

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

ALBERTSON, ET. AL.,	:	August Term, 2002
	Plaintiffs,	:
	:	:
vs.	:	No.: 002944
	:	:
WYETH, INC., ET. AL.,	:	:
	Defendants.:	:

FINNEGAN, ET. AL.,	:	August Term, 2002
	Plaintiffs,	:
	:	:
vs.	:	No.: 000007
	:	:
WYETH, INC., ET. AL.,	:	:
	Defendants.:	:

EVERETTE, ET. AL.,	:	August Term, 2002
	Plaintiffs,	:
	:	:
vs.	:	No.: 000935
	:	:
WYETH, INC., ET. AL.,	:	:
	Defendants.:	:

ORDER AND MEMORANDUM

AND NOW, this 3rd day of May 2005, upon consideration of Plaintiffs' Motion for Class Certification, all responses in opposition, the respective memoranda, all matters of record, and in accordance with the contemporaneous Memorandum Opinion, it hereby is **ORDERED** and **DECREED** as follows: Plaintiffs Motion for Class Certification is **DENIED**.

BY THE COURT:

**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
	:	
WYETH, ET. AL.,	:	
Defendants.	:	

MEMORANDUM OPINION

Presently before this court is plaintiffs’ motion for class certification arising from the ingestion of Prempro, an estrogen-progestin combination or hormone replacement therapy (HRT) drug. Pursuant to Pennsylvania Rule of Civil Procedure 1710 (a), this court accompanies its Order with the following Findings of Fact, Conclusions of Law, and discussion.

FINDINGS OF FACT

1. Plaintiffs seek to certify a class defined as: All post-menopausal women residing in the Commonwealth of Pennsylvania, who have taken high dose Prempro on a daily basis for at least one year, who began such use prior to the announcement of the Women’s Health Initiative Study on July 9, 2002, and who are presently asymptomatic (i.e., have not been diagnosed with breast cancer) (the “Class”).
2. Plaintiffs seek to certify a sub-class defined as: All post-menopausal women residing in the Commonwealth of Pennsylvania who have taken high dose Prempro on a daily basis for at least one year, who began such use prior to the announcement of the Women’s Health Initiative Study results on July 9, 2002, and who changed their prescriptions to a

new, low dose of Prempro (i.e., < .625 mg CEE / 2.5 mg MPA), and who are presently asymptomatic (i.e., have not been diagnosed with breast cancer) (the “Subclass”).

3. Plaintiff Claudette Albertson is a citizen of the Commonwealth of Pennsylvania.

Albertson was prescribed, purchased and ingested Prempro or Premarin plus a progestin tablet, in the early-mid 1990’s until July 2002. Albertson has not been diagnosed with breast or other cancers as a result of Prempro use.

4. Plaintiff Thelma Reese is a citizen of the Commonwealth of Pennsylvania. Reese was prescribed purchased and ingested Prempro, or Premarin plus a progestin tablet in the early 1990’s until July 2002. Reese was again prescribed, purchased, and ingested Prempro for a short period in September 2002 until May 2003. Reese has not been diagnosed with breast or other cancers as a result of Prempro use.

5. Plaintiff Rosemarie Finnegan is a citizen of the Commonwealth of Pennsylvania.

Finnegan was prescribed, purchased and ingested Prempro or Premarin plus a progestin tablet, in the September 1996 until the summer of 2002. Finnegan has not been diagnosed with breast or other cancers as a result of Prempro use.

6. Plaintiff Vashti Everette is a citizen of the Commonwealth of Pennsylvania. Everette was prescribed, purchased and ingested Prempro or Premarin plus a progestin tablet, in April 1993 until the summer of 2002. Evertte was again prescribed, purchased, and ingested Prempro for a short term in 2003. Everette has not been diagnosed with breast or other cancers as a result of Prempro use.

7. Plaintiff Fran Rosenstock is a citizen of the Commonwealth of Pennsylvania. Rosenstock was prescribed, purchased and ingested Prempro or Premarin plus a progestin tablet, in June 1993 until the summer of 2002. Rosenstock was again prescribed, purchased, and

has ingested low-doses Prempro from November 2003 to present. Rosenstock has not been diagnosed with breast or other cancers as a result of Prempro use.

8. Defendants Wyeth and Wyeth Pharmaceuticals Inc. (“Wyeth”) are Delaware corporations with principal places of business in New Jersey and Pennsylvania, respectively.
9. Wyeth manufactures, distributes, and sells branded pharmaceuticals, including the prescription drug, Prempro
10. Prempro is a prescription form of postmenopausal hormone therapy combining estrogen and progestin.
11. Prempro is indicated for use by women in the treatment of menopausal symptoms, such as hot flashes, vaginal atrophy, and for the prevention of osteoporosis.
12. Premarin, also a Wyeth product, is a form of estrogen alone that has been approved for use by the Food and Drug Administration (“FDA”) and prescribed by healthcare providers since 1942.
13. Before Prempro was introduced, physicians often prescribed estrogen, such as Premarin, in combination with progestin for their patients to alleviate certain symptoms of menopause.
14. Prempro was approved as safe and effective by the FDA in 1994.
15. Initially, Prempro consisted of two separate pills: one .625 mg tablet of Premarin brand of conjugated estrogens and one 2.5 mg tablet of Cycrin brand of medroxyprogesterone acetate (MPA).
16. In 1995, the FDA approved the current form of Prempro, with the estrogen and progestin components combined in a single pill.
17. In 1998, the FDA approved a third dosage form of Prempro, containing .625 mg of

Premarin and 5 mg of MPA.

