UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

Margaret B. Fraser and Joseph T. Fraser, *Plaintiffs*, *v.* Wyeth, Inc. and Wyeth Pharmaceuticals, Inc., *Defendants*.	Civil No. 3:04cv1373 (JBA) March 6, 2012

RULING ON MOTION FOR SUMMARY JUDGMENT

On August 18, 2004, Plaintiffs Margaret Fraser and Joseph Fraser filed a Complaint against Defendants Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. (collectively "Wyeth" or "Defendants"), claiming failure to warn, strict products liability, negligence, misrepresentation, and punitive damages under the Connecticut Product Liability Act ("CPLA"), Conn. Gen. Stat. § 52-272m, *et seq.* (Counts One–Five); breach of implied and express warranty (Counts Six–Seven); violations of the Connecticut Unfair Trade Practices Act ("CUTPA"), Conn. Gen. Stat. § 42-110a, *et seq.* (Count Eight); and loss of consortium (Count Nine). Defendants move [Doc. # 113] for summary judgment on all counts in Plaintiffs' Complaint. For the reasons stated below, Defendants' motion for summary judgment will be granted in part and denied in part.

I. Facts

Prempro is a hormone therapy medication combining estrogen and progestin in a single administration. (Prempro Summary Basis of Approval, Ex. A to Defs.' Loc. R. 56(a)1 Stmt. at 1–2.) Ms. Fraser testified in her deposition that "to the best of her recollection" she began taking Prempro when she was 49 or 50 years old in 1995 or 1996, after it was prescribed to her by her gynecologist, Dr. Tesoro (Margaret Fraser Dep., Ex. J to Defs.'

56(a)1 Stmt. at 132:11–134:19), and that she continued taking Prempro until September, 2001 (*id.* at 165:22–166:23).

A. Prempro Labeling

The Prempro label first appearing in the 1996 Physician's Desk Reference, approved by the FDA, included the following as its first entry in the "Warnings" section:

> *Breast cancer*. Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.0) in those women on estrogen replacement therapy taking higher doses, or in those taking lower doses for prolonged periods of time, especially in excess of 10 years. The majority of studies, however, have not shown an 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 those taking combination estrogen/progestin therapy has been reported. Other studies have not shown this relationship. In a one year clinical trial of PREMPRO, PREMPHASE and Premarin alone, 5 new cases of breast cancer were detected among 1377 women who received the combination treatments, while no new cases were detected among 347 women who received Premarin alone. The overall incidence of breast cancer in this clinical trial does not exceed that expected in the general population.
> Women on hormone replacement therapy should have regular breast examinations and should be instructed in breast self–examination, and women over the age of 50 should have regular mammograms.

(Prempro PDR Label 1996, Ex. 131 to Pls.' Loc. R. 56(a)2 Stmt. at 2803–04.) Beginning in 1997, the label added the following warning under the "Breast cancer" heading:

> In the three year clinical Postmenopausal Estrogen Progestin Intervention (PSPI) trial of 875 women to assess differences among placebo, unopposed Premarin, and three different combination hormone therapy regimens, one (1) new case of breast cancer was detected in the placebo group (n=174), one in the Premarin alone group (n=175), none in the continuous Premarin plus continuous medroxyprogesterone acetate group (n=174), and two (2) in the continuous Premarin plus cyclic medroxyprogesterone acetate group (n=174).

(Prempro PDR Label 1997, Ex. 132 to Pls.' 56(a)2 Stmt. at 2906–07.)

The Prempro Package Insert stated under "Risks of Estrogens and/or Progestins":

> *Cancer of the breast.* Most studies have not shown a higher risk of breast cancer in women who have ever used estrogens. However, some studies have reported that breast cancer developed more often (up to twice the usual rate) in women who used estrogens for long periods of time (especially more than 10 years), or who used high doses for shorter time periods. The effects of added progestin on the risk of breast cancer are unknown. Some studies have reported a somewhat increased risk, even higher than the possible risk associated with estrogens alone. Others have not. Regular breast examinations by a health professional and monthly self–examination are recommended for all women. Regular mammograms are recommended for all women over 50 years of age.

(*Id.* at 3.)

B. Ms. Fraser's Use of Prempro and Cancer Diagnosis

When asked at his deposition what recollection he had about his treatment and care of Ms. Fraser, Dr. Tesoro testified: "I can't recall very much." (Tesoro Dep., Ex. I to Defs.' 56(a)1 Stmt. at 46:21–47:9.) However, on both direct and cross examination, Dr. Tesoro reviewed and was asked questions regarding the warning labels for Prempro. After reviewing the warning label contain in the PDR, Dr. Tesoro agreed that he was aware of the information on the warning label at the time he prescribed Prempro to Ms. Fraser, and that he was aware of "the moderate increased risk" described in the label. (*Id.* at 51:15–53:20.) Dr. Tesoro also agreed that he would "[a]bsolutely" discuss with a patient the risks of hormone therapy, including "the moderate increased risk of breast cancer." (*Id.* at 55:19–56:1.) With respect to the package insert, Dr. Tesoro testified that the information contained in the "cancer of the breast" section would "[p]ossibly" indicate to a patient that

she should be aware of the risk of breast cancer associated with Prempro. (*Id.* at 58:22–59:16.)

