COMMENTS

RAGING HORMONES?: THE LEGAL OBSTACLES AND POLICY RAMIFICATIONS TO ALLOWING MEDICAL MONITORING REMEDIES IN HORMONE REPLACEMENT THERAPY SUITS

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In 2000, there were approximately 45.6 million women in the United States who were postmenopausal.[1] An additional 2.1 million women were expected to reach menopause during the year 2000, which equates to approximately 5,700 women reaching menopause per day.[2] To put this in perspective, a population the size of California, Arizona, and Nevada combined is postmenopausal, and a population the size of New Mexico joins them every year.[3] In 2002, approximately 38% of menopausal women were taking some type of hormone replacement therapy (HRT)[4] and an estimated six million of these women were using one drug, Prempro.[5]

Then the bombshell dropped on American women. A scientific study reported an association between HRT and increased risk of breast cancer, heart disease, stroke, and dementia.[6] Since the initial shock of the report, some members of the scientific community have questioned the strength of the

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* J.D., University of Wisconsin Law School, 2006; M.S., Population Health, University of Wisconsin–Madison, 1999; B.S., Natural Science, University of Wisconsin–Madison, 1997. I would like to thank my parents for their unwavering support. I would also like to thank the editors of the *Wisconsin Women's Law Journal*, especially Autumn Nero and Stephanie Czukas, for their assistance in writing this article.

1. NORTH AMERICAN MENOPAUSE SOCIETY, MENOPAUSE PRACTICE: A CLINICIAN'S GUIDE 11 (2004), *available at* http://www.menopause.org/04A.pdf.

2. *Id.*

3. *See* U.S. CENSUS BUREAU, AM. FACTFINDER (2000), http://factfinder.census.gov/home/saff/main.html?_lang=en (follow "Population Finder" hyperlink; then follow "alphabetic" hyperlink) (population values are estimates for 2005 based on Census 2000).

4. HRT is actually the term for hormones given to women who experience symptoms from menopause. If hormones are given preventively to women who do not yet have symptoms, this is called hormone therapy (HT). The prescription of hormones to menopausal women is generally known as menopausal hormone therapy. F. NAFTOLIN ET AL., INTERNATIONAL MENOPAUSE SOCIETY, GUIDELINES FOR HORMONE TREATMENT OF WOMEN IN THE MENOPAUSAL TRANSITION AND BEYOND (2004), *available at* http://www.imsociety.org/PDF/news_IMS_statement_15.10.04.pdf. The legal literature and cases refer only to HRT. Though it is unknown whether the legal literature is using precisely the correct term, this Comment will follow the trend and use HRT to refer to any prescription of hormones to menopausal women.

5. Albertson v. Wyeth Inc., 63 Pa. D. & C.4th 514, 517 (C.P. Ct. 2003).

6. Jacques E. Rossouw et al., *Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results from the Women's Health Initiative Randomized Controlled Trial*, 288 JAMA 321, 325 (2002).

study's findings.[7] Nevertheless, groups of women in several states filed class action suits against Wyeth,[8] the maker of Prempro, claiming causes of action for, among other things, negligence and medical monitoring.[9] So far, courts in those states denied class action certification, but allowed individual lawsuits to proceed.[10]

Medical monitoring claims are claims for payment of diagnostic testing after an individual has been exposed to a hazardous substance through the negligence of another.[11] These medical monitoring claims would require the manufacturers of HRT to pay for screening costs of the potential health risks for women who took HRT when these women exhibit no current symptoms of a disease or condition. This Comment examines whether HRT use warrants medical monitoring damages from a legal and policy standpoint.

This Comment does not purport to be a guide of how to make and win a medical monitoring claim against Wyeth. Instead, it seeks to refocus the legal community's attention on the millions of women who may eventually suffer the effects of HRT use. If plaintiffs' attorneys aspire to benefit their clients, then let this Comment serve as a cautionary tale. Caution is especially important if HRT cases are filed as class actions because such cases affect extremely large numbers of women, possibly even some women who were not involved in the suit. If suits against Wyeth proceed based on dubious scientific evidence without regard to the possible future consequences of bringing premature suits, then plaintiffs' attorneys may be hurting the very women they seek to help.

First, Part I of this Comment addresses the uses of HRT and examines a prominent study that indicated possible health risks from HRT use. Part II provides a background of the nature of medical monitoring claims. Medical monitoring claims are explored using both the approach of states that allow medical monitoring claims and the approach of states that do not allow such actions. Next, Part III describes several current cases in which plaintiffs are seeking medical monitoring recovery against Wyeth and analyzes the

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7. S. Mitchell Harman et al., *Is the Estrogen Controversy Over? Deconstructing the Women's Health Initiative Study: A Critical Evaluation of the Evidence*, 1052 ANNALS N.Y. ACAD. SCI. 43, 44-45 (2005); *see also* NAFTOLIN ET AL., *supra* note 4, at 4-5 (stating that the actions of various organizations in response to the publication of WHI data has raised concerns).

8. Wyeth pharmaceutical company is now Wyeth, Inc. and has formerly been known as American Home Products, Wyeth-Pharmaceuticals, and Wyeth-Ayerst Pharmaceuticals, Inc. Wyeth, Inc. v. Gottlieb, 930 So. 2d 635, 635 (Fla. Dist. Ct. App. 2006). For simplicity's sake, this Comment will refer to the company as Wyeth.

9. *Albertson*, 63 Pa. D. & C.4th at 524; *In re* Prempro Prods. Liab. Litig., No. 4:03-CV-1507-WRW, 2005 U.S. Dist. LEXIS 19153, at *5-6 (E.D. Ark. Aug. 30, 2005); *Gottlieb*, 930 So. 2d at 635-36; Vitanza v. Wyeth, Inc., No. ATL-L-2093-04-MT, 2006 WL 462470, at *1 (N.J. Super. Ct. Jan. 26, 2006).

10. *See, e.g.*, Albertson v. Wyeth, No. 2944, 2005 Phila. Ct. Com. Pl. LEXIS 604 at *46 (May 3, 2005) [hereinafter *Albertson II*].

11. Arvin Maskin et al., *Medical Monitoring: A Viable Remedy for Deserving Plaintiffs or Tort Law's Most Expensive Consolation Prize?*, 27 WM. MITCHELL L. REV. 521, 522 (2000).

application of the elements of medical monitoring claims to lawsuits involving HRT. Finally, Part IV explores the policy implications of awarding medical monitoring damages in HRT cases, including the application of claim preclusion to medical monitoring claims and financial ramifications to future claimants. This Comment concludes, in Part V, that HRT users' claims for medical monitoring may not meet the legal standard for awarding such damages. Furthermore, medical monitoring claims in HRT cases also have negative consequences from a policy standpoint. These legal and policy ramifications make medical monitoring claims for HRT use an unworkable and unwise course of action.

I. MENOPAUSE, HRT, AND RECENT STUDIES

A. Menopause Causes and Symptoms

Menopause is the phase of a woman's life where her menstrual periods cease.[12] Menstrual periods cease because the ovaries shrink and eventually produce greatly reduced amounts of the female hormones estrogen and progesterone.[13] Hot flashes are the most common symptom of menopause and are reported by approximately 65%–80% of menopausal women.[14] Hot flashes begin with a hot sensation through the face and progress to sweating.[15] Women also may experience night sweats during and after menopause and vaginal changes leading to urinary infections.[16] These symptoms and health consequences play a large role in the quality of life of menopausal women.

The menopausal phase in a woman's life is also marked by increased health risks with the greatest risks coming from heart disease and bone fractures due to osteoporosis.[17] After menopause, the rate of bone loss increases leading to osteoporosis.[18] The fluctuation of hormones and general decrease in the amount of estrogen in the body is believed to be the culprit behind the incidence of menopausal symptoms and increased risk of osteoporosis and other chronic diseases.[19]

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12. Arlene Michaels Miller et al., *Health Promotion: The Perimenopausal to Mature Years (45-64), in* WOMEN'S HEALTH ACROSS THE LIFESPAN 55, 55 (Karen Moses Allen & Janice Mitchell Phillips eds., 1997).

13. NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, FACTS ABOUT MENOPAUSAL HORMONE THERAPY 2 (2005), *available at* http://www.nhlbi.nih.gov/health/women/pht_facts.pdf.

14. Anna Ratka, *Menopausal Hot Flashes and Development of Cognitive Impairment*, 1052 ANNALS N.Y. ACAD. SCI. 11, 11 (2005).

15. *Id.* at 12.

16. NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, *supra* note 13, at 3; Jennifer Hays et al., *Effects of Estrogen Plus Progestin on Health-Related Quality of Life*, 348 NEW ENG. J. MED. 1839, 1841 (2003).

