiff. For example, Dr. Don Austin, one of plaintiff's expert witnesses, reviewed studies in this area and concluded "that [E+P hormone therapy] containing [natural] micronized progesterone or dydrogesterone has no elevated risk, in contrast to [E+P hormone therapy] containing [medroxyprogesterone acetate]," the synthetic form of progesterone. See Pl. Ex. 67, at 20, 27 (Report of Dr. Don Austin). Where an alternative drug design would nearly eliminate the overall risk of cancer, it follows a fortiori that it would also diminish that risk in the plaintiff's specific case. Wyeth may dispute Dr. Austin's conclusion, but viewing the record in a light most favorable to the plaintiff, which is appropriate at this stage, a genuine issue of material fact remains on the causation element of this claim. Accordingly, summary judgment is not appropriate for the negligent design defect claim.

Id. at 901 (alterations in original).

The court finds this reasoning persuasive and adopts it here. Inasmuch as plaintiff has, like the plaintiff in Torkie, offered expert evidence showing that OMP generally creates a lesser risk of breast cancer than synthetic progestin when used in an HRT regimen, (see Pl.'s Opp., Exs. 9-11, 28), a genuine issue of fact exists as to whether OMP would have avoided plaintiff's breast cancer.

Defendants next assert that OMP is not a true "alternative design" but a different product altogether. They

note that (1) OMP has a different chemical makeup than synthetic progestin; (2) substituting OMP for synthetic progestin in a hormone therapy regimen may require drastic changes in dosage and methods of administration; and (3) the FDA has approved OMP as a separate drug (under the brand name Prometrium).

Defendants are correct than an "alternative design must not be an altogether essentially different product." Torkie, 739 F. Supp. 2d at 900. Stated differently, "an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product." Id.; see also Caterpillar, Inc. v. Shears, 911 S.W.2d 379, 385 (Tex. 1995) (noting, in design defect context, that "[a] motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle."); Kimball v. RJ Reynolds Tobacco Co., No. C03-664, 2006 WL 1148506, *3 (W. D. Wash. Apr. 26, 2006) (holding that a plaintiff "cannot point to an entirely different product as an alternative design"). However, the reasonableness of an alternative design is generally a question of fact for the jury. See Torkie, 739 F. Supp. 2d at 900; Kimball, 2006 WL 1148506, at *3.

The court again views Torkie as instructive. There the court concluded that the question of whether OMP was a reasonable alternative to the synthetic progestin component of Prempro

presented a factual issue for jury determination:

> If Wyeth could have used a natural progesterone instead of synthetic progestin and accomplished a similar positive therapeutic effect, a jury may reasonably decide that the refusal to employ such a design was negligent. On the other hand, Wyeth may [marshal] evidence to show that this proposed alternative design would fundamentally alter Prempro, in which event a jury might reasonably conclude that such an alteration would result in a wholly different product -- Prempro would no longer be Prempro, much as a four-wheel vehicle with a cab would cease to be a motorcycle. In short, on this issue -- alternative design -- the summary judgment record presents a genuine issue of fact for trial.

Torkie, 739 F. Supp. 2d at 900-901. The plaintiff in this case has presented evidence regarding the comparability of OMP and synthetic progestin in treating menopausal symptoms. Defendants dispute this evidence. Thus, whether OMP was a reasonable alternative to synthetic progestin is a question for the jury.

Lastly, defendants maintain that because OMP was available at the time plaintiff's doctor prescribed HRT drugs with synthetic progestin (i.e., Provera and Preempro), plaintiff's real complaint is with her doctor's prescription decision and her alternative design theory fails as a matter of law. As support for this proposition defendants cite Theriot v. Danek Medical, Inc., 168 F.3d 253 (5th Cir. 1999). In Theriot, the plaintiff underwent a spinal fusion operation wherein his surgeon used pedicle screws manufactured by the defendant. Claiming that the screws caused him chronic pain following the surgery, the

plaintiff brought a products liability action against the defendant manufacturer. On appeal, the plaintiff argued that the district court should have considered as "alternative designs" surgical treatments that did not use pedicle screws. The Fifth Circuit rejected this contention, reasoning as follows:

> Theriot claims that the product at issue here is a product whose purpose is to provide biomechanical stability. Theriot therefore argues that other products that do not use pedicle screws should be considered as alternative designs, such as external neck braces or internal systems that use hooks or wires. Underlying this argument is the assumption that all pedicle screws are defective and there can be no system using pedicle screws that would be an acceptable product. The problem with this argument is that it really takes issue with the choice of treatment made by Theriot's physician, not with a specific fault of the pedicle screw sold by Danek.

Id. at 255.

Defendants' reliance on Theriot is unavailing. To reiterate, the court there took issue with the plaintiff's proposal of completely different products as "alternative" designs, which revealed his underlying "assumption that all pedicle screws are defective and there can be no system using pedicle screws that would be an acceptable product." Id. The plaintiff's alternative design here, by contrast, does not rest on an assumption that all HRT drugs are defective. Rather, she proposes an alternative progestin drug, OPM, that is within the same class of HRT drugs that allegedly injured her (the only difference being that it is "natural" instead of "synthetic"

progestin). It appears, then, that plaintiff's complaint lies not with her doctor's decision to prescribe her HRT drugs, but with defendants' decision to use synthetic progestin instead of OPM.

III. Conclusion

For the foregoing reasons, the court ORDERS as follows:

1. That defendants' motion for partial summary judgment as to plaintiff's claim for breach of the implied warranty of merchantability be, and it hereby is, denied.
2. That defendants' motion for partial summary judgment as to plaintiff's claim for breach of the implied warranty of fitness for a particular purpose be, and it hereby is, granted, and the claim is dismissed.
3. That defendants' motion for partial summary judgment on design defect be, and it hereby is, denied.

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

DATED: May 23, 2011

John T. Copenhaver, Jr.
United States District Judge