18. In 2003, the FDA approved another form of Prempro, containing .45 mg of Premarin and 1.5 mg of MPA (“the lower dose”) and a fourth dosage form of Prempro, containing .3 mg of Premarin and 1.5 mg of MPA
19. Prempro is currently FDA-approved in all four of these single-pill dosage forms.
20. Plaintiffs’ claim is against Wyeth for “negligence/medical monitoring.”
21. At least 20% of post-menopausal women require hormone therapy to treat their severe vasomotor symptoms.
22. Doctors, including plaintiff’s expert witness Dr. Cherry, continue to prescribe Prempro in its various dosage forms to patients who require it because of the severity of their menopausal symptoms.
23. Dr. Nancy Elliott, is plaintiffs’ expert in breast surgery and treatment. She is the founder and director of the Montclair Breast Center in Montclair, New Jersey. Dr. Elliott evaluates 3500 women per year, 90% of whom are at a high risk for developing breast cancer.
24. Dr. Sheldon Cherry is plaintiffs’ expert in obstetrics and gynecology. He is an obstetrician and gynecologist who practices in New York City. Dr. Cherry is a clinical professor of obstetrics and gynecology at Mount Sinai School of Medicine, where he is also an attending obstetrician and gynecologist. He has authored or co-authored such books as, The Menopause Book (1994) and The Answer to Cancer (2004).
25. Dr. Ronald Ross is plaintiffs’ expert in epidemiology and preventative science medicine. He is an epidemiologist and professor at the Keck School of Medicine at the University of Southern California, where he is also the chair of the department of preventative

medicine. Dr. Ross is also the deputy director of the Norris Comprehensive Cancer Center at the University of Southern California, where he leads the programs in cancer epidemiology and cancer prevention. Dr. Ross previously taught epidemiology to graduate and medical school students at the University of Southern California.

26. Dr. Daniel Kopans is defendant's expert in breast imaging. Dr. Kopans is a professor of radiology at Harvard Medical School and has been the Director of the Breast Imaging Division at the Massachusetts General Hospital from 1978 to the present. Dr. Kopans has authored the leading textbook on breast imaging and has published hundreds of peer-reviewed articles on breast cancer detection and diagnosis. Dr. Kopans is a fellow of the American College of Radiology and a member of its breast committee.
27. Dr. Marie Savard is defendant's expert in breast cancer risk. Dr. Savard is a practicing Philadelphia internist with a special interest in women's health. She has been the director of the Center for Women's Health at the University of Pennsylvania, an associate professor at the Medical College of Pennsylvania / Hahnemann Hospital and a member of the American Board of Internal Medicine's Subcommittee on Clinical Competency in Women's Health. She is widely published. She was an advisor to the United Nations World Conference on Women. She has conducted clinical trials regarding women's health issues.
28. Some post-menopausal women who require the "higher dose" of Prempro.
29. Determining a plaintiff's risk of developing breast cancer turns on an evaluation of individualized breast cancer risk factors.
30. A woman's age is a significant risk factor for developing breast cancer.
31. Having a mutated BRCA 1 or BRCA 2 gene is a significant risk factor for breast cancer.

32. A personal history of atypical hyperplasia is a significant risk factor for breast cancer.
33. Prior chest radiation is a significant risk factor for breast cancer.
34. A family history of breast cancer is an important risk factor for breast cancer.
35. Prior biopsies of any kind, whether benign or atypical, are a risk factor for developing breast cancer.
36. Having a first child after age 30 is an important risk factor for breast cancer.
37. Never having had a child is a risk factor for developing breast cancer.
38. Having one's first period before the age of 12 years is a risk factor for breast cancer.
39. Late menopause, that is, reaching menopause after age 51, is a significant risk factor for breast cancer.
40. Obesity is a significant risk factor for breast cancer.
41. Drinking alcohol is a significant risk factor for breast cancer.
42. Smoking is a significant risk factor for breast cancer.
43. Personal history of other cancer, such as uterine, ovarian, or colon is a significant risk factor for breast cancer.
44. Use of oral contraceptives may be a risk for breast cancer.
45. All of these risk factors constitute a woman's "baseline risk" for developing breast cancer.
46. The current standard of care for breast cancer screening in post-menopausal women is an annual clinical breast examination and screening mammogram.

DISCUSSION

The sole issue before this court is whether the prerequisites for certification as stated in Pa. R. C. P. 1702 are satisfied. The purpose behind class action suits is "to provide a means by

which the claims of many individuals could be resolved at one time, thereby eliminating the possibility of repetitious litigation and providing small claimants with a method to seek compensation for claims that would otherwise be too small to litigate”. DiLucido v. Terminix Intern, Inc., 450 Pa. Super. 393, 397, 676 A.2d 1237, 1239 (Pa. Super. 1996). For a suit to proceed as a class action, Rule 1702 of the Pennsylvania Rules of Civil Procedure requires that five criteria be met:

- (1) the class is so numerous that joinder of all members is impracticable;
- (2) there are questions of law or fact common to the class;
- (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class;
- (4) the representative parties will fairly and adequately assert and protect the interests of the class under the criteria set forth in Rule 1709;
- (5) a class action provides a fair and efficient method for adjudication of the controversy under the criteria set forth in Rule 1708.

Rule 1708 of the Pennsylvania Rules of Civil Procedure requires:

In determining whether a class action is a fair and efficient method of adjudicating the controversy, the court shall consider among other matters the criteria set forth [below]

a) Where monetary recovery alone is sought, the court shall consider

- (1) whether common questions of law or fact predominate over any question affecting only individual members;
- (2) the size of the class and the difficulties likely to be encountered in the management of the action as a class action;
- (3) whether the prosecution of separate actions by or against individual members of the class would create a risk of
 - (i) inconsistent or varying adjudications with respect to individual members of the class which would confront the party opposing the class with incompatible standards of conduct;
 - (ii) adjudications with respect to individual members of the class which would as a practical matter be dispositive of the interests of other members not parties to the adjudications or substantially impair or impede their ability to protect their interests;
- (4) the extent and nature of any litigation already commenced by or against members of the class involving any of the same issues;
- (5) whether the particular forum is appropriate for the litigation of the claims of the entire class;
- (6) whether in view of the complexities of the issues or the expenses of litigation the separate claims of individual class members are insufficient in amount to support separate actions;
- (7) whether it is likely that the amount which may be recovered by individual class members will

be so small in relation to the expense and effort of administering the action as not to justify a class action.