17. Miller et al., *supra* note 12, at 57.

18. NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, *supra* note 13, at 5.

19. Miller et al., *supra* note 12, at 65.

B. Benefits of HRT

To combat menopausal symptoms, such as hot flashes, and to reduce the risk of chronic disease, doctors have prescribed HRT.[20] HRT generally refers either to estrogen or a combination of estrogen and progestin.[21] The HRT drug Prempro is a combination of estrogen and progestin and was first approved as "safe and effective" by the Food and Drug Administration (FDA) in 1994.[22] Prempro, which is manufactured by Wyeth, will be the focus of this Comment since it is the subject of recent studies and lawsuits.[23] Prempro and other HRT drugs replenish some of the hormones that are no longer made by a woman's ovaries and stabilize any fluctuations in the amount of these hormones.[24] This, in turn, reduces or alleviates the symptoms and, according to the initial scientific data, health risks of menopause.[25]

Based on initial studies, HRT was expected to minimize the health risks that increase during menopause.[26] Specifically, these early studies revealed that HRT decreased its user's risk of coronary heart disease, colon cancer, and bone fractures from osteoporosis.[27] Additionally, early studies showed that HRT alleviated hot flashes, night sweats, and vaginal symptoms related to menopause.[28] Other positive effects from HRT included better overall physical functioning, reduction in bodily pain, and ability to sleep without disturbance.[29] Women taking HRT reported feeling better, feeling more attractive, and having better skin tone.[30] Based on initial studies and anecdotal reports, doctors

20. Adam L. Hersh et al., *National Use of Postmenopausal Hormone Therapy: Annual Trends and Response to Recent Evidence*, 291 JAMA 47, 52 (2004).

21. NAFTOLIN ET AL, *supra* note 4. Estrogen and progesterone are hormones. NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, *supra* note 13, at 2. Progestin is a synthetic form of progesterone. *Id* at 3. Women with a uterus are given progestin and estrogen. *Id.* Women without a uterus, such as those who underwent a surgical hysterectomy, have no need for the progestin and are given estrogen alone. Nancy Fugate Woods & Ellen Sullivan Mitchell, *Preventive Health Issues: The Perimenopausal to Mature Years (45-64), in* WOMEN'S HEALTH ACROSS THE LIFESPAN: A COMPREHENSIVE PERSPECTIVE 72, 83 (Karen Moses Allen & Janice Mitchell Phillips eds., 1997).

22. *Albertson II*, No. 2944, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *4 (May 3, 2005).

23. To be clear, Prempro is not the only form of HRT drug. Premarin is another HRT drug that contains only estrogen. NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, *supra* note 13, at 9. Premarin has been prescribed since 1942. *Albertson II*, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *4. Premarin is also manufactured by Wyeth. Albertson v. Wyeth Inc., 63 Pa. D. & C.4th 514, 516 (C.P. Ct. 2003).

24. *See* Miller et al., *supra* note 12, at 65 (citing various studies reviewing the prescribed uses of HRT)

25. *Id.*

26. *Id.*; Woods & Mitchell, *supra* note 21, at 84.

27. Rossouw et al., *supra* note 6, at 322.

28. Woods & Mitchell *supra* note 21, at 84.

29. Hays et al., *supra* note 16, at 1846.

30. *Id.* at 1852.

prescribed HRT for a variety of reasons including alleviation of symptoms and improvement of quality of life.[31]

C. Reported Risks of HRT

Lawsuits regarding Prempro and other types of HRT stem from recent reports of increased health risks for those taking HRT.[32] In contradiction to initial studies, recent studies have associated HRT use with an increased risk of breast cancer, coronary heart disease, stroke, dementia, and pulmonary embolism.[33] The Women's Health Initiative (WHI) study is the most commonly cited study that drew these associations between the use of HRT, specifically Prempro, and adverse health events.[34] In addition to adverse effects on chronic disease risk, the WHI study researchers reported that HRT had no "clinically meaningful" effect on any aspect of the quality of life.[35] Essentially, the WHI study contradicted all of the conventional wisdom surrounding the use of HRT.

D. Criticism of the WHI Study

Typically, clinical studies such as the WHI study are rigorously designed and scheduled to last a specific length of time to ensure reliable results.[36] The WHI study, however, ended prematurely when the independent data and safety monitoring board charged with overseeing the study determined that the risk of cancer from taking Prempro outweighed the benefits.[37] It is important to note that it is unknown whether the data would have revealed an actual increase in cancer incidence had the study been continued until its scheduled completion.

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31. *See* Hersh et al., *supra* note 20, at 52.

32. Albertson v. Wyeth Inc., 63 Pa. D. & C.4th 514, 522 (C.P. Ct. 2003).

33. Garnet L. Anderson et al., *Effects of Conjugated Equine Estrogen in Postmenopausal Women with Hysterectomy: The Women's Health Initiative Randomized Controlled Trial*, 291 JAMA 1701, 1708 (2004); Rossouw et al., *supra* note 6, at 325.

34. *See* Chi-Ling Chen et al., *Hormone Replacement Therapy in Relation to Breast Cancer*, 287 JAMA 734, 734 (2002) (discussing the association between HRT and breast cancer); Rossouw et al., *supra* note 6, at 321, 325 (comparing the risks and benefits associated with HRT).

The WHI study, which began in 1993, enrolled women between the ages of fifty and seventy-nine in a randomized clinical trial designed to examine the health effects of estrogen and progestin combination therapy on women with an intact uterus and of estrogen alone on women who had a prior hysterectomy. Rossouw et al., *supra* note 6, at 321. The combination of estrogen and progestin was given in the form of Prempro in the study. *Id.* at 322. The WHI estrogen-progestin study was scheduled to continue until March 2005. However, it ended in May 2002 because evidence of breast cancer and the risk of other disease outweighed evidence of any benefit. *Id.* at 321, 325. Several other studies have supported the WHI study results. *See, e.g.*, Chen et al., *supra*, at 734.

35. Hays et al., *supra* note 16, at 1852.

36. *See* LEON GORDIS, EPIDEMIOLOGY 98-109 (1996).

37. *Id.*

Despite the seemingly damning results of the WHI study, some analysts question the validity of the WHI study's results since its findings revealed only a low statistical risk for health problems.[38] A finding of low statistical risk means that there was a weak association between HRT and adverse health events.[39] These analysts question the WHI study's disparate results showing increased risk of coronary heart disease because previous studies had shown precisely the reverse.[40] Other analysts looking at the WHI study's findings regarding breast cancer concluded that the finding of increased risk of breast cancer was due to the WHI study's design and not the HRT use.[41] Due to the contradicting information from the WHI study and other studies, the International Menopause Society considers the question of the association between HRT use and breast cancer to be unresolved.[42]

Critics of the WHI study have given several explanations for its disparate results.[43] The WHI study's findings may be explained in part by the age of the women using HRT in the study.[44] Participants in the WHI study did not begin using HRT until at least age fifty which is much later than many women are typically started on HRT.[45] It is possible that the precursors to coronary heart disease were already irreversibly ravaging participant's bodies before the HRT could have any protective effect.[46] Furthermore, since the study population was older, the results should not be deemed definitive for a younger population.[47] Researchers should not generalize the results of a study to a population of a different age because age is a major factor in chronic disease occurrence.[48]

Another possible explanation for the WHI study's disparate results is that the WHI study population was more obese, contained more diabetic women, and more smokers than the typical clinical population.[49] Because the WHI study population was less healthy, there was a greater possibility that these women would contract chronic diseases regardless of HRT use.[50]

Additionally, the WHI study ended after discovering a small number of adverse health events.[51] The fewer adverse events, the more difficult it is to

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38. Harman et al., *supra* note 7, at 44-45; *see generally* NAFTOLIN ET AL., *supra* note 4 (challenging conclusions and implications drawn from the WHI study).

39. Rossouw et al., *supra* note 6, at 331.

40. Harman et al., *supra* note 7, at 44-45.

41. NAFTOLIN ET AL., *supra* note 4, at 2-4.

42. *Id.* at 5.

43. Harman et al., *supra* note 7, at 44-45.

44. *Id.* at 45.

45. *Id.*

46. *Id.* The logic is that the cardiovascular plaques that were forming before women took the HRT appeared once the WHI study began. This could also explain the increased risk of stroke found in the WHI study. *Id.* at 46.

47. NAFTOLIN ET AL., *supra* note 4, at 3.

48. *Id.*

49. Harman et al., supra note 7, at 49.

50. *See id.*

51. Rossouw et al., *supra* note 6, at 331.

make a definitive statistical calculation about the results.[52] The WHI study participants did not have enough adverse health events compared with the placebo group to determine whether there was a real association between HRT use and health risks.[53] In other words, the WHI study did not have the statistical power to support its purported connection between HRT use and chronic disease occurrences.

Despite the criticisms of the WHI study, the study has provided the basis for lawsuits against Wyeth, the maker of Prempro. According to the lawsuits, the WHI study provided evidence that HRT use enhanced the risk of disease in menopausal women.[54] An enhanced risk of disease, coupled with a possibility that Wyeth knew of this risk,[55] provides grounds for negligence claims and a possible medical monitoring claim.

