IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

ALBERTSON, *et al.*		: AUGUST TERM, 2002
	Plaintiffs	: No. 2944
v.		:
WYETH INC. *et al.*	Defendants	:
FINNIGAN, *et al.*		: AUGUST TERM, 2002
	Plaintiffs,	: No. 0007
v.		:
WYETH INC. *et al.*	Defendants,	:
EVERETTE, *et al.*,		: DECEMBER TERM 2002
	Plaintiffs,	: No. 0935
v.		:
WYETH INC., *et al.*	Defendants.	: **Commerce Program Class Actions**
		: Motion Control No. 020676

O R D E R

AND NOW, this 8th day of July 2003, upon consideration of Wyeth's Preliminary Objections to the consolidated, Amended Complaint and Wyeth's Motion to Strike plaintiffs' request for attorney fees, the responses in opposition, the respective memoranda, all matters of record, and after oral argument and

in accord with the contemporaneous Opinion being filed of record, it is **ORDERED** that:

(a) Wyeth's Preliminary Objection to plaintiffs' negligence/medical monitoring claim (Count I) is **Overruled**;

(b) Wyeth's Preliminary Objection to plaintiffs' unjust enrichment claim (Count II) is **Sustained**;

(c) Wyeth's Preliminary Objection to plaintiffs' claim under the UTPCPL (Count III) is **Sustained**;

(d) Wyeth's Preliminary Objection to plaintiffs' breach of fiduciary duty claim (Count IV) is **Sustained**;

(e) Wyeth's Preliminary Objection to plaintiffs' fraud claim (Count V) is **Sustained**; and

(f) Wyeth's Motion to Strike plaintiffs' request for attorney fees is **Granted**. The court finds that plaintiffs' claim for attorney fees is premature and is at this juncture dismissed without prejudice.

BY THE COURT,

ALBERT W. SHEPPARD, JR., J.

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O P I N I O N

Albert W. Sheppard, Jr., J. ..... July 8, 2003

Presently before the court are the Preliminary Objections of Wyeth, Inc. and Wyeth Pharmaceuticals Inc. a/k/a Wyeth-Ayerst Pharmaceutical ("Wyeth"). These objections present a demurrer to plaintiffs' consolidated, Amended Complaint and a Motion to Strike plaintiffs' request for attorney fees.

FACTUAL BACKGROUND

The consolidated, Amended Complaint ("Complaint" or "Compl.") sets forth the following factual allegations.[1]

Wyeth manufactures, promotes and distributes three estrogens or hormone replacement drugs known as "Premarin," "Prempro" and "Premphase." Compl. ¶ 13. Premarin is a conjugated estrogen that was first manufactured and marketed by Wyeth in 1942. Compl. ¶ 15. It is prescribed for women suffering from severe menopausal symptoms. Compl. ¶ 15. When taken alone (or "unopposed"), conjugated estrogen increases the risk of uterine cancer in post-menopausal women with intact uteri. The use of estrogen alone is referred to as estrogen replacement therapy ("ERT").

Prempro consists of two types of hormones: conjugated equine estrogens and progestins. Compl. ¶ 15-16. Because it combines estrogen and progestin, Prempro is often abbreviated as "E & P." The risk of uterine cancer is decreased when estrogen is combined with progestin. The use of estrogen and progestin in the treatment of menopausal symptoms is referred to as hormone replacement therapy ("HRT").

In December 1994, the United States Food and Drug Administration (FDA) granted Wyeth's petition for approval to market Prempro as separate tablets of Premarin (0.625 mg) and medroxyprogestrone acetate (MPA) called Cyrcrin (2.5 mg). Compl. ¶ 18. Prempro was to be prescribed for post-menopausal women with uteri for the treatment of moderate severe vasomotor symptoms

[1]For purposes of these objections, the court will accept, as true, the facts set forth in the Complaint.

associated with menopause, vulvar and vaginal atrophy and the prevention of osteoporosis. Compl. ¶ 18.

According to plaintiffs, there are an estimated fifty million post-menopausal women in the United States. Compl. ¶ 20. In July 2002, approximately 38% of post-menopausal women in the United States used estrogen or HRT. Compl. ¶ 21. At that time, about six million American women were taking Prempro. Compl. ¶ 22. Prempro is the best-selling HRT or estrogen-progestin combination drug in the United States. Compl. ¶23.

Wyeth has promoted Prempro and Premarin by marketing efforts directed to doctors and by direct-to-consumer efforts. According to plaintiffs, Wyeth utilized marketing techniques with the intention and effect of creating a lifelong demand for its estrogen replacement drugs on the part of post-menopausal women. Compl. ¶ 24. Wyeth's direct-to-consumer efforts have included print advertisements, videotapes, and brochures directed to consumers, as well as "product placement" efforts in which estrogen products are favorably positioned in entertainment vehicles or favorably described in the popular press by hired spokespersons. Compl. ¶ 25.

In 1999, Wyeth spent $34.7 million and in 2000, $37.9 million, on direct-to-consumer advertising for Prempro. Compl. ¶ 26. In 2001, Premarin became the first Wyeth brand to surpass $2 billion in annual sales. Compl. ¶ 27. According to plaintiffs, Wyeth's marketing of Prempro and Premarin present menopause symptoms in dire and detailed fashion, describe purported benefits of ERT/HRT that have never been proven and minimize and distort the risks associated with ERT/HRT. Compl. ¶ 30.