(b) Where equitable or declaratory relief alone is sought, the court shall consider

(1) the criteria set forth in subsections (1) through (5) of subdivision (a), and
(2) whether the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making final equitable or declaratory relief appropriate with respect to the class.

(c) Where both monetary and other relief is sought, the court shall consider all the criteria in both subdivisions (a) and (b).

The burden of showing each of the elements in Rule 1702 is initially on the moving party. This burden “is not heavy and is thus consistent with the policy that decisions in favor of maintaining a class action should be liberally made.” Cambanis v. Nationwide Ins. Co., 348 Pa. Super. 41, 45, 501 A.2d 635, 637 (Pa. Super. 1985). The moving party need only present evidence sufficient to make out a *prima facie* case “from which the court can conclude that the five class certification requirements are met.” Debbs v. Chrysler Corp., 2002 Pa. Super. 326, 810 A.2d 137,153-154 (2002) (quoting Janicik v. Prudential Ins. Co., 305 Pa. Super. 120, 451 A.2d 451, 455 (Pa. Super. 1982)

In other contexts, the *prima facie* burden has been construed to mean “some evidence,” “a colorable claim,” “substantial evidence,” or evidence that creates a rebuttable presumption that requires the opponent to rebut demonstrated elements. In the criminal law context, “the *prima facie* standard requires evidence of the existence of each and every element.” Commonwealth v. Martin, 727 A.2d 1136, 1142 (Pa. Super. 1999), *alloc. denied*, 560 Pa. 722, 745 A.2d 1220 (1999). However, “The weight and credibility of the evidence are not factors at this stage.” Commonwealth v. Marti, 779 A.2d 1177, 1180 (Pa. Super. 2001).

In the family law context, the term “‘*prima facie* right to custody’ means only that the

party has a colorable claim to custody of the child.” McDonel v. Sohn, 762 A.2d 1101, 1107 (Pa. Super. 2000). Similarly, in the context of employment law, the Commonwealth Court has opined that a *prima facie* case can be established by “substantial evidence” requiring the opposing party to affirmatively rebut that evidence. *See, e.g., Williamsburg Community School District v. Com., Pennsylvania Human Rights Comm.*, 512 A.2d 1339 (Pa. Commw. 1986).

Courts have consistently interpreted the phrase “substantial evidence” to mean “more than a mere scintilla,” but evidence “which a reasonable mind might accept as adequate to support a conclusion.” SSEN, Inc., v. Borough Council of Eddystone, 810 A.2d 200, 207 (Pa. Commw. 2002). In Grakelow v. Nash, 98 Pa. Super. 316 (Pa. Super. 1929), a tax case, the Superior Court said: “To ordain that a certain act or acts shall be *prima facie* evidence of a fact means merely that from proof of the act or acts, a rebuttable presumption of the fact shall be made;...it attributes a specified value to certain evidence but does not make it conclusive proof of the fact in question.”

Class certification is a mixed question of fact and law. Debbs v. Chrysler Corp., 2002 Pa. Super. 326, 810 A.2d,154 (Pa. Super. 2002). The court must consider all the relevant testimony, depositions and other evidence pursuant to Rule 1707 (c). In determining whether the prerequisites of Rule 1702 have been met, the court is only to decide who shall be the parties to the action and nothing more. The merits of the action and the plaintiffs’ right to recover are excluded from consideration. 1977 Explanatory Comment to Pa. R. Civ. P. 1707. Where evidence conflicts, doubt should be resolved in favor of class certification. In making a certification decision, “courts in class certification proceedings regularly and properly employ reasonable inferences, presumptions, and judicial notice.” Janicik, 451 A.2d at 454,455. Accordingly, this court must refrain from ruling on plaintiff’s ultimate right to achieve any

recovery, the credibility of the witnesses and the substantive merits of defenses raised.

“The burden of proof to establish the five prerequisites to class certification lies with the class proponent; however, since the hearing on class certification is akin to a preliminary hearing, it is not a heavy burden.” Professional Flooring Co. v. Bushar Corp., 61 Pa. D&C 4th 147, 153, 2003 WL 21802073 (Pa. Com. Pl. Montgo. Cty. Apr. 14, 2003), citing Debbs v. Chrysler Corp., 810 A.2d 137, 153-54 (Pa. Super. 2002); Janicik v. Prudential Inc. Co. of America, 451 A.2d 451, 455 (Pa. Super. 1982). *See also* Baldassari v. Suburban Cable TV Co., 808 A.2d 184, 189 (Pa. Super. 2002); Cambanis v. Nationwide Insurance Co., 501 A.2d 635 (Pa. Super. 1985). The *prima facie* burden of proof standard at the class certification stage is met by a qualitative “substantial evidence” test.

Our Superior Court has instructed that it is a strong and oft-repeated policy of this Commonwealth that, decisions applying the rules for class certification should be made liberally and in favor of maintaining a class action. Weismer by Weismer v. Beech-Nut Nutrition Corp., 615 A.2d 428, 431 (Pa. Super. 1992). *See also* Janicik, 451 A.2d at 454, *citing and quoting* Esplin v. Hirschi, 402 F.2d 94, 101 (10th Cir. 1968) (“in a doubtful case . . . any error should be committed in favor of allowing the class action”).

Likewise, the Commonwealth Court has held that “in doubtful cases any error should be committed in favor of allowing class certification.” Foust v. Septa, 756 A.2d 112, 118 (Pa. Commw. 2000). This philosophy is further supported by the consideration that “[t]he court may alter, modify, or revoke the certification if later developments in the litigation reveal that some prerequisite to certification is not satisfied.” Janicik, 451 A.2d at 454

Within this context, the court will examine the requisite factors for class certification.