II. MEDICAL MONITORING

Several groups of plaintiffs have brought suits against Wyeth for medical monitoring damages.[56] Medical monitoring claims request compensation for diagnostic testing.[57] Medical monitoring damages compensate the plaintiff for diagnostic testing for an injury that the individual did not have at the time of the lawsuit.[58] Unlike in a traditional negligence scheme, plaintiffs do not need to claim the existence of a current injury to pursue a medical monitoring claim.[59] Rather, plaintiffs generally must prove the following two elements: (1) they were exposed to a substance that increased their risk of adverse health consequences and the defendant was somehow responsible for the exposure,[60] and (2) a medical monitoring scheme is available to diagnose those health

52. *See* GORDIS, *supra* note 36, at 98-113.

53. NAFTOLIN ET AL., *supra* note 4, at 2-3, 5.

54. *See, e.g.*, Albertson v. Wyeth Inc., 63 Pa. D. & C.4th 514, 514 (C.P. Ct. 2003).

55. *See id.* at 520.

56. *Id.* at 524.

57. Maskin et al., *supra* note 11, at 522.

58. Kimberly Castelaz, Annotation, *Costs of Medical Tests and Surveillance in Absence of Present Injury*, 63B AM. JUR. 2D *Products Liability* §§ 1518, 1887 (1997). This Comment considers medical monitoring claims to be only for those plaintiffs who do not have an injury. Some commentators and courts may call any recovery for medical testing medical monitoring. Pankaj Venugopal, Note, *The Class Certification of Medical Monitoring Claims*, 102 COLUM. L. REV. 1659, 1659-60 (2002).

Several lawsuits have been initiated against Wyeth that claim actual injury. *See, e.g.*, Rush v. Wyeth, No. 4:03CV1507-WRW, 4:05CV00497, 2006 U.S. Dist. LEXIS 47472, at *2 (E.D. Ark. July 13, 2006); Sophia Pearson & Jef Feeley, *Mistrial Granted in Menopause-Drug Case Against Wyeth*, BLOOMBERG NEWS, Oct. 12, 2006, *available at* http://www.philly.com/ mld/inquirer/business/15736076.htm. To be clear, this Comment only addresses the ability of women without a current chronic illness to obtain medical monitoring damages and will not address those suits initiated by HRT users with present, actual diseases.

59. Perez v. Metabolife Int'l Inc., 218 F.R.D. 262, 264 (S.D. Fla. 2003).

60. *See* Maskin et al., *supra* note 11, at 522.

consequences.[61] Though states differ slightly in the specific elements required to establish a medical monitoring claim,[62] these two general elements are consistently required for medical monitoring claims.

The policy that underlies allowing medical monitoring claims is the same as that for public health measures: diagnosing a disease early will improve health care outcomes and result in lower costs to the patient, to the health care system, and to society as a whole.[63] Medical monitoring claims also have a deterrent effect and serve to provide justice to the victims of wrongdoing.[64] Without medical monitoring damage awards, individuals exposed to dangerous chemicals, drugs, or other health risks due to the negligence of another would have to pay for their own diagnostic testing.[65] These considerations have persuaded courts to allow plaintiffs to recover medical monitoring damages in a variety of situations.[66]

A. Origins of Medical Monitoring

While obtaining recovery for an actual injury is uncontroversial, the possibility of recovery by plaintiffs who are currently uninjured has not been addressed by the courts until relatively recently.[67] The United States District Court for the District of Columbia was reportedly the first court to award medical monitoring damages to plaintiffs without apparent injuries.[68] This case of first impression, *Friends For All Children v. Lockheed,* was a compelling one involving foreign orphans and a plane crash.[69]

When the fall of Saigon was imminent near the end of the United States' involvement in the Vietnam War, Vietnamese children from the orphanages of

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61. *Id.*; Redland Soccer Club, Inc. v. Dep't of the Army, 696 A.2d 137,145 (Pa. 1997).

62. Venugopal, *supra* note 58, at 1659-60.

63. Allan L. Schwartz, Annotation, *Recovery of Damages for Expense of Medical Monitoring to Detect or Prevent Future Disease or Condition,* 17 A.L.R.5th 327, 349 (2005).

64. *Id.*

65. *Id.*

66. *See, e.g.*, Potter v. Firestone Tire and Rubber Co., 863 P.2d 795, 824 (Cal.1993) (allowing recovery of medical monitoring damages where litigants were exposed to hazardous wastes disposed of in a landfill); *Redland Soccer Club, Inc*., 696 A.2d at 145 (citing Hansen v. Mountain Fuel Supply Co., 858 P.2d 970, 976-77 (Utah 1993)) (allowing recovery of medical monitoring damages where litigants were exposed to hazardous substances).

67. *See generally* Maskin et al., *supra* note 11 (discussing how the difficulties of proving that a defendant's actions caused illness or disease have led courts to create less traditional remedies, including the claim for medical monitoring expenses).

68. Friends For All Children v. Lockheed Aircraft Corp., 746 F.2d 816, 819 (D.C. Cir. 1984).

69. *Id.* at 816. Litigation surrounding the plane crash began with three "bellwether" trials: Marchetti v. Lockheed Aircraft Corp., 656 F.2d 899 (Table) (D.C. Cir. 1981); Schneider v. Lockheed Aircraft Corp., 658 F.2d 835 (D.C. Cir. 1981); Zimmerly v. Lockheed Aircraft Corp., 656 F.2d 901 (Table) (D.C. Cir. 1981). *Friends For All Children*, 746 F.2d at 820-21.

Saigon were evacuated as a part of "Operation Babylift."[70] An aircraft carrying Vietnamese orphans to the United States malfunctioned shortly after takeoff.[71] The cargo door and ramp fell off the rear of the aircraft causing decompression and loss of oxygen in the passenger cabin.[72] The pilot attempted to bring the plane down safely, but the plane crashed and broke into pieces.[73] One hundred fifty of the 258 orphans on board survived the decompression and the crash.[74] A large number of survivors sued the aircraft manufacturer for medical monitoring damages.[75]

Representatives for the surviving children claimed that the children were at risk for developing Minimal Brain Dysfunction (MBD), a neurological development disorder, as a result of their ordeal.[76] MBD is characterized by hyperactivity, chronic inattention, and personality disorders.[77] MBD may be caused by hypoxia which means a lack of oxygen, dehydration, malnutrition, or deprived family background.[78] The plaintiffs claimed that when the plane underwent decompression, the children were at risk for hypoxia and therefore at risk for MBD.[79] The defendant, Lockheed, claimed that if the children developed MBD, it was caused by the conditions of being an orphan in Saigon and not by the plane's decompression and crash.[80]

At the district court, the plaintiffs prevailed and the court granted a preliminary injunction requiring Lockheed to create a pool of funding in the amount of $450,000 for diagnostic examinations for the children.[81] The district court found that the plane crash was the proximate cause of the need for examinations and was concerned that leaving the possible neurological disorder undiagnosed would result in poor prognoses for the children.[82] In granting the injunction, the district court held that the plaintiffs demonstrated that the jury would award damages for reasonable diagnostic examinations.[83]

The United States Court of Appeals for the District of Columbia affirmed the medical monitoring damages injunction.[84] The court explained that medical monitoring fulfilled two purposes of tort law: deterring misconduct of the product manufacturer, and providing compensation to the victims of that

70. *Schneider*, 658 F.2d at 838.
71. *Friends For All Children*, 746 F.2d at 819.
72. *Id.*
73. *Id.*
74. *Schneider*, 658 F.2d at 838.
75. *Friends For All Children*, 746 F.2d at 820-21.
76. *Id.* at 819.
77. *Schneider*, 658 F.2d at 844.
78. *Id.*
79. *Friends For All Children*, 746 F.2d at 825.
80. *Id.* at 826.
81. *Id.* at 823. At the time, there were fifty-three children who lived in countries such as France that would not pay for the cost of the diagnostic testing. *Id.* at 822.
82. *Id.* at 822-23.
83. *Id.* at 823.
84. *Id.* at 816, 819.

misconduct.[85] Thus, a precedent for allowing medical monitoring damages was established.

Since the *Friends For All Children* decision, courts have allowed medical monitoring claims and damages in various cases.[86] A landmark case following *Friends For All Children* allowed medical monitoring damages for plaintiffs who claimed that they faced an increased risk of disease because their drinking water wells were polluted by the township-owned landfill.[87] Since then, medical monitoring damages have been awarded in cases running the gamut from toxic chemical spills to asbestos exposure to radiation exposure and others.[88] With courts willing to allow medical monitoring claims and damages for various types of cases, the limits on a court are those imposed by that jurisdiction's law.