Premarin and Prempro were designed and have been approved by the FDA to relieve only menopausal symptoms, such as hot flashes, vaginal atrophy and osteoporosis. Compl. ¶ 32. However, according to plaintiffs, Wyeth has long touted its estrogen products as having additional benefits. Compl.

¶ 32. Thus, in print advertisements, brochures, and magazine advertisements, Wyeth claimed that Premarin could be used to relieve various ills including tension, irritability, headaches, undue fatigue, depression and insomnia when caused by declining menopausal estrogen levels. Compl. ¶ 33. Additionally, Wyeth claimed that Alzheimer's disease, vision problems, tooth loss, heart disease and colon cancer could be treated with Premarin or Prempro. Compl. ¶ 35. Wyeth also suggested that its conjugated equine estrogen was appropriate for treating or preventing, among other things, memory loss, colon cancer and age-related vision loss. Compl. ¶ 36.

In 1993, Wyeth distributed a videotape to consumers entitled "What every woman should know about estrogen." The videotape claimed to be a seminar for women and depicted a female doctor advising women about menopause, conjugated equine estrogen (CEE) and progestin. Wyeth's video seminar warned of a wide variety of illnesses and ailments purportedly associated with menopause. Among other things, Wyeth represented that estrogen loss causes bone to become brittle, skin to become dryer and sexual intercourse to become "painful and irritating." Plaintiffs allege that while the videotape was exhaustive in its warnings about menopause, it glossed over the dangers and risks associated with ERT. Compl. ¶ 43. Additionally, the video "seminar" recommended that estrogen should be combined with progestin when taken by women who have not had hysterectomies. Compl. ¶ 45. The video seminar also represented that estrogen provided "long term health protection" and should be continued indefinitely, even after short term menopausal symptoms, such as hot flashes, had subsided. When a purported consumer inquired how long Premarin should be taken, Wyeth's doctor spokesperson responded "anywhere from five to ten years in order to get protection from long term problems." Compl. ¶ 46.

With regard to breast cancer risks, Wyeth represented in its video seminar that the benefits of taking estrogen "far outweigh the risks for women unless they faced a particularly high risk of breast cancer." Plaintiffs allege that the opposite is true: the risks of taking Prempro far outweigh the benefits. Compl. ¶ 47. Wyeth also allegedly misrepresented that most studies showed no increased risk of breast cancer associated with taking estrogen at usual doses, and that breast cancer risks were only elevated when estrogen was taken at higher doses "for more than ten years."

At least until mid-2002, Wyeth distributed a Prempro promotional brochure targeted for women consumers that had the words "Starting your Hormone Replacement Therapy" at the top of the front cover. At the bottom of the cover of this brochure and at the bottom of nine of its seventeen pages of text, the following words appear: "Say yes to PREMPRO." Compl. ¶ 49. Wyeth's "Say yes to PREMPRO" brochure contains testimonials from six women who claim to have used estrogen or Prempro for an average of 12.2 years. Each of these women is reported to have used Prempro and/or Wyeth's estrogen-only therapy, Premarin, for at least seven years. Compl. ¶ 50. Wyeth's annual report contains a similar testimonial from a woman. Compl. ¶ 52.

According to plaintiffs, Wyeth's "Say yes to PREMPRO" brochure does not warn about, among other things, breast cancer even though its profiles all have used estrogen or Prempro for more than five years. Compl. ¶ 53. In the section of Wyeth's "Say yes to PREMPRO" brochure devoted to "side effects," Wyeth warns about uterine cancer (associated with estrogen-only therapy), worsening diabetes, blood clots, nausea, abdominal pain, irregular bleeding, headache, hair loss, and breast tenderness, but does not warn about breast cancer. Compl. ¶ 54.

Until mid-2002, Wyeth used a Prempro package insert, which states under the subheading "Cancer of the breast":

> Most studies have not shown a higher risk of breast cancer in women who have ever used estrogen. However, some studies have reported that breast cancer developed more often (up to twice the usual rate) in women who used estrogen for long periods of time (especially more than ten years), or who used high doses for shorter time periods.

Compl. (¶ 55).

Though worded slightly differently, this same statement appears in a November 2001 Wyeth leaflet that addresses estrogens generally. According to plaintiffs, the information provided by Wyeth to consumers from at least 1993 to mid-2002 consistently and uniformly misrepresented that its estrogen replacement products (with or without progestin) were to be used by consumers on a long term basis, even after menopausal symptoms had subsided, and did not present significant breast cancer risks unless consumed for ten years or more in unusually high doses. Wyeth also omitted from its 1993-2002 warnings and direct-to-consumer promotions any mention of the diminished effectiveness of standard mammography attributable to HRT. Compl. ¶ 61.