I. Numerosity

To be eligible for certification, Appellant must demonstrate that the class is "so numerous that joinder of all members is impracticable." [Pa.R.C.P. 1702\(1\)](#). A class is sufficiently numerous when "the number of potential individual plaintiffs would pose a grave imposition on the resources of the court and an unnecessary drain on the energies and resources of the litigants should plaintiffs sue individually." [Temple University v. Pa. Dept. of Public Welfare, 30 Pa.Cmwlth. 595, 374 A.2d 991, 996 \(1977\)](#) (123 members sufficient); [\[FN4\] ABC Sewer Cleaning Co. v. Bell of Pa., 293 Pa.Super. 219, 438 A.2d 616 \(1981\)](#) (250 members sufficient); [Ablin, Inc. v. Bell Tel. Co. of Pa., 291 Pa.Super. 40, 435 A.2d 208 \(1981\)](#) (204 plaintiffs sufficiently numerous). Appellant need not plead or prove the actual number of class members, so long as he is able to "define the class with some precision" and provide "sufficient indicia to the court that more members exist than it would be practicable to join." [Janicik, 451 A.2d at 456](#).

In the case at bar, plaintiffs seek to certify the following class:

All post-menopausal women residing in the Commonwealth of Pennsylvania, who have taken high dose Prempro (i.e., $\geq .625$ mg CEE/ 2.5 mg MPA) on a daily basis for at least one year, who began such use prior to the announcement of the Women's Health Initiative Study on July 9, 2002, and are presently asymptomatic (i.e., have not been diagnosed with breast cancer) (the "Class").

Plaintiffs also seek to certify a subclass, defined as follows:

All post-menopausal women residing in the Commonwealth of Pennsylvania who have taken high dose Prempro on a daily basis for at least one year, who began such use prior to the announcement of the Women's Health Initiative Study results on July 9, 2002, and who changed their prescriptions to a new, low dose of Prempro (i.e., $< .625$ mg CEE/ 2.5 mg MPA), and who are presently asymptomatic (i.e., have not been diagnosed with breast cancer) (the "Subclass").

Plaintiffs allege that the class numbers in the hundreds of thousands and may include as many as 720,000 women. There is no reason to dispute this contention. The plaintiffs have demonstrated the numerosity requirement for class certification purposes.

II. Commonality

The second prerequisite for class certification is that “there are questions of law or fact common to the class.” Pa. R. Civ. P. 1702(2). Common questions exist “if the class members’ legal grievances arise out of the ‘same practice or course of conduct on the part of the class opponent.” Janicik, supra. 133, 451 A.2d at 457. Thus, it is necessary to establish that “the facts surrounding each plaintiff’s claim must be substantially the same so that proof as to one claimant would be proof as to all.” Weismer by Weismer v. Beechnut Nutrition Corp., 419 Pa. Super. 403, 615 A.2d 428 (Pa. Super. 1992)). However, where the challenged conduct affects the potential class members in divergent ways, commonality may not exist. Janicik , supra. 457 fn. 5

“While the existence of individual questions is not necessarily fatal, it is essential that there be a predominance of common issues shared by all class members which can be justly resolved in a single proceeding.” D’Amelio v. Blue Cross of Lehigh Valley, 347 Pa. Super. 338, 487 A.2d 995, 997 (Pa. Super. 1985). In examining the commonality of the class’ claims, a court should focus on the cause of injury and not the amount of alleged damages. “Once a common source of liability has been clearly identified, varying amounts of damages among the plaintiffs will not preclude class certification.” See Weismer by Weismer v. Beech-Nut Nutrition Corp., 419 Pa. Super. 403, 409, 615 A.2d 428, 431 (Pa. Super.). However, where there exists intervening and possibly superseding causes of damage however, liability cannot be determined on a class-wide basis. Cook v. Highland Water and Sewer Authority, 108 Pa. Cmwlth. 222, 231, 530 A.2d 499, 504 (Pa. Cmwlth. 1987).

Plaintiffs argue that questions of law and fact common to the class exist. Defendants claim that individual issues of law and fact exist and predominate. After reviewing the class

action complaint filed in this matter along with the deposition testimony, other documents, exhibits and the argument of counsel, this court finds that individual issues of fact exist and predominate, therefore the commonality requirement is not satisfied.

A. Class Claims present Individual Questions of Fact

The facts surrounding the Class's negligence claim demonstrates that proof as to one claimant would not be proof as to all. A myriad of individual causation inquiries exist in determining the level of risk for developing breast cancer.

a. Medical Monitoring

Plaintiffs seek certification of a Pennsylvania medical monitoring class. In 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 (Pa. 1997), the Pennsylvania Supreme Court articulated the following 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 program 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; (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles. Id. 146. The injury from which a medical monitoring claimant seeks recovery is the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm. Id. Courts prefer that plaintiffs recover these costs through a court supervised and administered trust fund instead of through lump sum damage award because a trust fund compensates the plaintiff only for the monitoring costs actually incurred, limiting defendants' liability. Redland at 189.

Plaintiffs seek certification of a Pennsylvania state medical monitoring program for all those who ingested Prempro and are at increased risk for breast cancer due to the ingestion of the drug. However, as demonstrated in Plaintiffs' own expert testimony, the proof falls far short on at least two of the requisite elements. Specifically, plaintiffs have failed to prove 1) that Prempro is a proven hazardous substance with regard to the class, and 2) that the prescribed monitoring regime is different from that normally recommended in the absence of exposure.

Plaintiff's witness, Dr. Nancy Elliott is an expert in breast cancer treatment. She is a graduate of the Mt. Sinai School of Medicine, and completed a fellowship in breast disease. Dr. Elliott is a fellow of the American College of Surgeons. She is also the founder and director of the Montclair Breast Center, an elite breast cancer screening and treatment center that caters to women who are able to afford Dr. Elliott's services without using insurance. At that center, Dr. Elliott evaluates about 3500 women per year, 90% of whom are considered to be at a "high risk" for developing breast cancer.