B. Approaches to Medical Monitoring Claims

Tort law is predominantly under the purview of state law, so it should come as no surprise that the elements of medical monitoring claims and the recognition of such claims are not uniform throughout the country.[89] With respect to medical monitoring claims, states fall into one of four categories: (1) states recognizing medical monitoring claims as a separate cause of action; [90] (2) states allowing medical monitoring damages to be awarded as part of a negligence or strict liability claim;[91] (3) states not allowing medical monitoring

85. *Id.* at 825.

86. Kara L. McCall, *Medical Monitoring Plaintiffs and Subsequent Claims for Disease*, 66 U. CHI. L. REV. 969, 975 (1999).

87. Maskin et al., *supra* note 11, at 525.

88. McCall, *supra* note 87, at 975 (citations omitted).

89. *In re* Prempro Prods. Liab. Litig., No. 4:03-CV-1507-WRW, 2005 U.S. Dist. LEXIS 19153, at *52 (E.D. Ark. Aug. 30, 2005); Venugopal, *supra* note 58, at 1659-60. Though most tort claims are settled through state law, federal statutes have put some torts under the jurisdiction of the federal courts. *See* McCall, *supra* note 88, at 975; *see also Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 426-30 (1997). In *Metro-North*, the U.S. Supreme Court had the opportunity to examine medical monitoring claims in the context of the Federal Employers' Liability Act (FELA). 521 U.S. at 444, 450. The Court, using the elements of a medical monitoring claim as established by the Third Circuit, refused to interpret the FELA to cover medical monitoring claim damages. *Id.* For more about the Supreme Court's analysis of *Metro-North*, *see* Matthew D. Hamrick, Comment, *Theories of Injury and Recovery for Post-Exposure, Pre-Symptom Plaintiffs: The Supreme Court Takes a Critical Look*, 29 CUMB. L. REV. 461 (1998).

90. States allowing medical monitoring as a cause of action include Arizona, Florida, Pennsylvania, Utah, and West Virginia. *See* Steven A. Boranian & Kevin M. Hara, *Medical Monitoring: Innovative New Remedy Or Money for Nothing?* 2-7 (Mealey's Hormone Replacement Therapy, Working Paper No. 11, 2006); Victor E. Schwartz et al., *Medical Monitoring: The Right Way and the Wrong Way*, 70 MO. L. REV. 349, 361 (2005).

91. States treating medical monitoring as an element of damages in an action for negligence or strict liability include California, the District of Columbia, New Jersey, and possibly Alaska. *See* Boranian & Hara, *supra* note 90; Schwartz et al., *supra* note 90, at 361 n.70. Some states allow medical monitoring damages but it is unknown if they would allow a separate cause of action. These states include Colorado, Illinois, Missouri, Montana, and

claims in any form;[92] and (4) states remaining silent on medical monitoring claims.[93]

To illustrate the approaches to and reasoning behind medical monitoring claims, this Section will explore cases from three states: Pennsylvania, which recognizes a medical monitoring cause of action; California, which allows medical monitoring damages in tort cases; and Kentucky, which does not allow medical monitoring claims at all.

1. Pennsylvania: Medical Monitoring As a Separate Cause of Action

Pennsylvania's courts recognize a medical monitoring claim as a separate cause of action.[94] The elements for Pennsylvania's current medical monitoring cause of action were established in a series of federal court decisions.[95] The Pennsylvania state court then adopted the federal court's medical monitoring claim elements in *Redland Soccer Club v. Department of the Army*.[96] To recover under a medical monitoring cause of action, plaintiffs must prove the following elements:

> (1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) monitoring procedure exists that makes 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

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Ohio. Boranian & Hara, *supra* note 90; Schwartz et al., *supra* note 90, at 361 n.70. Commentators in some states such as New York and Virginia cannot agree as to the state of the law on medical monitoring. *See* Boranian & Hara, *supra* note 90; Schwartz et al., *supra* note 90, at 361 nn.70-71.

92. The following states reportedly do not allow medical monitoring damages in any form Alabama, Connecticut, Indiana, Kentucky, Louisiana, Michigan, Mississippi, Nebraska, Nevada, North Carolina, North Dakota, Oregon, South Carolina, Tennessee, and Washington. *See* Boranian & Hara, *supra* note 90; Schwartz, *supra* note 90, at 361 n.71.

93. A search of Wisconsin cases revealed that Wisconsin has not specifically addressed medical monitoring. Any state not mentioned presumably has not addressed medical monitoring.

94. Schwartz, *supra* note 90, at 361 n.70.

95. Redland Soccer Club, Inc. v. Dep't of the Army, 696 A.2d 137, 144 (Pa. 1997) (citing *In re* Paoli R.R. Yard PCB Litigation, 916 F.2d 829, 852 (3d Cir. 1990) (*Paoli I*) and *In re* Paoli R.R. Yard PCB Litigation, 35 F.3d 717, 788 (3d Cir. 1994) (*Paoli II*)). If a state court has not yet decided an issue, the federal court must make a prediction as to how that state's highest court would decide the issue under the *Erie* Doctrine. *Id.* at 143. Pennsylvania had not yet made a determination about medical monitoring claims, so the Third Circuit created the elements of the claim as it believed Pennsylvania's highest court would do. *Id.* at 142-43.

96. *Paoli I*, 916 F.2d 829, 852; *Paoli II*, 35 F.3d 717, 788.

> monitoring regime is reasonably necessary according to contemporary scientific principles. [97]

The *Redland* elements have been adopted by several other states. For example, Florida adopted the identical test in a case involving diet drugs known as Phen-Fen.[98] Justice Ginsburg also quoted the *Redland* elements in her dissent in the case *Metro-North Commuter Railroad v. Buckley*.[99] Additionally, two HRT cases, *Albertson v. Wyeth, Inc.* and *Wyeth, Inc. v. Gottlieb*, have articulated the *Redland* elements as the legal standard for making a compensable medical monitoring claim.[100]

2. California: Medical Monitoring Damages in Negligence and Strict Liability Cases

Unlike Pennsylvania law, which recognizes medical monitoring as a separate cause of action, California allows medical monitoring damages in conjunction with a negligence or strict liability action, but does not treat medical monitoring as a separate cause of action.[101]

One of the landmark medical monitoring damages cases in California was *Potter v. Firestone Tire & Rubber Co*.[102] *Potter* examined whether future medical monitoring was a "recoverable item of damage" where a plaintiff had no present injury or illness.[103] The plaintiffs were landowners who lived next to a landfill.[104] Despite admonitions to refrain from dumping toxic substances into that landfill, Firestone used the landfill to dispose of toxic waste.[105] The plaintiffs sued Firestone after discovering that Firestone dumped chemicals, some of them carcinogens, into the landfill and contaminated plaintiffs' drinking water wells.[106] Because of their exposure to toxic waste, the plaintiffs claimed that they faced an enhanced risk of developing cancer in the future.[107]

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97. *Redland Soccer Club, Inc.*, 696 A.2d at 145-46. These elements are hereinafter referred to as the *Redland* elements.

98. Petito v. A.H. Robins Co., 750 So. 2d 103, 104, 106-107 (Fla. Dist. Ct. App. 1999).

99. 521 U.S. 424, 450 (1997) (Ginsburg, J., dissenting).

100. *Albertson*, 63 Pa. D. & C.4th 514, 526-27 (C.P. Ct. 2003); *Gottlieb*, 930 So. 2d 635, 540 (Fla. Dist. Ct. App. 2006). Two other cases, *Vitanza* and *In re Prempro*, have yet to articulate a test for medical monitoring damages. Vitanza v. Wyeth, Inc., No. ATL-L-2093-04-MT, 2006 WL 462470 (N.J. Super. Ct. Jan. 24, 2006); *In re* Prempro, 230 F.R.D. 555 (E.D. Ark. 2005).

101. Potter v. Firestone Tire & Rubber Co., 863 P.2d 795, 823 (Cal. 1993).

102. 863 P.2d 795.

103. *Id.* at 800.

104. *Id.* at 801.

105. *Id*.

106. *Id.* at 801-02.

107. *Id.* at 801.