In July 8, 2002, the National Heart, Lung, and Blood Institute ("NHLBI") of the National Institutes of Health ("NIH") announced that it had decided to terminate prematurely a portion of its Women's Heath Initiative ("WHI") Study that was designed to examine the effect of estrogen plus progestin on the prevention of heart disease and hip fractures, and to identify any associated cancer risks ("WHI Study"). Compl. ¶ 64. The WHI Study was designed in light of earlier studies that had demonstrated that long term HRT or ERT increased breast cancer risks as well as the risks of blood clots in the legs and lungs. Compl. ¶ 75. The WHI Study was designed to continue for 8.5 years or until 2005. The NHLBI stopped the HRT

portion of the study, however, after an average follow-up of only 5.2 years, primarily due to an unacceptable risk of invasive breast cancer associated with Prempro. Compl. ¶ 65. Prempro was the only HRT drug given to the women who participated in the WHI study. Compl. ¶ 66.

In the WHI study, the risk of invasive breast cancer increased by 26% after using Prempro for an average of 5.2 years. Compl. ¶ 67. The WHI study also demonstrated that, after five years of use, the overall risks of Prempro outweigh any benefits which it may produce. Compl. ¶ 68. In addition to the increased breast cancer risk associated with Prempro, the WHI Study showed the following increases among the women who participated in the Study: (1) a 41% increase in strokes, (2) a 29% increase in heart attacks, and (3) more than doubling in the rates of venous thromboembolism (blood clots). The benefits of Prempro revealed in the WHI Study appear to be fewer colorectal cancers and hip fractures. Compl. ¶ 69. When the WHI Data and Safety Monitoring Board decided to terminate the WHI Study prematurely, it sent a letter to each Study participant informing them that the Board had concluded that "it has become clear that the health risks of taking estrogen plus progestin now exceeds the benefits." As a result, the WHI Study participants were instructed to "Stop taking your pills, maintain their clinic appointments and receive yearly mammograms." Compl. ¶ 73.

Although the WHI Study was the first large, randomized, and placebo-controlled trial to examine the risks and benefits for healthy women of taking estrogen and progestin over an extended period of time, a number of peer-review studies had previously shown higher breast cancer rates among women who were HRT users, especially those who were taking a formulation that, like Prempro, contained progestin and particularly when the drug was taken for five or more years. Compl. ¶ 81-93. According to the plaintiffs, Wyeth knew or should have known that it was misleading to suggest to women that breast cancer only

became pronounced after ten years or more of the estrogen use, particularly at unusually high doses. Compl. ¶ 94.

By early 1997, the evidence of an association between HRT and breast cancer was strong enough to lead to the publication of a letter in the British Journal of Medicine entitled, "Women need to be warned about dangers of hormone replacement therapy." Compl. ¶ 95. HRT significantly increases the risk of breast cancer to a far greater extent than does estrogen-only therapy. Compl. ¶ 97. A report published in Steroids 2000 Oct-Nov estimated that increased risk of breast cancer attributable to HRT use is some 212-fold greater than the effect of ERT. Compl. ¶ 97. Other studies have demonstrated that estrogen and progestin taken in combination increase breast tissue density to a greater extent than post-menopausal ERT alone and that HRT shows an increase in breast density on mammograms. Compl. ¶¶ 98-99. Increasing breast tissue density decreases the effectiveness of standard mammography. Compl. ¶ 100.

Plaintiffs allege that the substantially increased risk of invasive breast cancer associated with long term use of estrogen and/or progestin had been clearly demonstrated well before the WHI Study. Wyeth failed to acknowledge and provide this warning. Instead, Wyeth warned that the effect of adding progestins for the risk of breast cancer was unknown and suggested that ten years of exposure was the threshold for harm. Compl. ¶ 106.

In July 2002, as the result of the premature termination of the Prempro component of the WHI Study, Wyeth acknowledged the significant risks of breast cancer and cardiovascular disease presented by hormone therapy. In July 2002, Wyeth changed its warning labels and curtailed its direct to consumer marketing of Prempro. On September 4, 2002, Wyeth amended Prempro and Premarin package inserts in light of the WHI Study. Compl. ¶ 107. Wyeth forwarded letters to physicians informing them of the

package insert update. Wyeth did not utilize a direct-to-consumer campaign to inform consumers of the package insert update. Compl. ¶ 108. The amended package insert acknowledges that "Prempro . . . may increase your risk of getting breast cancer, blood clots, heart attacks and strokes." Compl. ¶ 109. The new package insert does not refer to "a long term," or give any indication that the risk refers to a time period other than the "ten years or more" period about which Wyeth warned previously. Compl. ¶ 109. The package insert also states, "Mammography should be scheduled depending on your risks' factors" and that in light of associated health risks Prempro should only be used "as long as needed for relief from menopausal symptoms." Compl. ¶ 111.

On August 21, 2002, plaintiffs Claudette Albertson and Thelma D. Reese, E.D. filed a complaint against Wyeth. On or about the same date, plaintiff Finnegan filed a similar complaint, followed by plaintiff Everette. On January 22, 2003, the matters were consolidated and a consolidated, Amended Complaint was filed. The Complaint asserts five counts against Wyeth: (a) negligence/medical monitoring (Count I), (b) unjust enrichment (Count II), (c) violation of the Pennsylvania Unfair Consumer Practice and Consumer Protection Law (Count III), (d) Breach of Fiduciary Duty (Count IV) and (e) Fraud (Count V). Wyeth has filed Preliminary Objections in the nature of a demurrer. Wyeth also contemporaneously filed a Motion to Strike plaintiffs' claim for attorney fees.

DISCUSSION

A preliminary objection in the nature of a demurrer tests the legal sufficiency of the complaint. Constantino v. University of Pittsburgh, 2001 Pa. Super. 4, 766 A.2d 1265, 1268 (2001). The question presented by a demurrer is whether, on the facts averred, the law says with certainty that no recovery is possible. Viglione v. Pennsylvania Dept. of Corrs., 781 A.2d 248, 250 n.3 (Pa. Commw. 2001). When

considering preliminary objections, all material facts set forth in the complaint, as well as all inferences reasonably deducible therefrom are accepted as true, while conclusions of law, unwarranted inferences from facts, argumentative allegations or expressions of opinion need not be regarded as such. Wagner v. Waitlevertch, 2001 Pa. Super. 100, 774 A.2d 1247, 1250 (2001).

Preliminary objections may only be granted in cases where it is clear and free from doubt that the facts alleged are legally insufficient to establish a right to relief. Stair v. Turtzo, Spry, Sbrocchi, Faul & LaBarre, 564 Pa. 305, 309, 768 A.2d 299, 301 (2001). For that reason, a demurrer should not be sustained simply because of the novelty of a claim. Denton v. Silver Stream Nursing and Rehabilitation Center, 739 A.2d 571, 575 (Pa. Super. 1999). Furthermore, if there is any doubt as to whether a demurrer should be granted, it should be resolved in favor of overruling the preliminary objections. Lennon ex rel. v. Wyeth-Ayerst Laboratories Inc., 2001 WL 755944, *1 (Pa. Super. June 14, 2001).

A. Demurrer to Count I (Negligence/Medical Monitoring)

Wyeth first asserts that Count I of plaintiffs' Complaint alleging a medical monitoring claim should be dismissed. This objection is overruled.

In Simmons v. Pacor, Inc., 543 Pa. 664, 674 A.2d 232 (Pa. 1996), our Supreme Court recognized medical monitoring as a viable cause of action under Pennsylvania law. In Simmons, the plaintiffs developed asymptomatic pleural thickening as a result of their occupational exposure to asbestos and sought damages for increased risk and fear of cancer. The Supreme Court held that damages for increased risk and fear of cancer were too speculative to be recoverable where cancer was not present. Because the plaintiffs in Simmons had not developed cancer, the court did not permit them to recover for their increase risk and fear of cancer. However, the Supreme Court did permit plaintiffs with asbestos-

related asymptomatic pleural thickening to recover for medical monitoring. Redland Soccer Club, Inc. v. Department of the Army and Dept. of Defense of the U.S., 548 Pa. 178, 696 A.2d 137, 145 (1997).

In Redland Soccer Club Inc., *supra*., the Pennsylvania Supreme Court extended medical monitoring claims to non-asbestos-related injuries and articulated the necessary elements to state a claim for medical monitoring: 1) exposure greater than normal background levels; 2) to a proven hazardous substance; 3) caused by defendants' negligence; 4) as a proximate result of the exposure, plaintiffs have a significantly increased risk of contracting a serious latent disease; 5) a monitoring procedure exists that makes the early detection of the disease possible; 6) the prescribed monitoring regime is different from that normally recommended in the absence of exposure; and 7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles. Redland, 548 Pa. at 195-196, 696 A.2d at 145-146. The Supreme Court noted that expert testimony is required to prove each of these elements. *Id*. at 196, 696 A.2d at 146.

The Redland court cited four important policy reasons for recognizing claims for medical monitoring. First, "medical monitoring promotes early diagnosis and treatment of disease resulting from exposure to toxic substances caused by a tortfeasor's negligence." Second, "allowing recovery for such expenses avoids the potential for injustice of forcing an economically disadvantaged person to pay for expensive diagnostic examinations necessitated by another's negligence" and "affords toxic-tort victims, for whom other sorts of recovery may prove difficult, immediate compensation for medical monitoring needed as a result of exposure." Third, medical monitoring "furthers the deterrent function of the tort system by compelling those who expose others to toxic substances to minimize risks and costs of exposure." Finally, permitting the claim is "in harmony with the important public health interest in fostering

access to medical monitoring testing for individuals whose exposure to toxic chemicals creates an enhanced risk of disease." Redland at 194, 696 A. 2d at 145 (quoting Hansen v. Mountain Fuel Supply Co., 858 P. 2d 970, 976-977 (Utah 1993)).

Wyeth argues that plaintiffs have failed to meet the criteria enunciated in Redland, *supra*. to establish a claim for medical monitoring. Specifically, Wyeth contends that plaintiffs have failed to allege that they were exposed to a proven hazardous substance. Wyeth maintains that Prempro, a FDA approved drug, is not a hazardous substance since it is still on the market as a safe and effective treatment.

Wyeth further maintains that it cannot be negligent for its pre-WHI Prempro warnings because the language it used was the precise warning language the FDA told Wyeth it should use. In other words, Wyeth claims that the pervasive scheme of federal regulation governing the production, labeling, and distribution of prescription drugs by the FDA implicitly preempts Pennsylvania's tort claims for prescription drug manufacturers' breach of duty to warn consumers.

The concept of preemption has its roots in the supremacy clause of the U.S. Constitution, art. VI, cl. 2. Preemption may be express or implied. Hillsborough County, Fla. v. Automated Medical Laboratories, Inc., 471 U.S. 707, 105 S. Ct. 2371 (1985). Since Wyeth makes no claim that Congress expressly preempted state tort law, only the issue of implied preemption need be discussed.

Implied preemption arises in two ways. First, Congress may indicate an intent to assign an entire field of regulation in a given area to the federal government. Fidelity Federal Sav. and Loan Ass'n. v. de la Cuesta, 458 U.S. 141, 102 S. Ct. 3014 (1982). Second, Congress may preempt state law to the extent that state law actually conflicts with federal law. Such a conflict arises when compliance with both federal and state law is impossible or when state law frustrates the purpose of federal law. Michigan

Canners and Freezers Ass'n. v. Agricultural Marketing and Bargaining Bd., 467 U.S. 461, 104 S. Ct. 2518 (1984).

There is no question that federal regulation of prescription drugs is comprehensive. Under the Food and Drug Administration ("FDA") regulatory scheme, a manufacturer must obtain approval from the FDA to distribute its product. Sokoloski v. American Home Products, 2003 WL 1875113, *6 (Pa. Com. Pl. 2003), citing Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et. seq*. That approval is secured by formal application, which must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." Sokoloski, quoting 21 U.S.C. § 355(b)(1)(A). Additionally, subsequent to FDA approval, a manufacturer is required to provide updated data or information to the FDA Secretary, to enable the Secretary to determine whether grounds exist for revocation of approval for the drug. 21 U.S.C. § 355(k)(1). Moreover, the manufacturer, distributor or seller of the drug has the duty to label the prescription drug it has manufactured. *Id*., citing 21 U.S.C. § 352(b); 21 CFR § 201.100.

Preemption of state tort law, however, does not automatically follow extensive federal regulation. Mazur v. Merck & Co. Inc., 742 F. Supp. 239, 245 (E.D. Pa. 1990) citing Hillsborough, 471 U.S. at 715, 105 S. Ct. at 2376. In the absence of express preemption, there is a strong presumption that Congress did not intend to displace state law. *Id*. at 256. The presumption against preemption is even stronger when federal regulation would work to preempt state tort remedies. *Id*., citing Silkwood v. Kerr-Mcgee Corp., 464 U.S. 238, 251, 104 S. Ct. 615, 623 (1984).

In Silkwood v. Kerr-McGee Corp., *supra*., the Court found that the Atomic Energy Act and its enacting regulations did not preclude an award of punitive damages under state law. The Court recognized that states had been expressly prohibited from regulating the safety aspects of hazardous materials, but refused to extend that prohibition to state law remedies for persons injured from radiation exposure in nuclear plants. *Id*. at 250–51, 104 S. Ct. at 622-23. The Court rejected the contention that the award of damages would conflict with the federal remedial scheme, finding that "paying both federal fines and state-imposed punitive damages for the same incident would not appear to be physically impossible." *Id*. at 257, 104 S. Ct. at 626. The Supreme Court has since unanimously confirmed that "ordinarily, state causes of action are not preempted solely because they impose liability over and above that authorized by federal law." English v. General Elec. Co. , 496 U.S. 72, 89, 110 S. Ct. 2270, 2280 (1990) (citation omitted).

Here, if federal regulation of prescription drugs were deemed exclusive, Pennsylvania's ability to protect its citizens from the dangers of prescription drug use would be severely hampered. Further, it would leave Pennsylvania citizens harmed by prescription drugs without a state tort remedy. This court submits that Congress did not intend such a result. The tort law here is remedial and compensatory in nature, and does not conflict with any aspect of the FDA's regulatory scheme. Thus, preemption of the state remedial measures available to plaintiffs cannot be implied.

Wyeth seeks to shield itself from liability, arguing that the language used for the warning label of Prempro was the precise language which the FDA approved. The same argument was raised and rejected in Mazur v. Merck & Co. Inc., 742 F. Supp. 239, 247 (E.D.Pa. 1990). In Mazur, the defendant asserted that the pervasive scheme regulating all aspects of vaccines compelled a finding of implied preemption. The Court disagreed, stressing the strong presumption against preemption of state tort remedies in areas of

health and safety, and noting that preemption would leave Pennsylvania citizens harmed by vaccines without a remedy.

The Court in Mazur also rejected the defendant's narrower conflict preemption argument based on two observations appropriate to the circumstances here:

> Mere compliance with a FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant. First, compliance with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not necessarily absolve the manufacturer of all liability. See, e.g., Brochu v. Ortho Pharmaceutical Corp. , 642 F. 2d 652, 658 (1st Cir. 1981). Manufacturers must meet state safety requirements, whether codified or embodied in the common law, in addition to satisfying the initial FDA requirements. Second, federal regulation serves a very different purpose than state tort law. Essentially, federal regulation serves a deterrent purpose by limiting the manufacturer of inherently dangerous products to those applicants who meet certain stringent safety standards, while state tort law serves the equally important purpose of compensating individuals injured by those very same products. Because, compliance with FDA regulation will not ensure that a manufactured product will not cause injury, compliance will not necessarily exempt a manufacturer from liability. When those products do cause injuries, the state tort system provides a means of compensation. State tort law is intended to supplement federal regulation by providing a vehicle for compensation of vaccine related injuries.

Id. at 247 (footnote omitted) (emphasis added). This analysis in Mazur supports this court's refusal to find in this case that plaintiffs' state tort claim is preempted, especially on preliminary objections.[2]

Thus, Wyeth's preliminary objection on the ground that plaintiffs' claim is preempted by federal regulation is overruled.

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[2] In addition, this court finds Wyeth's reliance upon White v. Weiner, 386 Pa. Super. 111, 119, 562 A. 2d 378, 383 (1989), aff'd, 525 Pa. 572, 583 A. 2d 789 (1991), misplaced. In White, our Superior Court addressed a matter that involved bulk sale of the drug protamine sulfate. The product was sold to Upjohn Pharmaceuticals Company for conversion into a final product which would then be distributed to medical care providers for prescription to the individual parties. In White, the Court declined to impose on a bulk supplier of pharmaceutical chemicals the same strict duty to warn required of the manufacturer of the marketed drug.

In addition, this court finds, that the Complaint makes sufficient allegations to establish a claim for medical monitoring. Plaintiffs allege that Prempro is a hazardous substance, and that Wyeth failed to use reasonable care in informing consumers of the risks of Prempro which they knew, or about which they reasonably should have known. Compl. ¶ 127. Plaintiffs further allege that Wyeth breached the duty owed to plaintiffs and that Wyeth's breach of the duty was the proximate cause of the injuries suffered. Compl. ¶ 130. According to plaintiffs, Wyeth's actions that give rise to liability include: (1) erroneously suggesting to doctors and patients that the risk of breast cancer associated with Prempro use did not become substantial until ten or more years of use, (2) failing to distinguish between the breast cancer risks posed by Prempro versus those posed by estrogen alone, (3) failing to inform doctors and patients that long-term use of HRT diminishes the effectiveness of standard mammography, (4) failing to inform doctors and patients that any bone density benefit that may be associated with Prempro was outweighed by increased risks of invasive breast cancer and cardiovascular disease, (5) failing to inform doctors and patients that, overtime, the overall risks of daily use of Prempro, including risks of heart attack, stroke and blood clot, outweigh any associated osteoporosis benefits, and (6) combining progestin and estrogen in a product to be taken orally on a long term basis, thereby substantially increasing plaintiffs' risks of suffering breast cancer, heart attacks, strokes and blood clots. Compl. ¶ 129 a-e. Plaintiffs have sufficiently alleged that they are at a significantly increased risk of harm for developing breast cancer and have also pleaded with sufficiency that the monitoring regime is different from that normally recommended. Compl. ¶¶ 94, 100, 105, 131-32 a-n.

At this juncture it is important to reiterate two points noted earlier. First, preliminary objections may be granted only where it is free from doubt that the alleged facts are insufficient and, if there is any doubt whether a demurrer should be granted, it must be resolved in favor of overruling the objections.[3] Second, in Redland, *supra.*, our Supreme Court made clear that expert testimony is necessary to prove the elements requisite for a monitoring claim.[4]

Recognizing that Redland provides that expert testimony is required and that plaintiffs receive all inferences reasonably flowing from the pleading, leads this court to overrule Wyeth's Preliminary Objection that plaintiffs failed to plead the elements of a negligence/medical monitoring claim.[5]

B. Demurrer to Count II (Unjust Enrichment)

Wyeth next contends that plaintiffs' claim for unjust enrichment is insupportable as a matter of law because plaintiffs had no dealings with Wyeth that would support a quasi-contractual or equitable claim for unjust enrichment and because plaintiffs cannot point to any unjust benefit Wyeth received as a result of plaintiffs' purchases of Prempro. Defendants' Memo, p. 13.

"Unjust enrichment" is essentially an equitable doctrine. Mitchell v. Moore, 1999 Pa. Super. 77, 729 A.2d 1200, 1203 (1999). "Where unjust enrichment is found, the law implies a contract, which requires the defendant to pay the plaintiff the value of the benefit conferred." *Id.*, citing Schenck v. K.E. David, Ltd., 446 Pa. Super. 94, 666 A.2d 327 (1995). The elements necessary to prove unjust enrichment

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[3]Discussion, *supra.*, pp. 9-10.

[4]Discussion, *supra.*, p. 11.

[5]The court acknowledges that it may be that the plaintiffs' expert reports will not be sufficient to meet the mandates of Redland. However, at this point in the proceedings it would be improvident to dismiss the claim.

are: (1) benefits conferred on defendant by plaintiff; (2) appreciation of such benefits by defendant; and (3) acceptance and retention of such benefits under such circumstances that it would be inequitable for defendant to retain the benefit without payment of value. *Id.* at 1203. The application of the doctrine depends on the particular circumstances presented. Further, "in determining if the doctrine applies, the focus is not on the intention of the parties, but rather on whether the defendant has been unjustly enriched." *Id*. at 1203, quoting Schenck, A.2d 328.

To support their claim of unjust enrichment, plaintiffs allege: (a) that they purchased Prempro to obtain safe and effective treatment for certain medical symptoms (Compl. ¶ 135); (b) that defendants received payment from plaintiffs in exchange for Prempro under the guise that the drug was safe and effective (Compl. ¶ 136); (c) that as the intended and expected result of defendant's non-disclosure and other wrongdoing, defendants have profited and benefitted from the purchase of Prempro (Compl. ¶ 137); and (d) that defendants accepted and retained revenue and profits with full knowledge that plaintiff and the class were not receiving products of a quality, nature, fitness or value that they reasonably expected. (Compl. ¶ 138.)

The court finds plaintiffs' reliance upon Tesauro v. Quigley Corp., 2001 WL 1807782 (Pa. Com. Pl. 2001) unpersuasive. In Tesauro, plaintiffs alleged that defendant Quigley, the manufacturer of Cold-Eeze zinc lozenges, touted its ability to prevent colds and pneumonia and to reduce the severity of colds and allergies. The advertisements described these health claims as clinically proven. As a result, in 1997 the sales of Cold-Eeze reached $10.2 million. Several years later, the Federal Trade Commission ("FTC") filed a complaint against the defendant charging that the advertisements were false and misleading because defendant did not have a reasonable basis for claiming that Cold-Eeze had these beneficial health effects.

The FTC and the defendant entered into a consent order that defendant would make no further health claims about Cold-Eeze until it had reasonable basis for making such a claim. Tesauro filed a complaint against Quigley, alleging unjust enrichment along with other claims to which the defendants filed preliminary objections. The court overruled the defendants' preliminary objections regarding plaintiffs' unjust enrichment claim because the complaint set forth a claim that plaintiffs did not receive a cold remedy when they bought Cold-Eeze, and it would be inequitable for the defendant to keep the money if the plaintiffs did not, in fact, receive a cold remedy.

Here, unlike Tesauro, plaintiffs did receive the product they sought, a hormone replacement therapy. Plaintiffs merely allege that Prempro was not safe, and that Wyeth knew it was unsafe but promoted the drug anyway. These allegations are insufficient to state a claim for unjust enrichment.[6] The Preliminary Objection to Count II is sustained.

C. Demurrer to Count III (Pennsylvania's Unfair Trade Practices and Consumer Protection Law)

Wyeth preliminarily objects to Count III, alleging violations of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL"). Plaintiffs allege that Wyeth failed to provide plaintiffs with a full and accurate description of Prempro and knowingly and intentionally misrepresented, concealed or made false claims to plaintiffs regarding Prempro. Compl. ¶¶ 145-147. Plaintiffs urge that this conduct constitutes a violation of the UTPCPL. The UTPCPL makes unlawful unfair methods of

[6]Although Count II was designated a claim for unjust enrichment, the allegations suggest a claim for breach of an implied warranty of merchantability and fitness for a particular purpose. However, prescription drugs are not covered by a warranty of fitness for ordinary purpose. Luke v. American Home Products Corp., 1998 WL 1781624, *4-5 (Pa. Com. Pl. 1998).

competition and deceptive practices in the conduct of trade or commerce. Luke v. American Home Products Corp., 1998 WL 1781624 *8 (Pa. Com. Pl. 1998), citing 73 P.S. §§ 201-3. The Act provides a means for redress for various misrepresentations and fraudulent conduct that create a likelihood of confusion or misunderstanding. *Id.*, *See* 73 P. S. § 201-2(4).

Wyeth maintains that plaintiffs cannot assert a UTPCPL claim since the Act does not apply to claims by prescription drug users against prescription drug manufacturers. To support this argument, Wyeth relies upon the learned intermediary doctrine which provides that a prescription drug manufacturer must provide its warnings about a drug to prescribing physicians, but need not provide the warnings to patients who use the drug. Further, Wyeth argues that plaintiffs fail to make a single well-founded allegation in support of their UTPCPL claim.

Plaintiffs, on the other hand, argue that an unsettled question of law exists for this court to decide whether the UTPCPL applies to prescription drugs. Plaintiffs contend that the learned intermediary doctrine does not apply to the UTPCPL and that a drug manufacturer who engages in direct-to-consumer advertising has a duty not to withhold material information. Specifically, the plaintiffs urge that this court should create a limited exception to the learned intermediary doctrine where direct-to-consumer advertising is used.

In Luke v. American Home Products Corp., *supra.*, the court addressed this same issue. In Luke, the plaintiff was prescribed dexfenfluramine hydrochloride (a/k/a/ Redux) as a weight loss treatment. After taking Redux for several months, the plaintiff began to experience difficulty breathing and was subsequently diagnosed with primary pulmonary hypertension and was placed on the list for a double transplant. Plaintiff filed a complaint against the manufacturer of Redux alleging, *inter alia*, a violation of the UTPCPL. The

manufacturer filed preliminary objections. In sustaining the preliminary objections to plaintiffs' UTPCPL claim, the court reasoned that:

> Under the "learned intermediary doctrine," a manufacturer of prescription drugs must direct information and warnings to prescribing physicians, not the patient. See Taurino v. Ellen, 579 A.2d 925 (Pa. Super. Ct. 1990). There can be no cause of action based on Defendants' alleged omissions because defendants had no duty to disclose any information directly to plaintiff.
>
> Further, to permit a cause of action under the UTPCPL in this case would effectively make a drug manufacturer the absolute guarantor of the anticipated results and effects of a prescription drug. Pennsylvania law, however, recognizes that some prescription drugs by their very nature can never be made safe. See Makripodis by Makripodis v. Merrell-Dow Pharm., Inc., 523 A.2d 374 (Pa. Super. Ct. 1987). An inconsistency would result if we were to hold that drug manufacturers must guarantee that prescription drugs are completely safe. The premise behind the UTPCPL was not meant to engender such a result.

Luke, at *8.

This court finds the rationale in Luke persuasive, and believes it would be improvident to accede to plaintiffs' argument that a limited exception to the learned intermediary doctrine should be created based upon direct-to-consumer advertising. Media dissemination of information concerning the existence of these drugs does not enhance the public's ability to acquire them, as the skill and knowledge of the physician still must be brought to bear in a determination of whether the pharmaceutical is appropriate for the patient. Lennon ex rel. v. Wyeth-Ayerst Laboratories, Inc., 2001 WL 755944, *2 (Pa. Super. 2001). Here, although Wyeth engaged in direct-to-consumer advertising, the consumer still required a prescription from a physician, a learned intermediary, to acquire Prempro.

Wyeth's Preliminary Objections to Count III are sustained.[7]

D. Demurrers to Count IV (Breach of Fiduciary Duty) and Count V (Fraud)

Wyeth contends that plaintiffs' claims for breach of fiduciary duty and fraud are barred by the learned intermediary doctrine. The court agrees. The court finds that plaintiffs have no cause of action for breach of fiduciary duty and fraud in light of the learned intermediary doctrine. The Preliminary Objections with respect to plaintiffs' breach of fiduciary duty claim and fraud are sustained.

E. Motion to Strike Plaintiffs' Claim for Attorney Fees

In addition to the Preliminary Objections, Wyeth contemporaneously filed a Motion to Strike plaintiffs' request for attorney fees. Wyeth contends that plaintiffs' claim for attorney fees has no legal basis since there is no statutory or legal grounds that provides for such recovery. Wyeth further argues that medical monitoring does not give rise to counsel fees being paid out of a common fund.

Under Pennsylvania law, 'a litigant cannot recover counsel fees from an adverse party unless there is express statutory authorization, a clear agreement of the parties, or some other established exception." Snyder v. Synder, 533 Pa. 203, 212, 620 A.2d 1133, 1138 (1993). This is commonly referred to as the "American" rule. Jones v. Muir, 511 Pa. 535, 541, 515 A.2d 855, 858 (1986). However, Pennsylvania has long recognized the common fund doctrine as an exception to the "American" rule. *Id*. In Jones, our Supreme Court held that the common fund doctrine is within the parameters of Section 2503(8) of the Judicial Code, 42 Pa. C.S. § 2503(8). *Id*. At 542, 515 A.2d at 858-59. Section 2503(8) of the Judicial

[7]Because this court finds that plaintiffs have no cause of action under the UTPCPL based on the learned intermediary doctrine, it is not necessary to address Wyeth's further argument to the UTPCPL claim challenging the sufficiency of plaintiffs' pleading.

Code authorizes the award of attorney fees to "[a]ny participant who is awarded counsel fees out of a fund within the jurisdiction of the court pursuant to any general rule relating to an award of counsel fees from a fund within the jurisdiction of the court." 42 Pa.C.S. § 2503(8).

Our Supreme Court has repeatedly described the circumstances under which the "common fund" exception applies:

> Where many persons have a common interest in a trust property or fund, and one of them, for the benefit of all, at his own cost and expense, brings suit for its preservation or administration, the court of equity in which suit is brought will order plaintiff to be reimbursed his costs and expenses, including counsel fees, from the property of the trust, or order those benefit to contribute proportionately toward that expense.

International Organization Master, Mates and Pilots of America, Local No. 2 v. International Organization Master, Mates and Pilots of America, Inc. 497 Pa. 102, 439 A.2d 621, 627 (1981).

Here, the plaintiffs filed a negligence/medical monitoring claim against Wyeth and request the creation of a fund from which a monitoring system could be established for the early detection of breast cancer. At this time, a fund does not exist and plaintiffs' claim for attorney fees is premature.

Thus, for the present, this court grants Wyeth's Motion to Strike plaintiffs' claim for attorney fees and dismisses plaintiffs' claim for attorney fees without prejudice.

CONCLUSION

For the reasons discussed, this court finds that:

(a) Wyeth's Preliminary Objections to plaintiffs' negligence/medical monitoring claim (Count I) is **Overruled**;

(b) Wyeth's Preliminary Objection to plaintiffs' unjust enrichment claim (Count II) is **Sustained**;

(c) Wyeth's Preliminary Objection to plaintiffs' claim under the UTPCPL (Count III) is **Sustained**;

(d) Wyeth's Preliminary Objection to plaintiffs' breach of fiduciary duty claim (Count IV) is **Sustained**;

(e) Wyeth's Preliminary Objection to plaintiffs' fraud claim (Count V) is **Sustained**; and

(f) Wyeth's Motion to Strike plaintiffs' request for attorney fees is **Granted**. The court finds plaintiffs' claim for attorney fees is premature and is dismissed without prejudice.

This court will issue a contemporaneous Order consistent with this Opinion.

BY THE COURT,

ALBERT W. SHEPPARD, JR., J.