Plaintiffs presented Dr. Elliott as an expert in the area of breast cancer treatment to describe the special medical monitoring program required by the proposed plaintiff class due to their use of Prempro. The program includes: a review of the patient's medical history, yearly mammogram, a breast exam, performed by breast specialists, and lifestyle counseling. Some women, who have increased breast density, may require a breast ultrasound if the mammogram is unclear. A few women, who have an unclear ultrasound, may also require an MRI. Other women, who present very high risk factors, may need preventative surgery. And still other women may require preventative medication. This program mirrors the program used at Dr. Elliott's boutique Center for any woman having any increased risk of developing breast cancer.

A long list of risk factors make a woman at increased risk and therefore suitable for Dr.

Elliott's program. Most are entirely unrelated to Prempro usage. On cross-examination Dr.

Elliott testified:

Counsel: Is age alone... the single most important risk factor?
Dr. Elliott: Age is a risk factor.¹
Counsel: Is family history of breast cancer a risk factor?
Dr. Elliott: Yes, it is.
Counsel: Is having a BRCA one or two mutation a risk factor?
Dr. Elliott: Yes.
Counsel: History of ovarian cancer, is that a risk factor?
Dr. Elliott: Yes, it is.
Counsel: Having dense breasts independent of Prempro use, is that a risk factor?
Dr. Elliott: Yes.
Counsel: Having had in the past an abnormal biopsy, is that a risk factor?
Dr. Elliott: Yes.
Counsel: Having had radiation therapy in the chest area, is that a risk factor?
Dr. Elliott: Yes.
Counsel: You told me earlier that having a first period under 12 is a risk factor.
Dr. Elliott: Yes.
Counsel: Not having menopause until after the age of 51 is a high risk factor, correct?
Dr. Elliott: Correct.
Counsel: I know I asked you about not having any children until after 30. Having had no children is a significant risk factor, correct?
Dr. Elliott: Correct.
Counsel: Being overweight is a significant risk factor?
Dr. Elliott: Yes it is.
Counsel: Drinking two or more glasses of alcohol per day is a significant risk factor?
Dr. Elliott: Yes.
Counsel: Are there any other risk factors that I haven't named?
Dr. Elliott: Not that I can recall.
Counsel: If a woman had any one of these risk factors but had not used hormonal therapy, she would get the same recommendation that you would give to a woman who used hormone therapy, correct?
Dr. Elliott: Correct.²

Dr. Elliott considers: age, family history of breast cancer, mutated BRCA one or two gene, a

¹ Later, Dr. Elliott testified to the specific ages. She stated she would recommend the same monitoring regime to a 60 year old woman who never took Prempro, and had no other risk factors. She also conceded that she would recommend the same program for a woman who is 55 years old. Finally, she then conceded that she would recommend the same program for a woman who is 53 years old. (N.T. 93-94. January 12, 2005.)

² N.T. at 102-104 January 12, 2005.

history of ovarian cancer, dense breasts, past abnormal biopsies, radiation therapy in the chest area, having a first period before the age of twelve, not having menopause until after 51 years old, having children after age of thirty, not having had children, being overweight, and drinking two or more glasses of alcohol per day, and being over age 53 as individual risk factors. Dr. Elliott also believes that hormone therapy use is one of these many risk factors for developing breast cancer.

The medical monitoring program recommended by Dr. Elliott is not a program for Prempro users. It is the same program that Dr. Elliott believes should be employed for every woman that has any single risk factor. Dr. Elliott testified: “I believe that any factor that increases a woman’s risk for breast cancer is significant. In my opinion, they deserve enhanced surveillance and a high risk program.”³ Women often have multiple risk factors. According to Dr. Elliott, the Prempro class is not distinct. Women will fall into different categories of risk based upon individual risk factors, irrespective of past Prempro use. Dr. Elliot testified: “very often Prempro use is not the only risk factor that a woman has.”⁴ Indeed based on the panoply of risk factors identified by Plaintiff’s expert, it is difficult to isolate any woman who would not, in Dr. Elliott’s opinion, qualify for her program. Were it possible to insulate plaintiffs who had no risk factor other than past Prempro use, Dr. Elliott would nonetheless recommend a yearly mammogram and exam:

The Court:	If someone came to you with no relevant information other than Prempro use... would you recommend that they be examined more than one time per year?
Dr. Elliott:	No...
The Court:	The question of whether or not they should be seen more than one time a year would depend on other factors?

³ N.T. at 87, January 12, 2005.

⁴ N.T. pg. 88, January 12, 2005.

Dr. Elliott: Correct.

This “medical monitoring” recommendation, is precisely the same medical standard as recommended for all post-menopausal women. According to Dr. Daniel Kopans⁵, testimony, “the current standard of care for breast cancer screening in a post-menopausal population of women is an annual clinical breast examination and a screening mammogram.” Likewise, Dr. Marie Savard⁶ stated that “the current standard of care for breast cancer screening in a post-menopausal population of women is an annual clinical breast examination and screening mammogram.” Accordingly, Dr. Elliott’s opinion for necessary monitoring based solely on past Prempro use – a yearly examination – is no different than what should be recommended for any post-menopausal woman.

Dr. Elliott was asked whether there were any published medical treatment guidelines specifically for women who had used hormone therapy on which she was basing her testimony. Dr. Elliott claimed to rely on a single set of guidelines “recently published in the American Journal of Surgery... (by) the High Risk Assessment Working Group.” She asserted that these guidelines recommended increased surveillance for women who had taken hormone replacement therapy, however, Dr. Elliott could not remember either the specific recommendation in the guidelines or the issuing authority:

Counsel: My question is: Are you telling the Court that the organization you just described recommended that people who took Prempro need to have a

⁵ Dr. Kopans is a graduate of Harvard Medical School, and a Professor of Radiology at the Harvard Medical School. In the 1970’s he developed the United States’ first “Breast Imaging Division” of a Radiology Department at Massachusetts General Hospital. (Defendant’s Exhibit 18 at 4). The doctor personally reads several thousand mammograms each year, he personally reviews 700 breast ultrasounds each year, and personally reads and reviews hundreds of breast MRI’s each year.