After finding negligence against Firestone, the district court awarded medical monitoring damages to the plaintiffs.[108]

The California Court of Appeal reversed the medical monitoring damage award based on plaintiffs' failure to establish that the injury, in this case cancer, was reasonably certain to occur from their exposure to toxic waste.[109] The Court of Appeal reasoned that in order to recover medical monitoring damages, the plaintiffs either must have a present physical injury, or the plaintiffs must demonstrate that future injury is more likely than not to occur.[110]

The Supreme Court of California disagreed with the Court of Appeal.[111] The court held that plaintiffs must prove two elements to recover medical monitoring damages.[112] Plaintiffs must first prove that the need for future monitoring was a reasonably certain consequence of exposure.[113] Second, plaintiffs must prove that the recommended monitoring was reasonable.[114] Further, the court explained that plaintiffs did not need to establish with certainty that they would contract cancer or another disease.[115] The bottom line in California after *Potter* is that medical monitoring is a compensable item of damage in a negligence action.[116]

While not identical, the elements used by California courts to award medical monitoring damages in tort cases are quite similar to those used in states such as Pennsylvania, which allow medical monitoring as a cause of action. Under both Pennsylvania and California law, plaintiffs must prove that their exposure to a hazardous substance increased the risk of disease and that a medical regime exists to monitor the risk.[117] Pennsylvania's scheme, however, contains some additional elements.[118] Because Pennsylvania law recognizes a separate medical monitoring cause of action, Pennsylvania's test requires proof of the defendant's negligence.[119] California's medical monitoring test, however, only becomes applicable after a plaintiff has already proven the underlying negligence claim.[120] Additionally, Pennsylvania law requires proof not only that a medical monitoring regime exists, but also that the regime is

108. *Id.* at 802-03.
109. *Id.* at 804.
110. *Id.* at 822.
111. *Id*.
112. *Id*. at 824.
113. *Id*.
114. *Id.*
115. *Id.*
116. *Id.* at 800.
117. *Id.* at 824-25; Redland Soccer Club, Inc. v. Dep't of the Army, 696 A.2d 137, 145-46 (Pa. 1997).
118. *See Redland Soccer Club, Inc.*, 696 A.2d at 145-46 (listing elements a plaintiff must prove to sustain a cause of action for medical monitoring damages).
119. *See id.* at 145.
120. *See Potter*, 863 P.2d at 800 (stating that a plaintiff may receive medical monitoring damages in a negligence claim).

necessary and different from normal monitoring for those who were not exposed to a hazardous substance.[121]

3. Kentucky: Medical Monitoring Claims Prohibited

While Pennsylvania and California courts established methods to provide recovery for medical monitoring, Kentucky courts decided not to allow any medical monitoring recovery for currently uninjured plaintiffs. The Kentucky Supreme Court considered whether to allow recovery for medical monitoring in *Wood v. Wyeth-Ayerst Laboratories* in 2002.[122] The plaintiffs sued the manufacturer of a diet drug containing fenfluramine after a study revealed a possible increased risk of heart-valve disorders from use of the drug.[123] The court dismissed the medical monitoring claims because the plaintiffs did not offer proof of actual injury.[124] The court stated, "Where there is no injury, there can be no redress. If and when Appellant manifests an injury . . . , only then will she have a remedy under the law."[125] Kentucky courts have consistently required such a manifestation of actual physical injury.[126]

Part of the Kentucky court's rationale for requiring a present physical injury was that medical monitoring damage awards deplete defendants' resources before those who were actually injured could make their claims.[127] Regardless of the nature of the defendant's resources, the court further explained that claim preclusion would also bar a suit based on actual injury for those plaintiffs who had previously sued under medical monitoring damage claims.[128] The Kentucky Supreme Court sought to protect future rights by barring a premature claim when this premature claim served to preclude future claims.[129]

4. Effect of a State's Approach on HRT Plaintiffs

Pennsylvania, California, and Kentucky courts provide three of fifty possible viewpoints on the subject of medical monitoring. Some states have agreed with the approach taken by one of these states, but other states have not made a statement about whether they will allow medical monitoring recovery.[130] Therefore, before HRT users sue Wyeth, they should consider how their jurisdiction's courts have resolved the medical monitoring issue. Even

121. *Redland Soccer Club, Inc.*, 696 A.2d at 145-46.

122. 82 S.W.3d 849, 849-50 (Ky. 2002).

123. *Id.* at 851. Fenfluramine is a part of the controversial diet drug combination Phen-Fen that was withdrawn from the market in 1997 under suspicion of health consequences. *Id.* at 850-51.

124. *Id.* at 852.

125. *Id.* at 859.

126. *Id.* at 852.

127. *Id.* at 857.

128. *Id.* at 858.

129. *Id.*

130. *See supra* notes 89-92.

assuming that HRT users sue in a jurisdiction that allows either a medical monitoring cause of action or medical monitoring damages, those plaintiffs will still need to prove that HRT use meets the elements of medical monitoring recovery. While no court has reached this issue yet, Part III explores what may happen from a legal standpoint when a court does reach the issue.

III. MEDICAL MONITORING IN HRT LAWSUITS

Medical monitoring claims stemming from HRT use are beginning to move through the trial courts. The first case, *Albertson v. Wyeth Inc.*, was filed in Pennsylvania state court in 2002.[131] Following shortly after *Albertson*, three additional HRT cases were filed as class actions: *In re Prempro*[132] in Arkansas federal court, *Gottlieb v. Wyeth, Inc.*[133] in Florida state court, and *Vitanza v. Wyeth, Inc.*[134] in New Jersey state court. Class action status is important to plaintiffs because it allows for consolidation of resources.[135] The disadvantage of class actions is that plaintiffs have to prove the existence of additional circumstances in order to be certified to proceed as a class.[136] The plaintiffs in *Albertson*, *In re Prempro*, and *Gottlieb* were all denied class action certification in their respective courts.[137] However, these cases may proceed with individual plaintiffs,[138] and in fact, a plaintiff from the *In re Prempro* proposed class is proceeding individually.[139] In contrast to those three cases, *Vitanza* was dismissed for plaintiffs' failure to state a viable claim.[140] Because many of these cases are in the initial stages or have been dismissed, none of the courts in these cases have evaluated all of the elements of a medical monitoring claim. This Part describes the status of these current cases and evaluates the application of the facts of HRT use to the legal elements of a medical monitoring claim.

131. Albertson v. Wyeth Inc., 63 Pa. D. & C.4th 514, 524 (C.P. Ct. 2003).

132. 230 F.R.D. 555 (E.D. Ark. 2005).

133. 930 So. 2d 635 (Fla. Dist. Ct. App. 2006).

134. No. ATL-L-2093-04-MT, 2006 WL 462470 (N.J. Super. Jan. 24, 2006).

135. *See generally* Venugopal, *supra* note 58 (discussing the positive and negative consequences of class actions).

136. *Id.*

137. *Albertson II*, No. 2944, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *46 (May 3, 2005); *Gottlieb*, 930 So. 2d at 636; *In re Prempro*, 230 F.R.D. at 555.

138. *Albertson II*, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *46; *Gottlieb*, 930 So. 2d at 636; *In re Prempro*, 230 F.R.D. at 555.

139. *Bellwether Plaintiff Files Deluge of Pretrial Motions Seeking Exclusion of Evidence*, 2-12 MEALEY'S HORMONE REPLACEMENT THERAPY 10 (2006)

140. Vitanza v. Wyeth, Inc., No. ATL-L-2093-04-MT, 2006 WL 462470, at *1 (N.J. Super. Ct. Jan. 24, 2006).

A. Status of HRT Lawsuits

1. Albertson v. Wyeth

On August 21, 2002, shortly after the release of the WHI study's findings, a group of women filed suit in Pennsylvania against Wyeth claiming negligence and a need for medical monitoring, among other claims.[141] All of the plaintiffs were women who had taken Prempro or another HRT drug beginning sometime in the 1990s and ending in the summer of 2002.[142] Two of these plaintiffs used Prempro again for a short time in 2003.[143] None of the plaintiffs had been diagnosed with breast cancer or any other disease and thus did not have a current injury from HRT use.[144] The defendant, Wyeth, filed a demurrer asking the court to dismiss the case on the ground that there was no legal basis for the case.[145] The court overruled Wyeth's demurrer but acknowledged that the plaintiffs may not be able to satisfy the elements required to prove a medical monitoring claim on the merits.[146]

In 2005, additional HRT users joined the plaintiffs in *Albertson* and attempted to certify the case as a class action under Pennsylvania law.[147] The proposed class included all postmenopausal Pennsylvania residents who took high dose Prempro for at least one year before the July 2002 announcement of the WHI study's results.[148]

The court found the plaintiffs fell short on two requirements: commonality which requires that the individual plaintiffs shared similar facts and law, and typicality which requires that the plaintiffs named in the class action adequately exemplified the situation of all the women bound by the class action.[149] The court held that the plaintiffs' facts were too personal and varied to meet these requirements.[150] The court also found that the plaintiffs as a class failed to prove two necessary elements of their medical monitoring claim, namely that (1) Prempro was a proven hazardous substance, and (2) the prescribed

141. Albertson v. Wyeth Inc., 63 Pa. D. & C.4th 514, 524 (C.P. Ct. 2003). The other counts against Wyeth included unjust enrichment, violation of Pennsylvania Unfair Trade Practices and Consumer Protection Law, breach of fiduciary duty, and fraud. *Id. Albertson* is a consolidation of several cases filed nearly the same date. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*

145. *Id*. at 534 n.5.

146. *Id.*

147. *Albertson II*, No. 2944, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *9 (May 3, 2005).

148. *Albertson II*, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *1. The plaintiffs also sought certification of a subclass of women who switched to the lower dose of Prempro in July 2002 instead of discontinuing Prempro use at that time. *Id.* at *1-2. Therefore, one named plaintiff was added who was taking low-dose Prempro at the time of the class certification decision. *Id.* at *3.