Dr. Tesoro also testified that the first two sentences of the breast cancer warning in the Prempro label[1] were "a little confusing" because "in one way they're saying that there is [a risk] if you use it for excess of ten years, and it's talking about other studies but they don't outline those studies." (*Id.* at 102:21–103:11.) He then agreed that "[b]y stating that 'the majority of studies show no risk,' [the label] was . . . reassuring that the risks were minimal if not absent." (*Id.* at 103:12–16.) Dr. Tesoro further testified that the next part of the label—which stated "The effect of added progestins 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"—was "sort of a double–edged sword, confusing," and that it did not provide any actual warning of breast cancer. (*Id.* at 103:17–104:17.) He also agreed that the sentence in the warning "The overall incidence of breast cancer in this clinical trial does not exceed that expected in the general population" reassured him that "there is not really a breast cancer risk." (*Id.* at 104:18–105:20.)

Ms. Fraser testified that in prescribing Prempro for her, Dr. Tesoro told her that it "was a safe alternative to my hot flashes, and that it would help with [vaginal] dryness." (Margaret Fraser Dep. at 137:13–138:10.) She testified that she based her decision to take

[1] These sentences read: "Some studies have reported a moderately increased risk of breast cancer (relative risk of 1.3 to 2.0) in those women on estrogen replacement therapy taking higher doses, or in those taking lower doses for prolonged periods of time, especially in excess of 10 years. The majority of studies, however, have not shown an association in women who have ever used estrogen replacement therapy." (Prempro PDR Label 1996 at 2803.)

Prempro on Dr. Tesoro's advice rather than any particular advertisements for Prempro and that she continued to take it because "[i]t was working . . . and because my doctor felt it was safe." (*Id.* at 140:13–145:10.) Ms. Fraser added, however, that advertisements "enhanced" her decision to continue taking Prempro. (*Id.* at 145:11–13.)

Ms. Fraser did not recall having any discussion with Dr. Tesoro regarding the risks associated with Prempro but added: "Knowing Dr. Tesoro and knowing how he took care of me, he would—if it was unsafe, he would tell me." (*Id.* at 138:25–139:18.) Ms. Fraser also testified that she relied on Dr. Tesoro's knowledge in deciding to take, and continuing to take, Prempro and that she "depended on him to let me know if there was any harm that was going to come to me," but added "[i]f there had been huge, black, bold don't take this, it's going to cause cancer or it may cause cancer, I would not have taken it." (*Id.* at 141:16–142:6.) She also stated that she "may have" read the patient insert for Prempro and explained with respect to what could have led her to read the insert:

> Well, one of the things might have been what would have led me was if it was in bold letters, if there was something that said a side effect might be, that it would be harmful, or that it could cause an illness or cause cancer, I would read it. If it was bold, it was written that boldly. But I didn't read anything. I don't remember reading anything. I don't remember reading that. I would not have taken it if I thought I was going to be harmed by it. I trusted the drug maker and I trusted my doctor.

(*Id.* at 162:13–163:2.)

Ms. Fraser testified that she took Prempro from 1995 or 1996 until September 11, 2001, the day after she had a mammogram that revealed abnormal results. (*Id.* at 165:22–166:23.) Dr. Ken Kern performed a stereotactic biopsy on Ms. Fraser in October 2001 and diagnosed her with breast cancer. (*Id.* at 167:22–170:3.) Dr. Kern then performed

a lumpectomy on Ms. Fraser in November 2001, and she received six months of chemotherapy beginning in January 2002 and radiation therapy beginning in August 2002. (*Id.* at 175:23–181:2.) After completing radiation therapy, Ms. Fraser took Tamoxifen for two–and–a–half years and then Aromasin for two–and–a–half years. (*Id.* at 181:3–182:24.) At the time of her deposition, Ms. Fraser was cancer free and no longer taking any cancer medications. (*Id.* at 182:25–183:25.)

C. Risk of Cancer Associated with Prempro

Of the 43 studies regarding the risk of breast cancer associated with the use of estrogen and progestin between 1979 and the Women's Health Initiative ("WHI") published on July 9, 2002, which concluded that the health risks of combined estrogen plus progestin exceeded the benefits (WHI Study, Ex. 16 to Pls.' 56(a)2 Stmt.), 32 of them concluded that there was an increased risk of breast cancer associated with combined estrogen plus progestin therapy. (*See* Study Chart, Ex. 145 to Pls.' 56(a)2 Stmt.)