⁶ Dr. Savard is a nationally known internist and women’s health expert. Dr. Savard earned her M.D. from the University of Pennsylvania. She is the director of the Center for Women’s Health and Associate Professor at the Medical College of Pennsylvania/Hahnemann Hospital. She was also the technical advisor to the United Nations Fourth World Conference on Women, speaking on global women’s health issues.

breast examination more than once a year?
Dr. Elliott: I don't remember the exact recommendation. I would have to look, you know, at the paper again. They did put women, I believe they recommended increased surveillance in terms of physical exam. I would like to look at the paper in order to tell you precisely.
Counsel: The answer as given is that you're under oath, you're not sure, right?
Dr. Elliott: Correct.
Counsel: Sitting here today as an expert, you don't what those guidelines say...
Dr. Elliott: I'm not sure.⁷

Dr. Elliott was not able to provide the Court with the exact name of the one entity on which she was basing her testimony:

The Court: Do they have a name? You're not sure what their name is.
Dr. Elliott: Working group or task force.
The Court: Is that their name, High Risk Working Group or Task Force?
Dr. Elliott: No; either High Risk Assessment Task Force or working group.
The Court: You're not sure which of these two names they go by?
Dr. Elliott: No, I'm not.

Dr. Elliott actually conceded that the "increased surveillance" in this unidentified guideline consisted of nothing more than a yearly mammogram.

The Court: This is the only guideline for increased surveillance for hormone therapy use that you're aware of nationally; is that correct?
Dr. Elliott: Correct.
The Court: Have you reviewed that one guideline before coming into Court to testify about breast cancer surveillance in hormone use?
Dr. Elliott: Yes, I have.
The Court: Are you familiar with it?
Dr. Elliott: Yes, I am familiar with it...
The Court: If someone asked... I want to follow the guidelines of the High Risk Assessment Working Group, should I have all my patients examined more than once a year, what would your answer be?
Dr. Elliott: No. ⁸

Thus, Dr. Elliott's reliance on these "specialized guidelines" for past Prempro users, actually requires nothing more than the yearly mammogram, which is the nationally recognized medical

⁷ N.T. at 27, January 12, 2005.

⁸ N.T. at 37-40, January 12, 2005.

standard for all post-menopausal women.

The actual distinction, identified by Dr. Elliott, which does require a different medical approach involves breast density. The testimony revealed that breast density is not directly related to Prempro usage. Dr. Elliott addressed breast density. On direct examination Dr. Elliott testified that as breast density increases, the less effective traditional mammographic screening procedures become in detecting breast cancer. Therefore, Dr. Elliott recommended that women with increased breast density should receive a breast ultrasound in addition to the mammogram to ensure proper detection of cancer.⁹ However, like the other identified risk factors, increased breast density is a factor that affects women on an individual basis and can only be determined on an individual basis. Dr. Elliott testified that approximately 50% of women 60 years or older who never used hormone therapy have significant density in their breasts. Of those women who took Prempro, only about 25%-30% actually sustain breast density as a result of hormone replacement therapy. Further, according to Dr. Elliott any increased breast density in a woman 60 years old who has not taken Prempro for more than a year, probably has nothing to do with Prempro use.¹⁰ Moreover, plaintiff's other expert, Dr. Ronald Ross¹¹ was also questioned extensively on the relationship between breast density and hormone therapy. Dr. Ross' opinion is that the best study regarding breast density is "PEPI", a national study. Based upon this study, Dr. Ross essentially agreed with Dr. Elliott, stating that only 20-25% of women who use combination hormone therapy sustain any measurable increase in breast density. Dr. Ross

⁹ N.T. at 62, January 12, 2005.

¹⁰ N.T. at 106, January 12, 2005.

¹¹ Plaintiff's expert, Dr. Ronald Ross is an M.D. employed by the Keck School of Medicine at the University of Southern California, he has focused about 95% of his research on cancer epidemiology, and published many peer reviewed papers on the topic. Dr. Ross is the Chair of the Preventative Medicine department, is the deputy director of the Norris Comprehensive Cancer Center at the University of Southern California, and the director of the L.A. County USC Cancer Surveillance Program. Epidemiology is "the study of the distribution of diseases in population... modern day epidemiology tries to understand the reasons for those patterns." (N.T. 9)

testified that this density “dissipates relatively quickly” once a woman ceases use of Prempro. Thus, about half of all women over 60 have significant breast density irrespective of Prempro use. Of those women who potentially gained increased breast density due solely to Prempro use, the increased density dissipates rather quickly, usually, within a year. Thus the nature and level of increased breast density and any change in recommended medical monitoring would vary based on an individual plaintiff’s breast history and termination date of Prempro use. According to Plaintiff’s experts a maximum of 25% of class members who have taken Prempro within the past year have any breast density due to Prempro, Thus even under this analysis 75% of class members require no different medical monitoring.

Virtually all named plaintiffs ceased using Prempro more than one year ago. One named plaintiff continues Prempro use but has switched to the low dose. To evaluate class members breast density, an individual analysis needs to be conducted. Yet, even if an individual analysis were conducted, both Dr. Elliott and Dr. Ross agree that any increased breast density is unlikely to be related to Prempro use.

To meet the Redland Soccer Club standard for medical monitoring, a plaintiff class must prove that the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Redland Soccer Club, Inc. v. Department of the Army and Dept. of Defense of the U.S., 548 Pa. 178, 696 A.2d 137, 146 (Pa. 1997). Plaintiff has failed to demonstrate any distinct medical regime. In this case the uncontradicted evidence, mostly presented by Plaintiff’s expert witness, demonstrates that specialized treatment required by a member of the plaintiff class could only be based on an individual assessment of risk factors other than Prempro use.