149. *Id.* at *20, *43-44.

150. *Id.* at *20.

monitoring regime for HRT users was different from that recommended for non-HRT users.[151]

2. In re Prempro

The *Albertson* plaintiffs were not the only women to be denied class action certification. The United States District Court for the Eastern District of Arkansas, in *In re Prempro*, also denied certification of a class action to a group of HRT users who sued Wyeth.[152] As in *Albertson*, the plaintiffs claimed an increased risk of chronic diseases such as breast cancer, stroke, heart attack, dementia, and blood clots due to HRT use.[153] Specifically, the plaintiffs in this case sought monitoring for breast cancer and dementia.[154] The court denied class certification, not based on the substance of the medical monitoring claim per se, but based on its concern about the wide variety of states' laws involved since plaintiffs came from twenty-four different states.[155] The court specifically cited the wide variety of treatment of medical monitoring claims by various states as an obstacle to this litigation and then denied class certification.[156] The court did not address, however, whether the alleged facts satisfied the elements for medical monitoring damages under any state's medical monitoring schemes.[157]

3. Gottlieb v. Wyeth

In *Gottlieb*, the question again was whether a class of HRT users should be certified.[158] Initially, the Florida Circuit Court certified a class in the suit against Wyeth.[159] The District Court of Appeal then evaluated whether the circuit court's certification of the class action was erroneous.[160] The plaintiffs relied on the WHI study's findings of increased risk of breast cancer to substantiate their class certification claim.[161] Using the same elements of medical monitoring as the *Albertson* court, the appellate court examined the commonality and typicality requirements for class action certification.[162] The

151. *Id.* at *22.

152. 230 F.R.D. 555 (E.D. Ark. 2005).

153. *Id.*

154. *Id.* at 560.

155. *Id.* at 555. Proposed medical monitoring classes included all women in Arizona, Arkansas, California, Colorado, Connecticut, Florida, Illinois, Indiana, Kansas, Maryland, Michigan, Missouri, Nevada, New Jersey, New York, Ohio, Pennsylvania, Puerto Rico, Tennessee, Texas, Utah, Vermont, West Virginia, and Wyoming who used Prempro for two years or more prior to July 2002. *Id.* at 558.

156. *Id* at 573.

157. *See In re Prempro*, 230 F.R.D. 555.

158. Gottlieb v. Wyeth, Inc., 930 So. 2d 635, 637 (Fla. Dist. Ct. App. 2006).

159. *Id.* at 638.

160. *Id.*

161. *Id.* at 637.

162. *Id.* at 639-40.

court held that the plaintiffs failed to establish commonality, and also determined that named plaintiff Ms. Gottlieb's experience was not typical of the class because of individual factual differences between the plaintiffs.[163] Therefore, the court of appeals decertified the class.[164]

4. Vitanza v. Wyeth

In *Vitanza*, another lawsuit brought by users of HRT against Wyeth, the New Jersey Superior Court did not reach the question of whether class certification was appropriate.[165] Rather, the court dismissed the medical monitoring claims in the plaintiffs' complaint.[166] Referring to the New Jersey case law's strong stance on limiting the use of medical monitoring remedies, the court stated, "Medical monitoring is a remedy that 'is not easily invoked.'"[167] New Jersey precedent indicated that medical monitoring remedies had previously been allowed only in environmental toxin cases.[168] Courts permitted medical monitoring damages in environmental toxin exposure cases due to the concern that the injuries were latent and were difficult for plaintiffs to trace back to the toxin exposure.[169] For injuries that were more direct, the court explained that there were other remedies available, and therefore medical monitoring remedies were not needed.[170] By limiting medical monitoring damages to environmental toxin cases and refusing to extend such damages to HRT cases, the court essentially added a new requirement to the elements of medical monitoring: lack of another appropriate remedy.[171] The New Jersey Superior Court, viewing *Vitanza* as a products liability case, explained that there were other remedies available to plaintiffs in products liability cases.[172] Standing firm against expanding the use of medical monitoring remedies, the *Vitanza* court dismissed the plaintiffs' medical monitoring claims.[173]

Although the *Vitanza* plaintiffs' claim was dismissed, the plaintiffs involved in *Albertson*, *In re Prempro*, and *Gottlieb* are free to pursue individual lawsuits. In addition, plaintiffs in other states may file new claims after learning the lessons from these cases. It is unknown whether any of these potential future plaintiffs' medical monitoring claims will succeed since no

163. *Id.* at 642-43.

164. *Id.* at 643.

165. Vitanza v. Wyeth, Inc., No. ATL-L-2093-04-MT, 2006 WL 462470 (N.J. Super. Ct. Jan. 24, 2006).

166. *Id.* at *9.

167. *Id.*

168. *Id.* at *6.

169. *Id.* at *4-6.

170. *Id.* at *6.

171. *Id.*

172. *Id.* at *7-9. In fact, New Jersey had a Product Liability Act to address these cases. *Id.* at *9.

173. *Id.*

court has yet evaluated all the merits of medical monitoring claims in HRT cases. Therefore, the question still remains whether awarding medical monitoring claims to plaintiffs who used HRT is warranted from a legal or policy perspective. Before exploring the policy aspects, the next Section examines the legal factors courts need to evaluate before awarding medical monitoring damages in HRT cases.

B. Legal Application of Medical Monitoring in HRT Cases

In examining the legal issues surrounding the HRT lawsuits, this Section will use the *Redland* elements of medical monitoring claims discussed above.[174] Since they are the most widely accepted elements for medical monitoring claims, using the comprehensive *Redland* elements should provide some insight into how any court in a state allowing medical monitoring damages may consider medical monitoring remedies in HRT cases. Even though the courts in *Albertson*, *In re Prempro*, and *Gottlieb* have not yet evaluated all of the *Redland* elements in relation to the substance of the case, portions of those proceedings will be used to illustrate the possible difficulty in satisfying the *Redland* elements. With the evidence currently available, it is questionable whether plaintiffs could establish a claim for medical monitoring. The plaintiffs' largest hurdles will be proving that HRT is dangerous and that a monitoring scheme would be necessary beyond that already prescribed for those who do not use HRT.

1. Exposure Greater than Background

Under the first *Redland* element, the court must look at whether the intake of HRT was "exposure greater than normal background levels."[175] The issue here is whether HRT supplies more hormones than a woman who has not yet gone through menopause would naturally produce. Since the purpose of HRT is to replenish hormones, using HRT will provide more hormones than the woman would otherwise have in her system. None of the existing cases mentioned this element presumably because there would be no dispute that HRT use is designed to expose the woman to more hormones than normal background levels.

2. Proven Hazardous Substance

Second, plaintiffs need to establish that HRT is a proven hazardous substance.[176] Plaintiffs likely will point to the WHI study and contend that the study's results prove that HRT is hazardous. Wyeth will likely question the

174. *See supra* Parts II.B.1-2.
175. Redland Soccer Club, Inc. v. Dep't of the Army, 696 A.2d 137, 145 (Pa. 1997).
176. *Id.*

WHI study results, which has already been done in the scientific community.[177] As mentioned, the WHI study is not without its critics, and those critics have some strong scientific evidence that the WHI study may not provide the definitive proof that HRT causes adverse health events.

Besides challenging the scientific data, Wyeth may also argue that HRT is not a hazardous substance because the FDA, which originally approved Prempro, has not removed Prempro from the market.[178] In fact, Wyeth has already claimed that the drug could not be hazardous because the FDA can only approve drugs it deems as safe and effective, and Prempro is still on the market.[179] Wyeth argued that the FDA's failure to remove HRT from the market leads to the inference that HRT is not hazardous.[180] The *Albertson* court was not persuaded by the defendant's claim and found that the plaintiffs sufficiently established they were at increased risk for breast cancer.[181] In contrast, the *Gottlieb* court agreed with Wyeth's argument that FDA refusal to remove the drug from the market equates to the drug not being hazardous.[182] It is possible that another court may agree with the *Gottlieb* court, but it is generally unclear how future courts will rule on this issue.

Another obstacle to proving that Prempro is a hazardous substance is that doctors continue to prescribe Prempro, despite the WHI study's findings.[183] The *Albertson* and *Gottlieb* plaintiffs' physicians prescribed Prempro to patients contemporaneously with the litigation.[184] Continuing to prescribe Prempro may be a common practice among plaintiffs' doctors, making it more difficult to prove that the very product they prescribe to patients is hazardous.

3. Exposure Caused by Defendant's Negligence

The third *Redland* element requires plaintiffs to prove that their exposure to the hazardous substance was through negligence of the defendant.[185] Here the plaintiffs will need to establish that Wyeth knew HRT was associated with health risks but marketed it anyway.[186] This is precisely what the plaintiffs in *Albertson* argued.[187] The court, however, has not yet ruled on this argument.[188]

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177. *See generally* Harman et al., *supra* note 7, at 44-45; NAFTOLIN ET AL., *supra* note 4.