On October 17, 1994, an internal Wyeth memorandum from Suzanne Joyner to John Leone states that Dr. Trudy Bush "reported that data from Katherine Fletcher at the National Cancer Institute, in a retrospective study conducted in the 70's saw an increased risk of breast cancer in women on HRT any dose as compared to ERT." (10/17/94 Wyeth Memo, Ex. 82 to Pls.' 56(a)2 Stmt.) On July 15, 1995, Dr. Graham Colditz published an article in the New England Journal of Medicine that concluded that the risk of breast cancer "was significantly increased among women who were currently using . . . estrogen plus progestin . . . as compared with postmenopausal women who had never used hormones." (Colditz Study, Ex. 83 to Pls.' 56(a)2 Stmt.) Dr. Colditz testified during his deposition that when he

discussed the results of his study with Wyeth, "[t]hey basically didn't want to hear what we were finding." (Colditz Dep., Ex. 85 to Pls.' 56(a)2 Stmt. at 805:11–20.)

In August of 2000, Dr. Susan Allen, Director of Reproductive and Urologic Drug Products at the FDA, wrote to Joseph Sonk, Senior Director of Women's Health Care Products at Wyeth, informing him that the Warnings and Precautions sections of the Prempro labeling were "being reviewed in accordance with the updated information regarding" the risk of breast cancer. (Allen Letter, Ex. 105 to Pls.' 56(a)2 Stmt. at 1.) Dr. Allen requested the following change to the breast cancer warning on the Prempro label:

> While some epidemiologic studies suggest a very modest increase in breast cancer risk for estrogen alone users versus non–users, other studies have not shown any increased risk. The addition of progestin to estrogen may increase the risk for breast cancer over that noted in non–hormone users more significantly (by about 24–40%), although this is based solely on epidemiologic studies, and definitive conclusions await prospective, controlled clinical trials.
> . . .
> Women with a uterus who are candidates for long–term use of estrogen/progestin therapy should be advised of potential benefits and risks (including the potential for an increased risk of breast cancer).

(*Id.*)

D. Changes in Prempro Labeling

The Prempro label in the 2010 PDR contains the following warning regarding breast cancer:

> The most important randomized clinical trial providing information about this issue in estrogen plus progestin users is the Women's Health Initiative (WHI) substudy of daily conjugated estrogens (CE 0.625 mg) plus medroxyprogesterone acetate (MPA 2.5 mg). In the estrogen plus progestin substudy, after a mean follow–up of 5.6 years, the WHI substudy reported an increased risk of breast cancer in women who took daily CE/MPA. In this substudy, prior use of estrogen alone or estrogen plus progestin therapy was

> reported by 26 percent of the women. The relative risk of invasive breast cancer was 3.24 (96 percent nominal confidence interval {pCI} 1.01–1.540, and the absolute risk was 41 versus 33 cases per 10,000 women–years, for estrogen plus progestin compared with placebo, respectively. Among women who reported prior use of hormone therapy, the relative risk of invasive breast cancer was 1.86, and the absolute risk was 46 versus 25 cases per 10,000 women–years, for estrogen plus progestin compared with placebo. Among women who reported no prior use of hormone therapy, the relative risk of invasive breast cancer was 1.09, and the absolute risk was 40 versus 36 cases per 10,000 women–years for estrogen plus progestin compared with placebo. In the same substudy, invasive breast cancers were larger and diagnosed at a more advanced stage in the CE/MPA group compared with the placebo group. Metastatic disease was rare, with no apparent difference between the two groups. Other prognostic factors, such as histologic subtype, grade and hormone receptor status did not differ between the groups. (See Clinical Studies.)
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> . . .
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> The results from observational studies are generally consistent with those of the WHI clinical trial. Observational studies have also reported an increased risk of breast cancer for estrogen plus progestin therapy, and a smaller increased risk for estrogen alone therapy, after several years of use. The risk increased with duration of use, and appeared to return to baseline over about 5 years after stopping treatment (only the observational studies have substantial data on risk after stopping). Observational studies also suggest that the risk of breast cancer was greater, and became apparent earlier, with estrogen plus progestin therapy as compared to estrogen alone therapy. However, these studies have not found significant variation in the risk of breast cancer among different estrogens or among different estrogen plus progestin combinations, doses, or routes of administration.

(Prempro PDR Label 2010, Ex. 87 to Pls.' 56(a)2 Stmt. at 3553–54.)

After reviewing this label during his deposition, Dr. Tesoro testified that if he had all of this information at the time he prescribed Prempro to Ms. Fraser, "I would have probably given her less of an option to go on it if she didn't—if she continued to want to go on it she would have to be willing to agree that these side effects and symptoms possibly could occur." (Tesoro Dep. at 138:2–139:14.)

Dr. Cheryl Blume, whom Ms. Fraser has named as her expert pharmacologist to opine on Wyeth's labeling, concludes that "[b]ased on information provided in the literature, foreign databases, clinical studies, cancer registries and FDA records, there were ample signals available to Wyeth demonstrating a breast cancer risk with its hormone therapy drugs but Wyeth chose to not conduct adequate studies to define this risk." (Blume Summary of Testimony, Ex. 151 to Pls.' 56(a)2 Stmt. at 21.) Dr. Blume further opines:

> From at least 1975 to 2002, Wyeth failed to adequately warn prescribing doctors, practitioners and patients that the harms of Premarin and MPA outweighed the benefits for many, if not most, women. . . . [D]ata and information linking estrogen and/or estrogen/progestin use with endometrial cancer, breast cancer and cardiovascular events were either known or knowable to Wyeth years before inclusion of these events in the U.S. labeling. . . . Doctors and patients were denied this information because Wyeth, through both its actions and failure to act, delayed disclosure of these issues.

(*Id.* at 58.)

II. Discussion[2]

Defendants move for summary judgment in their favor on all of Plaintiffs' claims, arguing 1) that the CPLA provides the exclusive remedy against a product seller and thus Plaintiffs' failure to warn, strict liability, negligence, misrepresentation, and punitive damages claims (Counts One–Five) are improperly plead and should be dismissed and

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[2] "Summary judgment is appropriate where, construing all evidence in the light most favorable to the non-moving party," *Pabon v. Wright*, 459 F.3d 241, 247 (2d Cir. 2006), "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)(2). An issue of fact is "material" if it "might affect the outcome of the suit under the governing law," and is "genuine" if "a reasonable jury could return a verdict for the nonmoving party" based on it. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "Unsupported allegations do not create a material issue of fact." *Weinstock v. Columbia Univ.*, 224 F.3d 33, 41 (2d Cir. 2000).

Plaintiffs' breach of implied and express warranty claims (Counts Six and Seven) cannot be asserted in addition to CPLA claims and thus should be dismissed; 2) that Wyeth's warnings were adequate as a matter of law and Plaintiffs cannot prove proximate cause; 3) that they are entitled to summary judgment on any design defect claims because strict liability and negligence claims premised on design defect are barred by Comment (k) of the Restatement (Second) of Torts § 402A and because Plaintiffs cannot provide sufficient evidence of a design defect; 4) that Plaintiffs' punitive damages claims must fail if summary judgment is granted in Defendants' favor on Plaintiffs' other claims; 5) that Plaintiffs' breach of warranty claims should be dismissed because they are barred by the CPLA, because the breach of implied warranty claim is duplicative of Plaintiffs' design defect claims, and because Plaintiffs cannot establish the breach of an express warranty; 6) that Plaintiffs' CUTPA claims should be dismissed because the CPLA is the sole remedy for products liability claims; 7) that Plaintiffs' loss of consortium claim should be dismissed if summary judgment is granted as to Plaintiffs' other claims; and 8) that all Plaintiffs' claims fail as a matter of law for lack of expert evidence showing that Prempro caused Ms. Fraser's breast cancer.

A. Proper Pleading Under the CPLA

Defendants argue that because the CPLA provides the exclusive remedy for products liability claims and requires that all claims be brought under one unified count, Plaintiffs' individual counts for failure to warn, strict liability, negligence, misrepresentation, punitive damages, and breach of implied and express warranty should be dismissed. Plaintiffs object to Defendants' "hyper–technical" interpretation of the pleading requirements under the CPLA, and ask the Court to treat the claims under the CPLA "as one unified product liability claim, with theories of recovery pled in separate counts." (Opp'n [Doc. # 127] at 24.)

Although the CPLA provides the exclusive remedy for product liability claims, it was "not meant to alter the substance of a plaintiff's rights," *Walters v. Howmedica Osteonics Corp.*, 676 F. Supp. 2d 44, 48 (D. Conn. 2009) (quoting *LaMontagne v. E.I. DuPont De Nemours & Co., Inc.*, 41 F.3d 846, 855 (2d Cir. 1994)), and it "does not preempt all common law theories of product liability; rather, 'the CPLA bars separate common law causes of action in product liability cases,'" *id.* (quoting *Densberger v. United Technologies Corp.*, 297 F.3d 66, 70 (2d Cir. 2002)). A plaintiff bringing a cause of action under the CPLA therefore retains the right to allege traditional theories of recovery under one unified CPLA claim. *Id.*

The CPLA permits Plaintiffs to allege failure to warn, strict liability, negligence, misrepresentation, punitive damages, and breach of implied and express warranty, but requires that each of the allegations be brought under a single CPLA claim. Rather than reading the pleading requirements under the CPLA to bar the constituent common law allegations that make up Plaintiffs' CPLA claims, the Court will instead read the first seven counts of the Complaint to constitute a single CPLA claim broken up into individual common law theories of products liability.

B. Adequacy of the Warnings

Defendants argue that they are entitled to summary judgment in their favor on Plaintiffs' failure to warn, strict liability, negligence, misrepresentation, punitive damages, and breach of warranty claims, which are all based on allegations that Wyeth failed to warn Ms. Fraser about breast cancer risk, because the warnings on the Prempro label were adequate as a matter of law. Under Connecticut law, a "product seller" may be liable for harm caused by a defective product for which adequate warnings or instructions were not provided. Conn Gen. Stat. § 52-572q; *see Montagnon v. Pfizer, Inc.*, 584 F. Supp. 2d 459, 462

(D. Conn. 2008). Factors relevant to the adequacy of the warnings for a defective product include: "(1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions." Conn. Gen. Stat. § 52-572q(b).

The learned intermediary doctrine, as recognized by Connecticut law, provides:

> [A]dequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on the principle that prescribing physicians act as "learned intermediaries" between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess [the] risks and benefits of a particular course of treatment.

Vitanza v. UpJohn Co., 257 Conn. 365, 376 (2001) (internal citations omitted). Generally, where a prescribing physician is made aware of the risk of the particular injury suffered by a plaintiff, the product seller has satisfied its duty to adequately warn, *see Goodson v. Searle Labs.*, 471 F. Supp. 546, 549 (D. Conn. 1978), however an overly broad or confusing warning may not sufficiently alert the prescribing physician of the specific risk faced by a plaintiff. *De Souza v. Tap Pharm., Inc.*, 3:03cv2247 (MRK), 2006 WL 1328754, *1 (D. Conn. Jan. 3, 2006).

Courts have held that the "mere mention of a possible injury . . . is not necessarily adequate" and an equivocal warning may not be adequate to convey the risk created by a particular drug. *Thom v. Brisol–Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003) (holding that the warning in the package insert for the drug Serzone indicating "only that 'rare reports' of priapism were 'temporally associated' with Serzone . . . [and] that a 'causal

relationship [of priapism] to nefazodone has not been established" fell "well short" of an adequate warning); *see also Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 267 (5th Cir. 2002) ("[A] mere reference to an adverse effect is not necessarily an 'adequate warning.'"); *Erony v. Alza Corp.*, 913 F. Supp. 195, 200 (S.D.N.Y. 1995) (finding that even though warnings included with Duragesic patches "were generally thorough" and stated that they should be kept away from children, a reasonable jury could find that they were inadequate because they were incomplete in that they did not state that oral ingestion could result in death, and because the treating physician attested that he did not understand that used patches contained narcotic residue and an expert in pharmacology attested that the warnings "did not adequately inform users of the potential dangers from used patches").

Defendants argue that the FDA–approved label at the time Ms. Fraser began taking Prempro was adequate in that it specifically warned of the exact injury suffered by Ms. Fraser: breast cancer. Although the label contains a warning entitled "Breast cancer," that warning contains the following equivocal language concerning the relationship between Prempro and breast cancer: "The effect of added progestins 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." (Prempro PDR Label 1996 at 2803–04.) Dr. Tesoro, who prescribed Prempro to Ms. Fraser, upon reviewing the label, testified that the warning reassured "that the risks [of breast cancer] were minimal if not absent." (Tesoro Dep. at 103:12–105:20.) He also described the warning as confusing. (*Id.* at 102:21–104:17.) Dr. Tesoro later added that if he had all of the information ultimately available in the 2010 warning for Prempro at the time he prescribed the drug to Ms. Fraser, he would have "probably given her less of an

option to go on it," and would only prescribe it if Ms. Fraser were willing to agree to the heightened risk of breast cancer. (*Id.* at 138:2–139:14.) Dr. Blume, Ms. Fraser's expert pharmacologist, has opined that Wyeth knew or should have known of the heightened risk of breast cancer associated with Prempro "years before inclusion of these events in the U.S. labeling" and that Wyeth failed to adequately warn physicians and patients of these risks. (Blume Summary of Testimony at 58.)

A reasonable jury, taking into account Dr. Tesoro's and Dr. Blume's testimony, could find that the mention of breast cancer in the 1996 Prempro label was inadequate to warn Dr. Tesoro of the risk of breast cancer associated with Prempro. The equivocal language in the warning could be interpreted to fall short of Wyeth's duty to warn. *See Thom*, 353 F.3d at 853. Plaintiffs' counsel posited at oral argument that *Vitanza* recognized several exceptions to the learned intermediary doctrine, *see* 257 Conn. at 393–94, however the Court need not explore these exceptions as *Vitanza* makes clear that only *adequate* warnings obviate the need for drug manufacturers to directly warn consumers. There is sufficient evidence here for a reasonable jury to find that Wyeth did not adequately warn Dr. Tesoro of the risk of breast cancer associated with Prempro.

In arguing that they adequately warned of the risk of breast cancer, Defendants rely on three cases in which other courts found that Wyeth was entitled to summary judgment in its favor that the Prempro warnings were adequate as a matter of law. In *Browning v. Wyeth, Inc.*, 831 N.Y.S.2d 804, 804 (N.Y. App. Div. 2007), the New York Supreme Court, Appellate Division, upheld summary judgment in Wyeth's favor and held that the Prempro warning "portrayed with 'sufficient intensity' the risks involved in taking the drugs" and that "the conclusory opinion of plaintiff's expert was insufficient to raise an issue of fact." In

Kaufman v. Wyeth, LLC, No. 1:02–cv–22638, slip. op. at 10–11 (S.D. Fla. Aug. 15, 2011), the Southern District of Florida found that "Plaintiff must offer expert testimony to prove the inadequacy of the warning to appraise [her prescribing physician] of the increased risk that Plaintiff says was caused by her use of Prempro," and because the court had excluded the testimony of the only expert the plaintiff offered to provide such testimony, Wyeth was entitled to summary judgment in its favor on the plaintiff's inadequate warnings claims. In *Bailey v. Wyeth, Inc.*, —A.2d—, 2008 WL 8658571, *23 (N.J. Super. Ct. Law Div. July 11, 2008), the New Jersey Superior Court found that Wyeth was entitled to summary judgment in its favor on the plaintiff's inadequate warnings claims because the FDA approved the Prempro label, and there was no evidence that Wyeth intentionally withheld any risk information from the FDA.

Unlike in those three cases, Plaintiffs here have pointed to genuine disputes of material fact regarding the adequacy of the warnings contained in the Prempro labeling. Dr. Tesoro has testified that, upon reading the Prempro label, he found it to be confusing and equivocal as to the risk of breast cancer associated with Prempro and Dr. Blume has opined regarding the misleading nature of the Prempro warning. In addition, although the FDA approved the Prempro label, "the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009). Evidence in the record could allow reasonable jurors to conclude that Wyeth failed to adequately warn both Dr. Tesoro and Ms. Fraser of the risk of breast cancer associated with Prempro. The learned intermediary doctrine therefore does not bar

Plaintiffs' claims, and the Court declines to find that Wyeth's warnings were adequate as a matter of law.

C. Proximate Cause

Defendants also argue that they are entitled to summary judgment on all of Plaintiffs' failure to warn claims on the ground that Plaintiffs cannot establish proximate cause because they cannot show that different warnings would have changed Dr. Tesoro's decision to prescribe Prempo to Ms. Fraser, or that Ms. Fraser would not have used Prempro had the warnings been different. However, both Dr. Tesoro and Ms. Fraser testified that different warnings would have altered their decision–making and actions. Dr. Tesoro testified that if he had all of the information regarding breast cancer risk contained in the 2010 Prempro label when he prescribed Prempro in 1995 or 1996, he "would have probably given [Ms. Fraser] less of an option to go on it" and would have prescribed it only if she were "willing to agree that these side effects and symptoms possibly could occur." (Tesoro Dep. at 138:2–139:14.) Ms. Fraser testified that she trusted and relied on Dr. Tesoro in deciding to take Prempro, and that "[i]f there had been huge, black, bold don't take this, it's going to cause cancer or it may cause cancer, I would not have taken it." (Margaret Fraser Dep. at 141:16–142:6.) There is therefore evidence in the record from which a reasonable jury could infer that if different warnings had been provided, Dr. Tesoro would have changed his approach in recommending Prempro to Ms. Fraser and that Ms. Fraser would not have taken Prempro had Dr. Tesoro advised her differently. Accordingly, Defendants are not entitled to summary judgment in their favor that Wyeth's warnings did not proximately cause Ms. Fraser's injuries.

D. Design Defect Claims

Defendants argue that "[t]o the extent Plaintiffs' strict liability and negligence claims sound in defective design, they are not cognizable under Connecticut law because Connecticut has adopted Comment (k) of Section 402A of the Restatement (Second) of Torts, which expressly exempts unavoidably unsafe products from design defect claims." (Mem. Supp. [Doc. # 115] at 23.)

Comment (k) to Section 402A reads in part: "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." Rest. (2d) of Torts § 402A cmt. k. In order for a manufacturer to avoid liability under Comment (k), the unavoidably unsafe product must be accompanied by "proper directions and warning." *See Vitanza*, 257 Conn. at 375–76. As discussed above, there are genuine factual questions as to whether Wyeth's Prempro warnings were adequate, therefore Comment (k) does not operate to exempt Wyeth from liability on Plaintiffs' design defect claims at this stage.

Defendants also argue that they are entitled to summary judgment on Plaintiffs' design defect claims because Plaintiffs do not have any admissible expert evidence to support their failure to test claim or any evidence to support their alternative design claims, claiming that the expert opinions of Drs. Blume, Austin, and Tilley are inadmissible. Under Connecticut law, however, Plaintiffs are not required to prove either failure to adequately test Prempro or a safer alternative design to succeed on their design defect claims. To prevail on a design defect claim a plaintiff "must prove that the product is unreasonably dangerous." *Potter v. Chicago Pneumatic Tool Co.*, 241 Conn. 199, 214 (1997) (quoting

Giglio v. Conn. Light & Power Co., 180 Conn. 230, 234 (1980)). Unreasonably dangerous is defined under Connecticut law using the "consumer expectation" standard, "which provides that 'the article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id.* at 214–15 (quoting Restatement (Second) of Torts § 402A, cmt. (i).) This standard does not require Plaintiffs to prove "the existence of a reasonable alternative design in order to prevail on a design defect claim." *Id.* at 215.

The Connecticut Supreme Court held in *Potter*:

> In our view, the feasible alternative design requirement imposes an undue burden on plaintiffs that might preclude otherwise valid claims from jury consideration. Such a rule would require plaintiffs to retain an expert witness even in cases in which lay jurors can infer a design defect from circumstantial evidence. Connecticut courts, however, have consistently stated that a jury may, under appropriate circumstances, infer a defect from the evidence without the necessity of expert testimony.

Id. at 217–18. The court further held that in instances involving "complex product designs in which an ordinary consumer may not be able to form expectations of safety," the consumer's expectations may be viewed in light of several factors:

> [T]he relevant factors that a jury *may* consider include, but are not limited to, the usefulness of the product, the likelihood and severity of the danger posed by the design, the feasibility of an alternative design, the financial cost of an improved design, the ability to reduce the product's danger without impairing its usefulness or making it too expensive, and the feasibility of spreading the loss by increasing the product's price. . . . The availability of a feasible alternative design is a factor that the plaintiff may, rather than must, prove in order to establish that a product's risks outweigh its utility.

Id. at 219–221.

As set forth in *Potter*, to prevail on their design defect claims, Plaintiffs' need not present evidence of a safer alternative design, nor is there any one particular type of evidence that Plaintiffs must present to successfully demonstrate that Prempro was dangerous to an extent beyond that contemplated by the ordinary consumer. In arguing that Plaintiffs cannot prevail on their design defect claims without evidence of a safer alternative design, Defendants rely on *Brockert v. Wyeth Pharmaceuticals, Inc.*, 287 S.W.3d 760, 770–71 (Tex. App. 2009), in which the Texas Court of Appeals held that claims that Prempro should have not been composed of progestin plus estrogen, but instead would have been safer if it had been an entirely different product, was not a feasible alternative design claim and thus the plaintiff's design defect claim was fatally flawed. Under Texas law, however, "[a] plaintiff must prove that there is a safer alternative design to recover under design–defect theory." *Id.* at 769. *Potter* makes clear that this is not the case under Connecticut law.

Defendants' attacks on Plaintiffs' theories as to alternative design and the admissibility of their expert evidence on that particular argument, as well as their failure to test argument, therefore do not defeat Plaintiffs' design defect claims. Accordingly, Defendants are not entitled to summary judgment in their favor on these claims.

E. Punitive Damages Claims

Defendants argue that they are entitled to dismissal of Plaintiffs' punitive damages claims if summary judgment is awarded on Plaintiffs' other causes of action because punitive damages are not available where no liability exists. As discussed above, Defendants are not entitled to summary judgment in their favor on Plaintiffs' other causes of action, therefore they are not entitled to summary judgment on Plaintiffs' punitive damages claims.

F. Breach of Warranty

Defendants argue that Plaintiffs' breach of express warranty claim should be dismissed because 1) Plaintiffs have identified no specific statement regarding safety supporting this claim; 2) nowhere in its labeling or promotional materials did Wyeth "warrant or otherwise guarantee that taking Prempro was risk–free"; 3) statements in warning labels do not create warranties because they are not made to induce purchase of the product; and 4) neither Ms. Fraser nor her prescribing physician relied on any of Wyeth's statements in deciding to take or prescribe Prempro. (Mem. Supp. at 31–34.) Plaintiffs respond that there is ample evidence in the summary judgment record that Wyeth expressly warranted in its labels that most scientific studies researching estrogen plus progestin therapy showed no increased risk of breast cancer and that these promises became "part of the basis of the bargain" between Wyeth and Ms. Fraser.

An express warranty can be created by a seller of a product in any of the following ways:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description. (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Conn. Gen. Stat. § 42a-2-313. In their Opposition, Plaintiffs identify the specific statement that serves as the basis for their breach of express warranty claim: Wyeth's statements in the Prempro labeling that most scientific studies showed no increased risk of breast cancer from

estrogen plus progestin therapy. Plaintiffs claim this as the basis of the bargain between Wyeth and Ms. Fraser.

However, a drug manufacturer's representation in advertising or a warning label that a product is safe or effective, or an advertisement or warning label that does not adequately highlight a particular known or knowable risk does not create an express warranty in the absence of a guarantee that the particular product is free from all harmful side effects. *See Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 428 (2d Cir. 1969) (although the issue of strict liability for defendant's failure to warn plaintiff of the risk of chloroquine retinopathy from the drugs Aralen and Triquin was a jury question, plaintiff was not entitled to a jury instruction on express warranty because defendant "did not represent either (1) that its drugs were free from all harmful side effects or (2) that its drugs were absolutely harmless"); *In re Medidia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 818 (N.D. Ohio 2004) (under Ohio law, which applies the same express warranty standard as Connecticut law, "asserting that a product is 'safe and effective' is not sufficiently clear to create an express warranty"). Wyeth's warning that some studies show a moderately increased risk of breast cancer from estrogen plus progestin therapy, but most do not, is not a guarantee that a Prempro is free from all harmful side effects; to the contrary it acknowledges at least some risk. Although there is a factual dispute as to whether Wyeth adequately informed physicians and patients of the extent of that risk, Wyeth's statements in the warning do not create an express warranty. Defendants' motion for summary judgment as to Plaintiffs' breach of express warranty claim is therefore granted and Count Seven of the Complaint is dismissed.

G. CUTPA Claims

Defendants argue that they are entitled to summary judgment on Plaintiffs' CUTPA claims, Count Eight of the Complaint, because a plaintiff may not pursue damages under CUTPA for a claim governed by the CPLA. According to Conn. Gen. Stat. § 52-572n, "[a] product liability claim as provided in sections 52-240a, 52-240b, 52-572m to 52-572q, inclusive, and 52-577a may be asserted and shall be in lieu of all other claims against product sellers." This provision bars CUTPA claims that assert that a defendant's product is defectively designed or that the defendant failed to warn properly about a defective product. *Hurley v. Heart Physicians, P.C.*, 278 Conn. 305, 324 (2006). Defendants' motion for summary judgment as to Plaintiffs' CUTPA claims is therefore granted and Count Eight of the complaint is dismissed.

H. Loss of Consortium

Defendants move for summary judgment on Plaintiffs' loss of consortium claim, Count Nine of the Complaint, on the ground that loss of consortium is a derivative cause of action under the CPLA and that if summary judgment is granted as to Plaintiffs' other CPLA claims, the loss of consortium claim should be dismissed. As discussed above, Defendants are not entitled to summary judgment in their favor on Plaintiffs' CPLA claims. Therefore, Defendant' motion for summary judgment on Count Nine is denied.

I. Evidence Showing Prempro Caused Ms. Fraser's Cancer

Defendants lastly move for summary judgment on all of Plaintiffs' claims on the ground that Ms. Fraser's contemporaneous medical records show she only took Prempro for three years, yet all her experts are able only to testify regarding the impact of taking Prempro

for five years on Ms. Fraser's breast cancer. Plaintiffs argue that the length of time Ms. Fraser took Prempro is a material fact in dispute.

Dr. Tesoro does not have Ms. Fraser's medical records because he shredded them in 2008 or 2009 (Tesoro Dep. at 9:5–12:14), however, Ms. Fraser testified that she took Prempro from 1995 or 1996 until September 2001, a period of at least five years. Although "[i]t is Wyeth's position that Plaintiffs cannot prove more than three years of Prempro use" (Mem. Supp. at 36 n.84), Defendants do not point to any evidence in the record that definitively establishes that Ms. Fraser took Prempro for only three years. On her Fact Sheet submitted to the MDL court as a part of this case, Ms. Fraser indicated that she first used Prempro on November 19, 1998 and last used Prempro on September 11, 2001. This conflicts with her deposition testimony, but does not establish that Ms. Fraser in fact took Prempro for only three, rather than five, years. Given this factual dispute, Defendants' motion for summary judgment on all Plaintiffs' claims on the basis of the length of time Ms. Fraser took Prempro is denied.

III. Conclusion

For the reasons stated above, Defendants' motion [Doc. # 113] is GRANTED in part and DENIED in part. Counts Seven and Eight of the Complaint are dismissed. All other Counts remain for adjudication.

IT IS SO ORDERED.

/s/
Janet Bond Arterton, U.S.D.J.

Dated at New Haven, Connecticut this 6th day of March, 2012.