Plaintiff’s other expert, Dr. Sheldon Cherry is a specialist in obstetrics and gynecology

with a practice in New York City. Dr. Cherry is a clinical professor at Mount Sinai Hospital in New York City, an attending ObGyn at Mount Sinai Hospital, and has published peer review papers and textbooks. Dr. Cherry has also published books intended to educate the laywoman on women's health issues, specifically those surrounding menopause and cancer His books include The Menopause Book and The Answer to Cancer.

Plaintiffs offered Dr. Cherry as an expert in gynecology who has studied the issue of menopause, hormone therapy and related women's health issues for 30 years. Specifically, Plaintiffs presented Dr. Cherry to offer an opinion on the promotion, utility and risk of hormone replacement therapy products. On direct examination, Dr. Cherry testified generally with regard to the history of hormone therapy use and what he believes are the misconceptions of menopause. Dr. Cherry claims menopause was invented as a disease in the 1960's, and that women on the threshold of menopause were "frightened" by the "myth" that they were "going to dry up and be an old woman if she doesn't take estrogen."¹² Dr. Cherry maintains that this fear was capitalized upon by drug companies, such as Wyeth who sold Premarin and then Prempro to quell the vasomotor symptoms, such as flushing, searing, and atrophic vaginal wall associated with menopause. He discussed the mentality of the "medical milieu" which promoted hormone therapy as a "fountain of youth." For example, he discussed the fact that estrogen was promoted as a preventive measure against getting osteoporosis. Despite his severe criticism however, Dr. Cherry admits Prempro is effective for the 20% of women who do get osteoporosis.

Dr. Cherry's testimony was intended to explain that Prempro is a proven hazardous substance with regard to the class. However, Dr. Cherry conceded that some women actually need Prempro. His opinion is that one in five women need Prempro for a medical reason.

¹² Video Taped Deposition of Sheldon H. Cherry, M.D. of 1/7/2005 at 12

Counsel: Let's explore that for a minute. Of all the women going through menopause, your opinion is 80% of them don't need Prempro?"
Dr. Cherry: That's true.
Counsel: So 20% do?
Dr. Cherry: Ok.¹³

Dr. Cherry further testified that some women even require the higher dose Prempro.

Counsel: And some women don't respond to the lower dose, right?
Dr. Cherry: Sure.
Counsel: So, for those women, you have to use the higher dose?
Dr. Cherry: Correct.
Counsel: And you do?
Dr. Cherry: If we have to. The very subset of women that need it.
Counsel: Okay. And you would have to because their symptoms are so severe that they need the drug; right?
Dr. Cherry: Correct.¹⁴

With regard to Prempro use by women with osteoporosis, Dr. Cherry stated, "We know estrogen is very effective in treating osteoporosis," and that "maybe only 20% of women get osteoporosis." Therefore, for that 20% the estrogen therapy would be "very effective" treatment.¹⁵ In fact, Dr. Cherry himself continues to prescribe Prempro for those women that need it!

Counsel: When was the last day you prescribed Prempro? How Recently?
Dr. Cherry: Maybe this week.
Counsel: So you have prescribed Prempro the entire time it's been on the market?
Dr. Cherry: Yes.

To demonstrate a medical monitoring claim, plaintiff must prove exposure to a proven hazardous substance. However, Plaintiff claims that a class wide determination of "hazardous substance" can be made despite expert testimony that many women are in medical need of the substance.

Plaintiff's own expert continues to prescribe a medication characterized as a "hazardous

¹³ Video Taped Deposition of Sheldon H. Cherry, M.D. of 1/7/2005 at 51

¹⁴ Video Taped Deposition of Sheldon H. Cherry, M.D. of 1/7/2005 at 135, 136

¹⁵ Video Taped Deposition of Sheldon H. Cherry, M.D. of 1/7/2005 at 21, 34, 35

substance.” It certainly is not a hazardous substance for those for whom it is a necessary medical treatment including at least one named Plaintiff.

Moreover, Dr. Cherry agreed with Dr. Elliott that hormone therapy use is only one of a multitude of potential risk factors that could cause cancer.

Counsel: Let’s talk about what the risk factors for breast cancer are. Would you agree with me, Doctor, that age is the single most important risk factor?

Dr. Cherry: ... Yes.¹⁶

Counsel: Is family history of breast cancer a very significant risk factor?

Dr. Cherry: Yes.

Counsel: And having a mutated BRCA 1 or BRCA 2 gene is a very significant risk factor?

Dr. Cherry: Yes.

Counsel: And smoking is a significant risk factor?

Dr. Cherry: Yes.

Counsel: And having had or having ovarian or uterine or colon cancer is a significant risk factor for breast cancer; correct?

Dr. Cherry: Yes.

Counsel: And having had atypical hyperplasia at any point on a biopsy is a very significant risk factor; correct?

Dr. Cherry: Yes, yes.

Counsel: And having had radiation therapy in the chest area is a very significant risk factor; correct?

Dr. Cherry: Yes.

Counsel: And menstruating prior to the age of 12....

Dr. Cherry: It’s a different risk.

Counsel: And having a first child after the age of 30 is a significant risk factor; correct?

Dr. Cherry: Yes.

Counsel: Not having any children is a significant risk factor; correct?

Dr. Cherry: Yes.

Counsel: Breast-feeding, on the other hand lowers the risk; correct?

Dr. Cherry: Correct.

Counsel: Past history of oral contraceptives is a significant risk factor; correct?

Dr. Cherry: The jury is out.

Counsel: The jury is out?

Dr. Cherry: Yeah. Maybe.

Counsel: ... reaching menopause at or after age 51 is also a significant risk factor for breast cancer; correct?

Dr. Cherry: It increases the risk, yes.

¹⁶ Video Taped Deposition of Sheldon H. Cherry, M.D. of 1/7/2005 at 104

Counsel: And obesity is a significant risk factor; correct?
Dr. Cherry: Yes.
Counsel: And drinking alcohol is a significant risk factor; correct?
Dr. Cherry: Yes.¹⁷

Thus, both Dr. Cherry and Dr. Elliott, plaintiffs' experts, agree that all of these risks, along with long-term hormone replacement therapy use, must be considered to assess a woman's individual risk profile.