178. *See* Albertson v. Wyeth Inc., 63 Pa. D. & C.4th 514, 527-28 (C.P. Ct. 2003); Gottlieb v. Wyeth, Inc., 930 So. 2d 635, 637 (Fla. Dist. Ct. App. 2006).

179. *Albertson*, 63 Pa. D. & C.4th at 527-28.

180. *Id.*

181. *Id.* at 533-34.

182. *Gottlieb*, 930 So. 2d at 640.

183. *Albertson II*, No. 2944, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *38 (May 3, 2005).

184. *Id.*; *Gottlieb*, 930 So. 2d 635 at 640.

185. Redland Soccer Club, Inc. v. Dep't of the Army, 696 A.2d 137, 145 (Pa. 1997).

186. *Albertson*, 63 Pa. D. & C.4th at 523.

187. *Id.* at 527-28.

188. *Id.* at 534.

4. Increased Risk of Disease

Under the fourth element, plaintiffs must establish that they have a significantly increased risk of contracting disease as a proximate result of their exposure to HRT.[189] The *In re Prempro* court anticipated the difficulty plaintiffs will have proving this element.[190] Specifically, the court noted that plaintiffs must prove specific causation.[191] In other words, the court required the plaintiffs to prove that HRT use increased the risk of disease in each woman; proof that HRT increased health risks generally was not enough.[192]

This element may be difficult to prove because researchers have noted that the results of studies such as the WHI study cannot be generalized to an individual.[193] Therefore, the results of the WHI study alone are not sufficient to establish this element for a class of women, and further analysis of each individual woman's health status would be necessary.[194] This individualized analysis may entail a determination of each woman's risk for breast cancer, coronary heart disease, stroke, dementia, and other diseases before her HRT use began. The risk for each individual plaintiff would then need to be evaluated to determine what effect the HRT use had, if any. This need for individual evaluation will likely confound further attempts to certify class actions.

5. Monitoring Scheme Exists and Differs from Normal Recommendations

The fifth *Redland* element requires a determination of whether a monitoring procedure exists that can detect the disease before the individual experiences actual symptoms.[195] An additional complexity in the HRT context is that plaintiffs may claim increased risk of developing a variety of diseases. Obviously, the monitoring necessary to diagnose breast cancer is different than that for diagnosing dementia or coronary heart disease. The court would have to determine whether to analyze a plaintiff's monitoring scheme that incorporates all potential future diseases, or whether to analyze the monitoring regime for each disease separately. Some of the diseases for which plaintiffs have requested monitoring already have known monitoring schemes, but the determination of whether such a scheme is specific only to those who have used HRT is more difficult.

189. *Redland Soccer Club, Inc.*, 696 A.2d at 145.

190. *In re* Prempro, 230 F.R.D. 555, 570 (E.D. Ark. 2005).

191. *Id.*

192. *See id.*

193. Harman et al., *supra* note 7, at 43; *see generally* NAFTOLIN ET AL., *supra* note 4 (describing the study and taking the position that the small differences of events between groups during the trial makes conclusions regarding the possible value of hormone therapy highly uncertain and devalues or invalidates the conclusions from the initial publication).

194. *See generally* NAFTOLIN ET AL., *supra* note 4 (describing the study and taking the position that the small differences of events between groups during the trial makes conclusions regarding the possible value of hormone therapy highly uncertain and devalues or invalidates the conclusions from the initial publication).

195. Redland Soccer Club, Inc. v. Dep't of the Army, 696 A.2d 137, 146 (Pa. 1997).

The debate over the nature of the monitoring regime already cost the *Albertson* plaintiffs certification of their class because their expert admitted that risk factors other than HRT use were just as important as HRT use to the creation of a monitoring scheme for breast cancer.[196] The plaintiffs' expert, Dr. Elliot, testified to a list of risk factors for breast cancer independent of HRT use such as family history, never having children, and drinking two or more glasses of alcohol per day.[197] Elliot then stated that the monitoring program proposed by plaintiffs was the same monitoring program she would prescribe to a patient who had any of the other risk factors but had not used HRT.[198] When pressed further, Elliot even admitted that she would recommend the same monitoring program to any fifty-three-year-old woman who had never taken Prempro even if she had no other risk factors.[199] This testimony led the court to determine that the risk factors other than HRT use are just as important to a monitoring scheme.[200]

In some situations, the plaintiffs may be able to establish that HRT users require a distinct monitoring scheme. Creative plaintiffs, along with their experts, may design an excruciatingly complex and thorough monitoring scheme that a doctor would not recommend for a patient without significant risk factors for a disease. The problem with this strategy comes with proving that such an elaborate monitoring scheme is reasonably necessary, as is required by the next element.

6. Monitoring Reasonably Necessary

The final element required to prove a medical monitoring claim is that the monitoring scheme is "reasonably necessary according to contemporary scientific principles."[201] Expert testimony is generally required to establish that a monitoring scheme is "reasonably necessary."[202] The *Albertson II* court emphasized the importance of this element when it stated, "The proposed monitoring program must be medically necessary, not simply medically ideal for virtually all women."[203] Like the *Albertson II* court, other courts may put the emphasis on whether the medical monitoring tests are "necessary" in order to weed out those plaintiffs who merely list a battery of tests.

Presumably, an analysis of whether a monitoring scheme is reasonably necessary will hinge, in part, on whether early diagnosis aids in treating symptoms or curing the disease.[204] For example, dementia is a disease for

196. *Albertson II*, No. 2944, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *26 (May 3, 2005).

197. *Id.* at *23-24.

198. *Id.* at *23-25.

199. *Id.* at *25.

200. *Id.* at *26.

201. Redland Soccer Club, Inc. v. Dep't of the Army, 696 A.2d 137, 146 (Pa. 1997).

202. *Id.*

203. *Albertson II*, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *42.

204. *See* Schwartz et al., *supra* note 90, at 351.

which HRT users may make a medical monitoring claim.[205] For some types of dementia, however, there is no cure.[206] Some commentators argue that monitoring schemes revealing the presence of a disease or disorder for which there is no cure only serve to antagonize the individual who has the disorder.[207] Therefore, the monitoring scheme would not be necessary.

The phrase "reasonably necessary" may also entail examining the costs of medical monitoring and the risks from the diagnostic testing itself.[208] For example, it is recommended that women over forty years of age obtain yearly mammograms.[209] With every mammogram, women are exposed to radiation, which has its own health risks.[210] Any increase in the frequency of mammograms also increases the exposure to radiation. Yet alternatives to mammography may be prohibitively expensive in relation to their benefit.[211] Since breast cancer is one of the concerns of HRT use,[212] the risks of increased diagnostic testing for breast cancer will need to be weighed against the benefit of such testing.

IV. CONSEQUENCES OF MEDICAL MONITORING AWARDS

Whether HRT plaintiffs are able to prove the elements necessary to establish a medical monitoring claim, there are policy ramifications courts should consider before awarding medical monitoring damages. While medical monitoring damages may have the most negative effect on the defendant, in this instance Wyeth, medical monitoring awards also may negatively impact current HRT plaintiffs, possible future plaintiffs, and society as a whole. These negative consequences may include the bankrupting of defendants before all possible plaintiffs have an opportunity to recover damages, and the possibility that courts will apply claim preclusion, preventing plaintiffs from filing suits if and when they develop actual diseases. The practical consequences of these negative effects are discussed in detail below.

A. Financial Hardship on Defendants

The harsh reality for plaintiffs is that defendants have limited resources. The world of asbestos litigation teaches that lesson. Seventy companies filed for bankruptcy as a result of asbestos litigation, causing other solvent asbestos companies to pay more than their share of medical monitoring awards to

205. *In re* Prempro, 230 F.R.D. 555, 560 (E.D. Ark. 2005).

206. STEDMAN'S MEDICAL DICTIONARY 492 (26th ed. 1995).

207. Schwartz et al., *supra* note 90, at 354.

208. *Id.* at 349.

209. *Albertson II*, No. 2944, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *27 (May 3, 2005); Woods & Mitchell, *supra* note 21, at 81.

210. Schwartz et al., *supra* note 90, at 356.

211. *Albertson II*, 2005 Phila. Ct. Com. Pl. LEXIS 604, at *23.

212. Rowan Chlebowski et al., *Influence of Estrogen Plus Progestin on Breast Cancer and Mammography in Healthy Postmenopausal Women*, 24 JAMA 3243, 3243 (2003).

uninjured plaintiffs.[213] Because many of these companies declared bankruptcy as a result of paying medical monitoring damages, few companies remain to pay damages to future plaintiffs who develop lung cancer from asbestos exposure.[214] Such an inability to pay will likely be a dire consequence in the HRT litigation as well.

One difference between asbestos litigation and the HRT lawsuits that have been filed is particularly foreboding. The asbestos litigation involved so many defendants that seventy could declare bankruptcy without dissolving the litigation.[215] In contrast, the single defendant in the HRT cases is Wyeth.[216] Wyeth manufactures both Prempro and Premarin, the key HRT drugs used by millions of women.[217] With one possible defendant, it is more likely that numerous medical monitoring awards could severely impair the financial ability of Wyeth to fully compensate plaintiffs who actually develop diseases.[218] Furthermore, there are no other defendants to help Wyeth pick up the slack if Wyeth is unable to pay for all medical monitoring damages.

If faced with having to pay large medical monitoring awards, one possible solution for Wyeth would be to file bankruptcy. Defendant companies may file bankruptcy either because they are financially insolvent, or because they seek to release themselves from the litigation.[219] This strategy was employed by breast implant manufacturer Dow Corning in the midst of mounting breast implant litigation.[220] Dow Corning initially faced a $4.255 billion settlement in the breast implant litigation, but settlement negotiations broke down when this amount became inadequate for the unexpected 440,000 women who stepped forward to participate in the litigation.[221] Dow Corning filed for Chapter 11 bankruptcy, obtained a release of further personal injury liability, and received an injunction against parties seeking to bring further litigation against them.[222] Although this action brought finality to the litigation, the action also barred future claims for injuries resulting from breast implant rupture.[223] While Dow

213. Schwartz et al., *supra* note 90, at 375-76.

214. *Id.* at 376.

215. *Id.* at 375-76.

216. Albertson v. Wyeth, Inc., 63 Pa. D. & C.4th 514 (C.P. Ct. 2003); Gottlieb v. Wyeth, 930 So. 2d 635 (Fla. Dist. Ct. App. 2006); In *re* Prempro, 230 F.R.D. 555 (E.D. Ark. 2005); Vitanza v. Wyeth, Inc., No. ATL-L-2093-04-MT, 2006 WL 462470 (N.J. Super. Ct. Jan. 24, 2006).

217. *Gottlieb*, 930 So. 2d at 637.

218. This possibility is made real by the fact that 5,000 cases have already been filed against Wyeth by HRT users. Pearson & Feeley, *supra* note 58. Some of these suits are for current actual diseases, and some are for medical monitoring for future diseases, but the number is significant nonetheless. *Id.*

219. *Id.* at 284.

220. Jason J. Jardine, *The Power of the Bankruptcy Court to Enjoin Creditor Claims Against Nondebtor Parties in Light of 11 U.S.C. 524(e):* In re Dow Corning Corp., 2004 BYU L. REV. 283.

221. *Id.* at 283, 299.

222. *Id.* at 284.

223. *Id.* at 283.

Corning faced only 440,000 women, Wyeth may face up to six million women who used HRT.[224]

B. Preclusion of Future Claims for Actual Disease

Another consequence of allowing medical monitoring claims is that such proceedings may impair future plaintiffs' recovery through claim preclusion. Claim preclusion is the barring of an action due to previous litigation.[225] Plaintiffs are precluded from bringing additional claims against the same defendant if a court issued a final judgment on the merits and if the claim could have been raised in the initial litigation.[226] Medical monitoring claims, which do not require present injury, would only provide compensation for a portion of the medical costs incurred by a plaintiff.[227] Claim preclusion, if applied to medical monitoring claims, would not allow those bringing a medical monitoring claim to sue again when and if actual injury occurs.[228] For example, if claim preclusion is enforced, a woman suing for payment of mammography through medical monitoring would not be able to sue again for medical costs if she later develops breast cancer.

Commentators have weighed in on both sides of the claim preclusion issue. With competing arguments, there is no clear policy to dictate whether courts would and should allow preclusion of future claims after a successful medical monitoring claim. From a legal standpoint, at least one court has taken an adamant stance that claim preclusion applied to injury claims subsequent to a medical monitoring claim.[229] Several policy considerations support the court's application of claim preclusion after a medical monitoring claim. First, commentators suggest that recovery for medical monitoring will further increase health costs.[230] Second, without claim preclusion, the plaintiffs could bring two lawsuits for the same incident resulting in extensive legal fees for both the defendant and the plaintiffs. Furthermore, allowing plaintiffs to recover twice for the same use of HRT does not comport with general legal principles of encouraging final judgments and conserving judicial resources.[231]

Conversely, other commentators assume that claim preclusion will not apply to medical monitoring actions. A federal court in Pennsylvania assumed claim preclusion would not apply when it certified a class of smokers and stated, "Theoretically, Pennsylvania law allows these class members to bring subsequent suits to recover for the actual injury of the disease . . . ."[232] This

224. Albertson v. Wyeth Inc., 63 Pa. D. & C.4th 514, 517 (C.P. Ct. 2003).

225. Wood v. Wyeth-Ayerst Labs., 82 S.W.3d 849, 858 (Ky. 2002) (citing City of Louisville v. Louisville Prof'l Firefighters Ass'n, 813 S.W.2d 804, 806 (Ky. 1991)).

226. McCall, *supra* note 86, at 979.

227. *Id.* at 970-71.

228. *See* Venugopal, *supra* note 58, at 1659.

229. *Wood*, 82 S.W.3d at 858.

230. McCall, *supra* note 86, at 974 n.19 (citations omitted).

231. *Wood*, 82 S.W.3d at 859; *see also* McCall, *supra* note 86, at 984-85.

232. Arch v. Amer. Tobacco Co., 175 F.R.D. 469, 470, 480 (E.D. Pa. 1997).

question of whether claim preclusion would bar a subsequent suit for actual injury still has not been answered by a court.[233] Proponents of allowing both a medical monitoring suit and an actual damages suit correctly state that plaintiffs would not actually receive double recovery because the recovery in the first case would be for diagnostic testing while the recovery in the second case would be for medical care and treatment of the actual disease.[234] Though it may be unfair to preclude recovery for either diagnostic testing or for treatment of disease, there is considerable concern that courts are prohibited from considering fairness when evaluating whether to preclude a subsequent claim.[235]

Commentators have also noted negative consequences resulting from applying claim preclusion. Precluding future claims after medical monitoring claims would discourage potential plaintiffs from suing until the injury actually manifests itself.[236] This may lead to a failure in deterring those who put others at risk.[237] The most compelling problem caused by claim preclusion involves class actions. Certain class certifications under specific federal rules prevent potential class members from opting out of the class.[238] Therefore, the medical monitoring damage award would subject all members of the class to the judgment whether they were parties to the action or not.[239] If claim preclusion applied to all class members, it would severely curtail recovery for those who did not even seek medical monitoring damages at all.[240]

The bottom line for plaintiffs is that until the court in which their lawsuit is filed has declared its standpoint on the matter, it is uncertain whether claim preclusion will apply to claims filed subsequently to a medical monitoring claim. While the injustice of barring a woman's recovery for actual injury is foreseeable, the reaction of the courts to the claim preclusion question is unforeseeable. Because of the possibility of claim preclusion and the possibility of the financial insolvency of Wyeth, there are strong policy reasons for courts to prohibit medical monitoring claims for HRT use.

V. CONCLUSION

Lawsuits based on increased health risks from the use of HRT have started.[241] Unfortunately, these suits are based primarily on one questionable study.[242] This study has its critics in the scientific community, because it

233. *See* Venugopal, *supra* note 58, at 1674.
234. McCall, *supra* note 86, at 987-88; *Wood*, 82 S.W.3d at 858.
235. McCall, *supra* note 86, at 980-81.
236. *Id.* at 970.
237. *Id.*
238. Boranian & Hara, *supra* note 90; Venugopal, *supra* note 58, at 1671.
239. Venugopal, *supra* note 58, at 1681.
240. Boranian & Hara, *supra* note 90.
241. *See, e.g.*, Albertson v. Wyeth Inc., 63 Pa. D. & C.4th 514 (C.P. Ct. 2003).
242. *Id.* at 514; In *re* Prempro, 230 F.R.D. 555, 556 (E.D. Ark. 2005).

contradicted prior studies of HRT use.[243] Nevertheless, plaintiffs' attorneys have forged ahead to seek medical monitoring damage awards.

Thus far, courts considering some legal elements of medical monitoring have seen the plaintiffs' evidence fall short. The impending tragedy will result if thousands or even millions of postmenopausal women waste valuable time in the courts awaiting medical monitoring damages that never come. For these women, time and money may be better spent obtaining advice about preventive medicine and reducing exposure to other risk factors for disease.

A great concern for the menopausal women of America should be whether the plaintiffs' attorneys have really considered the consequences of a deluge of pre-injury litigation. If the WHI study is right, then there will be increased incidence of heart disease, breast cancer, stroke, and dementia in those women who took HRT. It would be a great tragedy to leave these injured women with a precluded claim and a bankrupt piggy bank from which to squeeze recovery. With this in mind, suits for medical monitoring for HRT use may not only be unworkable but also unwise.

243. Harman et al., *supra* note 7, at 44-45; *see generally* NAFTOLIN ET AL., *supra* note 4.