When specifically asked how the addition of Prempro use affects a woman's overall risk factor profile, Dr. Cherry stated that Prempro use alone is only a cumulative risk factor. He said, "when you add the estrogen, you don't know where that woman is already on her risk." Therefore, his testimony is clear, to evaluate class members' risk, it is necessary to know what each woman's individual risk factors are.

This opinion was confirmed when Dr. Cherry was asked about the proper treatment for women with increased risk for cancer. His book, The Answer to Cancer was discussed at length. This book, co-authored by Dr. Cherry and his wife, published in 2004, is intended to provide laywomen with up-to-date information about cancer, including breast cancer. Not once in 290 pages did Dr. Cherry recommend any special medical monitoring program or any special screening for women who have used Prempro.¹⁸ In fact, Dr. Cherry's new book encourages women to talk to their doctor about individual risk and develop screening tools that match those risks:

Dr. Cherry (reading from pg. 269 of The Answer to Cancer): "The recommended frequency of your screening tests will depend largely on your individual risk, which is why you and your doctor need to evaluate your risk factors for all of the major cancers. If you're of average risk, then the screening guidelines presented in Chapter 4 will likely be sufficient. If you're

¹⁷ Video Taped Deposition of Sheldon H. Cherry, M.D. of 1/7/2005 at 106-109

¹⁸ Video Taped Deposition of Sheldon H. Cherry, M.D. of 1/7/2005 at 89

above-average risk, based of your family history, your personal history, your lifestyle choices, you and your doctor should decide which screening tests you need and how often.”

Counsel: And that’s the advice that applies to people who have used hormone therapy and those who haven’t, correct?

Dr. Cherry: That they should be individualized?

Counsel: Yes.

Dr. Cherry: Yes.

The purpose of medical monitoring is to compensate claimants for “the quantifiable costs of periodic medial examinations necessary to detect the onset of physical harm” Redland Soccer Club, Inc. v. Department of the Army and Dept. of Defense of the U.S., 548 Pa. 178, 696 A.2d 137, 146 (Pa. 1997). The proposed monitoring program must be medically necessary, not simply medically ideal for virtually all women. The prescribed monitoring regime must be different from that normally recommended in the absence of the exposure. Based on Plaintiffs’ experts’ testimony, those women who would need special, necessary monitoring, exclusively due to Prempro use would be a very small subclass of the classes defined in this lawsuit for certification. This subclass would consist of women who are under 60 years old who had children before the age of 30 and did not breast feed, who had their first period after the age of 12, who began menopause before the age of 51, who have no personal or family history of cancer, who do not drink two or more glasses of alcohol a day, who do not smoke and who are not overweight.

Even for the women that actually fit into this defined subclass, the true difference in a monitoring regime would depend upon breast density. Of these women, who have dense breasts, 50% of them would have breast density whether or not they took Prempro. Any increased breast density due to Prempro use dissipates within a year. Therefore, the class of women who would have dense breasts due to Prempro use, would have to be limited to those still taking Prempro or

those who stopped taking it within the last year. To determine whether a woman matches these criterion, an individual analysis of all risk factors is needed.

Accordingly, this court finds that individual questions of law and fact exist with respect to the medical monitoring claim and commonality has not been even prima facie demonstrated.

III. Typicality

The third step in the certification test requires the plaintiff to show that the class action parties' claims and defenses are typical of the entire class. The purpose behind this requirement is to determine whether the class representatives' overall position on the common issues is sufficiently aligned with that of the absent class members, to ensure that pursuit of their interests will advance those of the proposed class members. DiLucido v. Terminix Intern, Inc., 450 Pa. Super. 393, 404, 676 A.2d 1237, 1242 (Pa. Super. 1996). For the reasons described above concerning commonality, typicality has also not been demonstrated. Accordingly, it is not necessary for this court to further consider the remaining requirements for certification.

IV. Adequacy of Representation

For the class to be certified, this court must also conclude that the plaintiffs "will fairly and adequately assert and protect the interests of the class." Pa. R. Civ. P. 1702 (4). In determining whether the representative parties will fairly and adequately represent the interests of the class, the court shall consider the following:

- “(1) whether the attorney for the representative parties will adequately represent the interests of the class,
 - (2) Whether the representative parties have a conflict of interest in the maintenance of the class action, and
 - (3) Whether the representative parties have or can acquire financial resources to assure that the interests of the class will not be harmed.”
- Rule 1709.

“Until the contrary is demonstrated, courts will assume that members of the bar are

skilled in their profession.” Janicik, 305 Pa. Super. at 136, 451 A.2d at 458. Here, defendants do not challenge plaintiffs’ counsels’ skill and therefore, the court presumes that counsel is skilled in their profession. However, it is not necessary for this court to consider the remaining requirements for certification since plaintiff failed to establish the requirements of Pa. R. Civ. P. 1702(a)(2), common questions of fact.

V. Fair and Efficient Method of Adjudication

The final criteria under Pa. R. Civ. P. 1702 is a determination of whether a class action provides a fair and efficient method for adjudication of the controversy under the criteria set forth in Rule 1708. Again, it is not necessary for this court to consider the remaining requirements for certification since plaintiff has failed to establish the requirements for certification.

Having weighed all class certification requirements, this court finds that a class action is not the appropriate method for adjudicating plaintiffs’ medical monitoring claim. Accordingly, this court makes the following conclusions of law.

CONCLUSIONS OF LAW

1. The class and subclass are sufficiently numerous that joinder of all its members would be impracticable.
2. Common questions of law do not exist with respect to the proposed Class and Subclass.
3. Individual questions of fact predominate with respect to the medical monitoring claims of the Class and Subclass.

CONCLUSION

For these reasons, this court denies Plaintiffs' Motion for Class Certification and the matter should proceed as to individual named plaintiffs.

BY THE COURT:
