

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

GERALDYNE FRAMBS
2250 Tulip Way
Sacramento, California 95821

Plaintiff

vs.

WYETH a/k/a WYETH, INC. (f/k/a
American Home Products Corporation),
WYETH PHARMACEUTICALS a/k/a
WYETH PHARMACEUTICALS, INC.
(f/k/a WYETH-AYERST
PHARMACEUTICALS, INC.) a
division of WYETH, PFIZER, INC.,
PHARMACIA & UPJOHN COMPANY,
LLC, PHARMACIA CORPORATION,
PHARMACIA & UPJOHN, LLC,
GREENSTONE LTD., BARR
LABORATORIES, INC., BARR
PHARMACEUTICALS, INC., and ESI
LEDERLE, INC.,

Defendants.

CASE NO.:

COMPLAINT
AND JURY DEMAND

For her Complaint for personal injury caused by Defendants’ prescription hormone replacement therapy (hereafter “HRT” or “HT”), Plaintiff alleges and avers as follows:

I. PARTIES, JURISDICTION AND VENUE

1. Plaintiff is a resident and citizen of the State of California, and resides in the County of Sacramento. Pursuant to Minn. Stat. section 303.02(6) (1990), Plaintiff who is a non-resident of Minnesota is able to bring action in this Court against foreign corporation Defendants WYETH a/k/a WYETH, INC. (f/k/a American Home Products Corporation), WYETH

PHARMACEUTICALS a/k/a WYETH PHARMACEUTICALS, INC. (f/k/a WYETH-AYERST PHARMACEUTICALS, INC.) a division of WYETH, PFIZER, INC., PHARMACIA & UPJOHN COMPANY, LLC, PHARMACIA CORPORATION, PHARMACIA & UPJOHN, LLC, GREENSTONE LTD., BARR LABORATORIES, INC., BARR PHARMACEUTICALS, INC., and ESI LEDERLE, INC. This Court has jurisdiction over this case under section 303.02(6), because Defendants conducted business in the State of Minnesota through pharmaceutical sales representatives conducting business in the State of Minnesota on behalf of Defendants, thus there exists a sufficient nexus between the Defendants' forum contacts and the Plaintiff's cause of action to justify assertion of jurisdiction in Minnesota. Beginning in approximately 1985, and continuing through approximately July 2003, Plaintiff underwent hormone replacement therapy, and was prescribed and ingested the pharmaceutical drugs Premarin, Cycrin, and Provera and/or Medroxyprogesterone Acetate ("MPA") which are manufactured, marketed and sold by Defendants. On or about August 2003, Plaintiff was diagnosed with breast cancer, and later underwent surgery consisting of a lumpectomy. The cancer and subsequent surgery, treatment, injury and damage to Plaintiff were caused by her use of the aforementioned drugs.

2. The Defendant, Wyeth a/k/a Wyeth, Inc. (f/k/a American Home Products Corporation and hereafter referred to as "Wyeth"), is a Delaware corporation headquartered and with its principal place of business in New Jersey. At all times material hereto, Wyeth was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy drugs, including Premarin, Prempro, Premphase, Cycrin and MPA.

3. Defendant, Wyeth Pharmaceuticals a/k/a Wyeth Pharmaceuticals, Inc. (f/k/a Wyeth-Ayerst Pharmaceuticals, Inc. and hereafter referred to as “Wyeth Pharmaceuticals”), is a subsidiary or division of Wyeth, and is a Delaware corporation headquartered and with its principal place of business in Pennsylvania. At all times material hereto, Wyeth Pharmaceuticals was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy drugs, including Premarin, Prempro, Premphase, Cycrin and MPA.

4. Defendant, Pfizer, Inc., is a Delaware corporation headquartered and with its principal place of business in New York. At all times relevant hereto, Pfizer Inc. was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy drugs, including Provera and/or MPA.

5. Defendant, Pharmacia & Upjohn Company, LLC, is a limited liability company whose sole member is Pharmacia & Upjohn, LLC, which is a limited liability company whose sole member is Pharmacia Corporation, which is a subsidiary of Pfizer, Inc. Pharmacia & Upjohn Company, LLC is a Delaware company with its principal place of business in New York. At all times relevant hereto, Pharmacia & Upjohn Company, LLC was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy drugs, including Provera and/or MPA.

6. Defendant, Pharmacia Corporation, is a wholly owned subsidiary of Pfizer, Inc.,

and is the sole member of the limited liability company Pharmacia & Upjohn, LLC, which is the sole member of the limited liability company Pharmacia & Upjohn Company, LLC. Pharmacia Corporation is Delaware corporation with its principal place of business in the state of New Jersey. At all times relevant hereto, Pharmacia Corporation was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy drugs, including Provera and/or MPA.

7. Defendant Pharmacia & Upjohn, LLC is a Delaware limited liability company whose sole member is Pharmacia Corporation, which is a subsidiary of Pfizer Inc. Pharmacia & Upjohn LLC is the sole member of the limited liability company Pharmacia & Upjohn Company LLC. Pharmacia & Upjohn LLC, at all relevant times, was licensed to do business in all states of the United States of America. At all relevant times, this Defendant was engaged in the design, manufacture, production, testing, inspection, mixture, labeling, marketing, advertising, sales, promotion and/or distribution of hormone therapy drugs including the drugs Provera, generic estrogen (including but not limited to FemHrt and Vagifem), and generic medroxyprogesterone acetate (MPA) and combination products (including Activella) for ultimate sale and/or use in the United States of America.

8. Defendant, Greenstone, Ltd., is a Delaware corporation headquartered and with its principal place of business in New Jersey. At all times material hereto, Greenstone, Ltd. was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy drugs, including Provera and/or MPA.

9. Defendant, Barr Laboratories, Inc., is a New York corporation headquartered and with its principal place of business in New Jersey. At all times relevant hereto, Barr Laboratories, Inc., was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy drugs, including Provera and/or MPA.

10. Defendant, Barr Pharmaceuticals, Inc., is a Delaware corporation headquartered and with its principal place of business in New Jersey. At all times relevant hereto, Barr Pharmaceuticals, Inc., was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy drugs, including Provera and/or MPA.

11. Defendant, ESI Lederle, Inc. is a subsidiary or division of Wyeth, and is a Delaware corporation headquartered and with its principal place of business in Madison, New Jersey and Collegeville, PA.. At all times material hereto, ESI Lederle, Inc. was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting, and/or selling, either directly or indirectly, through third parties or related entities, hormone therapy drugs, including MPA and Cycrin.

12. At all times relevant hereto, Defendants were in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising the pharmaceutical products Premarin, Cycrin, and Provera and/or MPA. Plaintiff alleges that Defendants transact business in the State of Minnesota and, at all times relevant herein, researched, designed, formulated, compounded, tested, manufactured, produced,

processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, and/or advertised the pharmaceutical products Premarin, Cycrin, and Provera and/or MPA in interstate commerce and in the State of Minnesota.

13. This action is venued in this District under favor of 28 U.S.C. 1391.

14. The amount in controversy exceeds seventy-five thousand dollars (\$75,000.00) exclusive of costs and interest, and diversity jurisdiction exists under 28 U.S.C §1332.

II. FACTUAL BACKGROUND

A. The Marketing of Hormone Therapy

15. Menopause is the cessation of menstruation caused by declining levels of estrogen and progesterone. It is a natural human phenomenon-- a phase of the female reproductive aging process-- and is not a disease. Symptoms, which vary in severity from woman to woman, may include hot flashes, chills, vaginal dryness, headache and irritability. Adverse consequences of the drop in estrogen levels which begin with menopause and continue after menopause include, *inter alia*, vaginal atrophy and dryness; an increase in LDL cholesterol levels; and, a decrease in bone density with resultant increased risk of osteoporosis.

16. These symptoms and consequences of menopause have been described in scientific literature since the late 1800s, and by the turn of the 20th century the search for an aid to alleviate them was widely pursued.

17. In 1942, Ayerst, the predecessor to Wyeth, received patent and FDA approval for Premarin, a mix of estrogens extracted from the urine of pregnant mares. Premarin was marketed to women and their physicians as the long sought after replacement for lost estrogen in menopausal women, and was referred to as "Replacement" estrogen therapy.

18. The FDA originally approved Premarin only to relieve menopausal symptoms, such as hot flashes and vaginal atrophy. Wyeth, however, has long touted additional benefits for Premarin, and its subsequently marketed hormone therapy drugs, Prempro, Premphase and medroxyprogesterone acetate.

19. In the 1960's, Wyeth's Premarin promotional materials utilized articles and books written Dr. Robert Wilson, a Brooklyn, New York, gynecologist, who recommended uses of Premarin far beyond those approved by the FDA. In a 1962 article, which appeared in the *Journal of the American Medical Association (JAMA)*, Dr. Wilson claimed taking estrogen during menopause *reduced* breast and genital cancers. In his 1966 bestselling book entitled *Feminine Forever*-- which Wyeth's sales forces distributed to physicians throughout the country-- Dr. Wilson wrote that "aside from keeping a woman sexually attractive and potent . . . estrogen preserves the strength of her bones, the glow of her skin, the gloss of her hair . . . Estrogen makes women adaptable, even-tempered, and generally easy to live with." In the book, Dr. Wilson again asserted that estrogen prevented cancers.

20. Following Dr. Wilson's publications, sales of Premarin quadrupled. Wyeth poured thousands of dollars into Dr. Wilson's research. By the mid-70s, more than 30 million prescriptions for Premarin were being written every year, eventually making it the fifth most frequently prescribed drug in the United States.

21. Physicians were instructed in advertisements to prescribe Premarin to achieve "tranquilizing" effects for their female patients-- as if that effect was a laudable goal: "Almost any tranquilizer might calm her down . . . but at her age, estrogen may be what she really needs."

22. The promotional advertising downplayed the risks of hormone therapy and over

promoted the benefits. A 1970's article in *Harper's Bazaar* claimed: "There doesn't seem to be a sexy thing estrogen can't and won't do to keep you flirtatiously feminine for the rest of your days . . . a real package deal that spruces up your vagina . . . Prevalent medical opinion is that the safety and benefits of ERT have been convincingly demonstrated."

23. But the "safety and benefits" of Premarin were cast in serious doubt following the 1976 publication in the *New England Journal of Medicine* of a study evidencing a causal relationship between estrogen and endometrial cancer. Sales plummeted, and physicians stopped prescribing Premarin except to those women who had hysterectomies and thus were not at risk for endometrial cancer.

24. A 1980 medical article suggested a solution. Dr. Don Gambrell reported in the journal *Obstetrics and Gynecology* that adding progestin to estrogen led to a *decline* in endometrial cancer. Wyeth thus produced and marketed progestin (i.e., synthetic progesterone or medroxyprogesterone acetate) as an adjunct to Premarin estrogen hormone therapy to protect against the risk of endometrial cancer.

25. Wyeth does now and has manufactured, marketed, and distributed medroxyprogesterone acetate for use in combination with Premarin under trademarked brand names such as Provera and Cycrin and as generic equivalents. And, Prempro and Premphase have the added synthetic progesterone.

26. Additional claims were made in the 1980's when Wyeth promoted hormone therapy to help prevent bone loss, and when Wyeth claimed that hormone therapy drugs could prevent cardiovascular disease. By claiming that hormone therapy drugs prevented osteoporosis and cardiovascular disease, Wyeth was able to promote Premarin as recommended treatment for

all women, whether or not they were experiencing menopause. As a result, between 1990 and 1995 Premarin became the most frequently dispensed prescription drug in the United States.

27. Premarin's huge success was bolstered by claims that indefinite, long term use of estrogen therapy was safe and efficacious. In an early 1990's promotional videotape distributed directly to consumers entitled "What every woman should know about estrogen," Wyeth represented to women that estrogen provided "long term health protection" and should be continued indefinitely, even after short-term menopausal symptoms, such as hot flashes, had subsided. When a purported consumer inquired how long Premarin should be taken, Wyeth's doctor-spokesperson responded "anywhere from five to ten years in order to get protection from long term problems." And, with regard to breast cancer risks, Wyeth represented to women that the benefits of taking estrogen "far outweigh[ed]" the risks for women unless they faced a particularly high risk of breast cancer.

28. Prior to 1995, Wyeth began to develop a combination therapy pill that would combine Premarin with progestin. This product development was necessary since Wyeth was faced with the threat of a shrinking market for Premarin at the end of its patent protection in 1995.

29. In 1995 Wyeth introduced Prempro and Premphase, "combination" hormone therapies that contained estrogen and medroxyprogesterone acetate (synthetic progestin).

30. Physicians and females were led by Wyeth to believe the promotional claims it made regarding Premarin. When Prempro and Premphase were introduced to the market by Wyeth, physicians and women were led to believe that the same claims existed for these hormone therapies as Wyeth had claimed about Premarin.

31. Wyeth over-promoted Prempro and Premphase just as it did Premarin. For example, Wyeth distributed a brochure that asked women to “Take a few minutes to think about the rest of your life,” and then listed medical conditions to “think about,” which neither Prempro nor Premarin had been approved by the FDA to treat, including Alzheimer’s disease, vision problems, tooth loss, heart disease, and colon cancer.

32. In a magazine advertisement featuring model Lauren Hutton, Wyeth made a rash of similar claims, suggesting that its hormone therapy drugs were appropriate for treating or preventing, among other things, memory loss, colon cancer, and age-related vision loss. In the March 19, 2000, edition of *Parade Magazine*, Wyeth spokesperson Lauren Hutton (who was not identified as a Wyeth spokesperson) was asked what she did to look good and feel fit, and she answered: “[M]y number one secret is estrogen. It’s good for your moods; it’s good for your skin. If I had to choose between all my creams and makeup for feeling and looking good, I’d take the estrogen.

33. Wyeth’s DTC (i.e., “direct-to-consumer” or “DTC” marketing) efforts have included overt advertising pieces, such as print advertisements, videotapes, and brochures directed to consumers, as well as “product placement” efforts in which hormone therapy drugs are favorably positioned in entertainment vehicles or favorably described in the popular press by hired spokespersons.

34. Wyeth has vigorously promoted hormone therapy to physicians, as well as to consumers directly. In 1999, Wyeth spent \$34.7 million on DTC advertising for Prempro. In 2000, Wyeth spent \$37.4 million on Prempro DTC advertising. The thrust of Wyeth’s marketing efforts has been to create a lifelong consumer demand for hormone therapy, and a belief by

physicians that the prescription is beneficial to menopausal and post-menopausal patients.

B. The WHI and NCI Studies

35. Wyeth's promotion of hormone therapy for long-term use proved false and misleading when studies released in July 2002 showed that such use substantially increases the risk of *causing* disease.

36. Two large cohort studies concluded that the risks of hormone therapy outweighed the benefits for most women: The WHI study, reported at Roussow JE, et al., *Risks and Benefits of Estrogen Plus Progestin in Healthy Post-menopausal Women*. (JAMA. 2002 Jul 17; 288:321-33.); and, the NCI study, reported at Lacey JV Jr., et al., *Menopausal hormone replacement therapy and risk of ovarian cancer*. (JAMA. 2002 Jul 17; 288(3):334-41.)

37. The Women's Health Initiative (WHI) is a group focused on defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in post-menopausal women. Between 1993 and 1998, the WHI enrolled 161,809 post-menopausal women in the age range of 50 to 79 years into a set of clinical trials and an observational study at 40 clinical centers in the United States. Included within the clinical trials was a study by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

38. Participants in the NHLBI component of WHI, like most women with a uterus who take hormone therapy, were given progestin in combination with estrogen (i.e., combination hormone therapy). The estrogen plus progestin trial of the WHI involved 16,608 women ages 50 to 79 years with an intact uterus. An important objective of the trial was to examine the effect of estrogen plus progestin on the prevention of heart disease and hip fractures, and any associated

change in risk for breast and colon cancer. The study did not immediately address the short-term risks and benefits of hormones for the treatment of menopausal symptoms.

39. Women enrolled in the estrogen plus progestin study were randomly assigned to a daily dose of estrogen plus progestin (0.625 mg of conjugated equine estrogens plus 2.5 mg of medroxyprogesterone acetate) or to a placebo. Those participants receiving the drug (not placebo) received Wyeth's drug Prempro. Participants were enrolled in the study between 1993 and 1998 at over 40 clinical sites across the country.

40. In 2000 and again in 2001, WHI investigators complied with a recommendation from the study's Data and Safety Monitoring Board (DSMB) to inform participants of a small increase in heart attacks, strokes, and blood clots in women taking hormones. The DSMB, an independent advisory committee charged with reviewing results and ensuring participant safety, found that the actual number of women having any one of these events was small and did not cross the statistical boundary established to ensure participant safety. Therefore, the group recommended continuing the trial due to the still uncertain balance of risks and benefits.

41. At the DSMB's meeting on May 31, 2002, the data review revealed for the first time that the number of cases of invasive breast cancer in the estrogen plus progestin group had crossed the boundary established as a signal of increased risk. The DSMB's May 31, 2002, recommendation to stop the trial was based on the finding of increased breast cancer risk, supported by the evidence of overall health risks exceeding any benefits. On July 8, 2002 participants started receiving letters informing them about the results and telling them that they should stop study medications.

42. The WHI Study found that for the estrogen plus progestin group (i.e., those

women who took Prempro) compared to placebo, overall there was a:

- i. 41 percent increase in strokes,
- ii. 29 percent increase in heart attacks,
- iii. a doubling of rates of venous thromboembolism (blood clots),
- iv. 22 percent increase in total cardiovascular disease,
- v. 26 percent increase in breast cancer,
- vi. a 37 percent reduction in cases of colorectal cancer, and
- vii. a one-third reduction in hip fracture rates.

43. The WHI Study concluded that the “Overall health risks exceeded benefits from use of combined estrogen plus progestin for an average 5.2-year follow-up among healthy postmenopausal US women.” The Study also found that the combination hormone regimen should not be initiated or continued for primary prevention of coronary heart disease.

44. Because of the importance of the report from the WHI investigators on the estrogen plus progestin study, the study was released early to the public on July 9, 2002, as an expedited article on the *JAMA* Web site. In commenting on the studies findings, NHLBI Director, Dr. Claude Lenfant, was unequivocal in his own conclusions:

The cardiovascular and cancer risks of estrogen plus progestin outweigh any benefits—and a 26 percent increase in breast cancer risk is too high a price to pay, even if there were a heart benefit. Similarly, the risks outweigh the benefits of fewer hip fractures.

45. Dr. Jacques Roussow, acting director of the WHI and lead author of the *JAMA* article, summarized the risks of combination hormone therapy in a very straightforward manner as he explained the statistical significance of the study results:

The WHI results tell us that during 1 year, among 10,000 post-menopausal women with a uterus who are taking estrogen plus progestin, ***8 more will have invasive breast cancer, 7 more will have a heart attack, 8 more will have a stroke, and 18 more will have blood clots, including 8 with blood clots in the lungs***, than will a similar group of 10,000 women not taking these hormones. This is a relatively small annual increase in risk for an individual woman. Individual women who have participated in the trial and women in the population who have been on estrogen and progestin should not be unduly alarmed. However, even small individual risks over time, and on a population-wide basis, add up to ***tens of thousands of these serious adverse health events***. (Emphasis added.)

46. Within a week after the WHI results were reported, another article appeared in JAMA related to the risk of long-term use of estrogen-only therapy. On July 17, 2002, JAMA published a NCI study, which found that women who took estrogen were more likely to develop ovarian cancer than those not on the hormone.

47. In the study, researchers from the NCI followed 44,241 women for 19 years who were taking estrogen only and found that these women had a 60% higher risk of ovarian cancer than women who had never used estrogen. The risk increased proportionately with longer duration of estrogen use. Women who took estrogen for 10 to 19 years had an 80% higher risk than those who did not take the pills. Those on the hormone therapy for 20 years or more were three times as likely to develop ovarian cancer as women who did not take it at all. Most of the NCI participants used Wyeth's brand of estrogen therapy, Premarin.

48. Lead author of the NCI study, James V. Lacey, summarized the results of his study with the following statement:

The main finding of our study was that post-menopausal women who used estrogen replacement therapy for 10 or more years were at significantly higher risk of developing ovarian cancer than women who never used hormone replacement therapy.

49. Dr. Lacey further underscored the implications of his NCI study, by explaining

that the findings translate into one or two additional ovarian cancers each year per 10,000 women taking estrogen alone. In 2000, eight million American women took Premarin, the leading estrogen therapy pill. The Lacey study demonstrates that Premarin usage is responsible for up to 1,600 additional ovarian cancer cases in the year 2000 alone.

50. In October 2003, the WHI study produced a report with findings similar to the NCI study regarding ovarian cancer. The October 1, 2003, issue of JAMA reported that combination hormone therapy was also associated with increased risk for ovarian cancer: the WHI investigators found that women randomized to received combined hormone therapy (i.e., estrogen plus progestin) experienced a 58% increase in ovarian cancer rates.

C. The Aftermath of the WHI and NCI Studies

51. The WHI and NCI studies received enormous media coverage: front-page newspaper headlines, magazine covers, and broadcast news programs urgently reported the alarming and significant findings.

52. Commenting on the WHI study, Dr. Leslie Ford, associate director for clinical research at the NCI's Division of Cancer Prevention, re-emphasized the risk of hormone therapy to patients:

The reduction in colorectal cancer risk in the WHI is intriguing, but the balance of harm versus benefit does not justify any woman beginning or continuing to take estrogen plus progestin for this purpose.

53. Dr. Isaac Schiff of Massachusetts General Hospital also commented on the WHI study, noting, "Quality of life is very, very important From a heart and breast cancer point of view, the drug should be outlawed. But for hot flashes, there's nothing better."

54. The WHI and NCI study conclusions regarding the unsafe and dangerous adverse

effects of hormone therapy have been verified by subsequent published research. A study on hormone therapy and breast carcinoma risk in Hispanic and non-Hispanic women, reported on September 1, 2002, in the journal *Cancer*, found that that Hispanic post-menopausal women have significantly increased breast cancer risk after long-term hormone therapy.

55. On October 23, 2002, the United Kingdom's Medical Research Council announced that it had ended a clinical study of the risks and benefits of long-term use of hormone therapy for "scientific and practical reasons." 5,700 women were enrolled in the "WISDOM" study (the Women's International Study of Long Duration Estrogen after Menopause). The study was to include 22,000 women. However, following the WHI study, the WISDOM study was canceled. The Medical Research Council concluded "There is strong evidence that taking hormone therapy long term increases the risks of some diseases such as breast cancer and decreases the risks of others such as osteoporosis."

56. Because of the significance of its findings, on March 17, 2003, the *New England Journal of Medicine* (NEJM) released a follow-up WHI study two-months in advance of its May 8th publication date. The follow-up study reported that hormone therapy failed to improve the quality of life for menopausal women.

57. The Quality of Life study which examined the same pool of 16,000 women as the July 9, 2002, WHI study, found that hormone therapy drugs do not do the very thing many women took them for in the first place— that is, to make them feel happier and healthier after menopause. A comparison of women who took hormone therapy to women given a placebo showed those women taking hormones did not report sleeping better or feeling better. The hormone therapy group also did not report less depression or more sexual satisfaction than the

placebo group.

58. According to the study's lead author, Dr. Jennifer Hays: "It's just not something that's going to make most women feel better. Even if it reduces your symptoms, that's not going to translate into a meaningful effect on a quality of life." Dr. Deborah Grady of the University of California, San Francisco, in an accompanying commentary in the same issue of the NEJM said that: "There is no role for hormone therapy in the treatment of women without menopausal symptoms" and that only women who were experiencing debilitating menopausal symptoms should take hormone therapy. She stated that those women who do continue with hormone therapy should take the lowest possible dose for the shortest possible time.

59. On May 21, 2003, JAMA published another study studying the efficacy of estrogen plus progestin therapy (e.g., Prempro) for prevention of bone loss in elderly women. The study involved 373 women ages 65 to 90 who had either thinning bones or full-blown osteoporosis and took one of four treatments for three years: (i) combination hormone therapy alone, (ii) a bone-building drug, alendronate (which is sold under the brand name, Fosamax), (iii) combination hormone therapy with Fosamax, or (iv) a placebo.

60. While the study found that the combination of hormone therapy and Fosamax was effective at treatment and prevention of post-menopausal osteoporosis, it also concluded that Fosamax alone was more effective than combination hormone therapy alone. After three years, hip bone density had increased nearly 6 percent in women on hormone therapy with Fosamax, 4 percent in those on Fosamax alone, and 3 percent in the hormones-only group.

61. Dr. Jennifer Hays, a WHI researcher and lead author of the May 8, 2003, JAMA study on hormone therapy and quality of life, said that the findings of the bone-loss study are not

convincing enough to recommend hormone therapy for osteoporosis prevention even in older women, especially because the study showed that the bone-enhancing benefits from estrogen come only after long-term use which also carries the highest risk of breast cancer or heart disease.

62. On May 28, 2003, JAMA published yet another study on the effects of hormone therapy, this time focusing on the risk of Alzheimer's disease and other types of dementia. The study found that combination hormone therapy, consisting of both estrogen and progestin, doubled the risk of dementia for woman who started hormones at age 65 or older.

63. The dementia study was based on a four-year experiment involving 4,532 women at 39 medical centers, where half took placebos and half took Prempro. In four years, there were 40 cases of dementia in the Prempro group and 21 in the placebo group. Translated to an annual rate for the population-at-large, the results mean that for every 10,000 women 65 and older taking hormone therapy, there will be 45 cases of dementia a year with 23 of them attributable to hormone use.

64. Dr. Sally A. Shumaker, the director of the dementia study and a professor of public health sciences at Wake Forest University, stated that the study's "clear message is that there's no reason for older women to be taking combination hormone therapy."

65. On June 25, 2003, JAMA published still another study analyzing the data from the Women's Health Initiative, which found that in addition to stimulating the growth of breast cancer, combination hormone therapy makes breast tumors harder to detect, leading to dangerous delays in diagnosis. The report found that breast abnormalities could develop soon after a woman starts taking hormone therapy. Consequently, the study's findings raise questions about

the safety of even short-term hormone use. In the same June 25, 2003, issue that reported this study, JAMA also published an editorial by Dr. Peter H. Gann, a cancer epidemiologist at Northwestern University, who stated that this study represents “further compelling evidence against the use of combination estrogen plus progestin hormone therapy.”

66. The connection between hormone therapy usage and breast cancer found in the WHI studies were confirmed by a similar study conducted in the United Kingdom. The August 9, 2003, issue of *Lancet* reported on the conclusions reached by *The Million Women Study* — a major research effort funded by Cancer Research UK — confirming that current and recent use of hormone therapy increases a woman’s chance of developing breast cancer, and that the risk increases with duration of use. Scientists at the Cancer Research UK analyzed data from over one million women between the ages of 50 and 64. Researchers found that post-menopausal women using combination hormone therapy were twice as likely to develop breast cancer as non-users (a 100 per cent increase).

67. In the August 7, 2003, issue of *NEJM*, the WHI study continued to yield important information regarding the safety of hormone therapy use. The study found that combination hormone therapy does not protect the heart and may even increase the risk of coronary heart disease (CHD). Specifically, the WHI study found that combination hormone therapy usage was associated with a 24% overall increase in the risk of CHD (6 more heart attacks annually per 10,000 women using combination therapy) and a 81% increased risk of CHD in the first year after starting combination therapy.

68. In addition to the studies published in *JAMA*, *NEJM*, and other medical journals, a recent federal agency report also revealed that estrogen could be dangerous to women taking it as

hormone therapy. On December 11, 2002, the National Institute of Environmental Health Sciences released its tenth annual report on carcinogens, which declared for the first time that estrogen is now on the federal government's list of "known human carcinogens."

D. Wyeth Changes Hormone Labels and Reverses Long-Term Marketing Strategy

69. In light of the WHI and NCI studies and other subsequent research reports, the labels provided by Wyeth for its Premarin and Prempro drugs were inadequate, misleading, and inaccurate. In fact, Wyeth changed warning labels on Premarin and Prempro during the last week of August 2002 to reflect the results of the July 2002 WHI and NCI studies.

70. Prior to the label change in August 2002, the Premarin warning label made no mention whatsoever of ovarian cancer.

71. The Prempro label warnings were likewise inadequate prior to August 2002. As to breast cancer, the Prempro warning explains the risk of breast cancer with conjugated estrogens (the Premarin component of Prempro), but then adds, with regard to the effect of added progestins on the risk of breast cancer: "The overall incidence of breast cancer does not exceed that expected in the general population." The WHI study plainly reveals that this warning is false and was known or should have been known by Wyeth to be false for decades.

72. The Prempro warnings were also inadequate for two thromboembolic disorders, pulmonary embolisms and blood clots: "The increased risk [of venous thromboembolism] was found only in current ERT [i.e., Premarin only] users." Furthermore, as to cardiovascular disease (heart attacks and strokes), the Prempro warning reads simply "Embolic cerebrovascular events and myocardial infarctions have been reported," without disclosing the true nature of the risk.

73. Under precautions, the Prempro label acknowledges: “The effects of estrogen replacement therapy on the risk of cardiovascular disease have not been adequately studied.” Nevertheless, Wyeth has long promoted the supposed benefits of long term hormone therapy for cardiovascular disease.

74. On January 6, 2003, Wyeth abandoned its long-standing marketing strategy of promoting the long-term use of Premarin and Prempro. Wyeth announced the reversal of its long-held promotional message in a “Dear Doctor” letter to Health Care Professionals that explained it was adopting new labeling for its hormone therapy drugs in light of the WHI findings.

75. According to the January 6, 2003, “Dear Doctor” letter, the labeling changes include boxed warnings:

[W]hich state that estrogens and estrogens plus progestin therapies should not be used for prevention of cardiovascular disease . . . The boxed warning also includes information [stating that because of the WHI study] . . . estrogens and estrogens plus progestin ***should be prescribed for the shortest duration consistent with treatment goals.*** (Emphasis added.)

76. In early June 2003, Wyeth commenced a new public marketing campaign with a full-page advertisement placed in 180 newspapers nationwide. The advertisement, styled “A Message from Wyeth,” disclosed that Wyeth was abandoning its decades long strategy of promoting long-term usage of Premarin and Prempro for post-menopausal women for a variety of conditions.

Hormone therapy is not a lifelong commitment. [¶] As a result of recent studies, we know that hormone therapy should not be used to prevent heart disease. These studies also report an increased risk of heart attack, stroke, breast cancer, blood clots, and dementia. Therefore, it is recommended that hormone therapy (estrogen, either alone or with progestin) ***should be taken for the***

shortest duration at the lowest effective dose.

(*Philadelphia Inquirer*, June 1, 2003, at C6; emphasis added).

77. Wyeth had recklessly and willfully failed to conduct adequate pre-approval research and post-approval surveillance to establish the safety of long-term hormone therapy. Nonetheless, Wyeth had vigorously promoted long term hormone therapy use. The studies, which the WHI and NCI conducted, could have and should have been conducted many years ago by Wyeth-- and before embarking on its long-term usage marketing campaign. Had it conducted the necessary studies and diligent post-marketing surveillance, Wyeth would have learned years ago that hormone therapy causes cardiovascular diseases, is marginally effective in preventing bone loss, does not promote well being, causes a number of cancers and dementia, and is even harmful on a short-term basis by increasing the risk of breast cancer.

III. FRAUDULENT CONCEALMENT

78. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by Defendants. Plaintiff has been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on her part.

79. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of their hormone therapy drugs to Plaintiff. Because of its concealment of the true character, quality and nature of their hormone therapy drugs, Defendants are estopped from relying on any statute of limitations defense.

CAUSES OF ACTION

COUNT ONE

NEGLIGENCE

80. Plaintiff incorporates by reference herein all paragraphs and allegations of this Complaint as though fully set forth herein:

81. Defendants had a duty to exercise reasonable care in the manufacture, sale and/or distribution of the hormone therapy drugs into the stream of commerce, including a duty to assure that their products did not cause users to suffer from foreseeable unreasonably dangerous side effects and serious health problems.

82. Defendants failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of the hormone therapy drugs into interstate commerce in that Defendants knew or should have known that the hormone therapy drugs created a foreseeable high risk of unreasonable, dangerous side effects and health hazards such as an increased risk of cardiovascular disease as well as the risk of invasive breast cancer, pulmonary embolism, blood clots, stroke, and heart attack.

83. Defendants were negligent in the design, manufacture, testing, advertising, warning, marketing and sale of the hormone therapy drugs in that they:

- a. Failed to use due care in designing and manufacturing the hormone therapy drugs so as to avoid the aforementioned risks to individuals when the hormone therapy drugs were being used;
- b. Failed to accompany the hormone therapy drugs with proper warnings regarding all possible adverse side effects and health risks associated with the use of the hormone therapy drugs and the comparative severity and duration of such adverse effects;

- c. Failed to give warnings accurately reflecting the symptoms, scope or severity of the side effects and health risks;
- d. Failed to conduct adequate pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the hormone therapy drugs;
- e. Failed to provide adequate training or information to medical care providers for the appropriate use of the hormone therapy drugs;
- f. Failed to adequately warn consumers and medical prescribers (but instead actively encouraged the sale of the hormone therapy drugs) about the following:
 - i. The need for comprehensive, regular medical monitoring to ensure early discovery of adverse events,
 - ii. The possibility of death and/or having to undergo surgery,
 - iii. That such surgery may cause extraordinary suffering and/or death, and
 - iv. That the health risks posed by the hormone therapy drugs may become debilitating, difficult, and painful, necessitating lengthy surgery and/or repeated visits to the doctor, clinic or hospital.
- g. Failed to adequately test and/or warn about the use of the hormone therapy drugs, including, without limitation, the possible adverse side effects and health risks caused by the use of the hormone therapy drugs;
- h. Failed to adequately warn users, consumers and physicians about the severity, scope and likelihood of adverse events and related dangerous conditions to individuals taking the hormone therapy drugs;
- i. Represented to physicians, including, but not limited to, Plaintiff's prescribing physicians, that the drugs were safe and effective for use and for use longer than one year;

- j. Failed to adequately, timely, and promptly relay information to the prescribing physicians or ultimate users of the serious health effects of the hormone therapy drugs, once Defendants were made aware of same through Adverse Drug Experience reports; and
- k. Were otherwise careless or negligent.

84. Despite the fact that Defendants knew or should have known that the hormone therapy drugs caused unreasonable, dangerous side effects and posed potentially fatal health risks which many users would be unable to remedy by any means, Defendants continued to market the hormone therapy drugs to prescribing physicians and consumers, including Plaintiff, when there were safer alternative methods of treatment available for their conditions.

85. Defendants knew or should have known that consumers such as the Plaintiff would suffer serious injury as a result of Defendants' failure to exercise ordinary care as described.

86. Likewise, Defendants were negligent and acted intentionally or with malice in ever seeking approval for the sale of the hormone therapy drugs given Defendants' knowledge of the dangers associated with the hormone therapy drugs.

87. Further, because of the breach of duty and negligent conduct of Defendants in the manner set forth above, the Plaintiff has sustained general and special damages. The acts and omissions of Defendants, in the manner described above, were the direct and proximate cause of Plaintiff's damages. Therefore, Plaintiff has a cause of action in negligence against Defendants in an amount substantially in excess of Seventy Five Thousand Dollars (\$75,000.00).

COUNT TWO

STRICT LIABILITY

88. Plaintiff incorporates by reference herein all paragraphs and allegations of this Complaint as though fully set forth herein:

89. The drug products previously described were defective at the time of their manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that, and not by way of limitation, said products and their warnings, instructions, and directions failed to warn of the dangerous propensities of said products, which risks were known or reasonably scientifically knowable to Defendants. Defendants, and each of them, knew or should have known of the defective condition, characteristics and risks associated with said products, as previously set forth herein.

90. At all times herein mentioned, the aforementioned products were defective, and Defendants, and each of them, knew that the products were to be used by the user without inspection for defects therein. Moreover, Plaintiff neither knew, nor had reason to know at the time of the use of the subject products, of the existence of aforementioned defects. Further, Plaintiff used the products without substantial change in condition in the products between the time of design and manufacture of the products and the time Plaintiff used the products as directed.

91. As a proximate result of the defective condition of the aforementioned products, Plaintiff suffered injuries and damages as alleged herein. Therefore, Plaintiff has a cause of action against Defendants in an amount in excess of Seventy Five Thousand Dollars (\$75,000.00).

COUNT THREE

BREACH OF IMPLIED WARRANTY

92. Plaintiff incorporates by reference herein all paragraphs and allegations of this Complaint as though fully set forth herein:

93. Prior to the time that the aforementioned products were used by Plaintiff, Defendants, and each of them, impliedly warranted to Plaintiff, her agents and physicians, that said products were of merchantable quality and safe and fit for the use for which they were intended.

94. Plaintiff was and is unskilled in the research, design and manufacture of the aforementioned products and reasonably relied entirely on the skill, judgment and implied warranty of Defendants, in that the hormone therapy drugs had dangerous propensities when put to their intended use and would cause severe injuries to the user.

95. The aforementioned products were neither safe for their intended use nor of merchantable quality, as warranted by Defendants, in that they had dangerous propensities when put to their intended use and would cause severe injuries to the user.

96. As a result of the aforementioned breach of implied warranties by Defendants, and each of them, Plaintiff suffered injuries and damages as alleged herein. Therefore, Plaintiff has a cause of action against Defendants in an amount in excess of Seventy Five Thousand Dollars (\$75,000.00).

COUNT FOUR

BREACH OF EXPRESS WARRANTY

97. Plaintiff incorporates by reference herein all paragraphs and allegations of this Complaint as though fully set forth herein:

98. At all times herein mentioned, Defendants expressly warranted to Plaintiff, her agents and physicians, by and through statements made by Defendants, orally and in written publications, packaged inserts, and other written materials intended for physicians, medical patients, and the general public, that the aforementioned products were safe, effective, fit and proper for their intended use.

99. In utilizing the aforementioned products, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of Defendants, and each of them. Said warranties and representations were false in that the aforementioned products were not safe and were unfit for the uses for which they were intended.

100. As a result of the foregoing breach of express warranties by Defendants, and each of them, Plaintiff suffered injuries and damages as alleged herein. Therefore, Plaintiff has a cause of action against Defendants in an amount in excess of Seventy Five Thousand Dollars (\$75,000.00).

COUNT FIVE

FRAUD

101. Plaintiff incorporates by reference herein all paragraphs and allegations of this Complaint as though fully set forth herein:

102. Defendants, and each of them, from the time that the aforementioned products were first manufactured, marketed and distributed, and up to the present, willfully deceived Plaintiff by concealing the true facts concerning the hormone therapy drugs, which Defendants, as manufacturers, marketers, and distributors of the products, had a duty to disclose to Plaintiff.

103. Defendants willfully deceived Plaintiff with the intent to induce the use of the

hormone therapy drugs.

104. Defendants represented and suggested as a fact to Plaintiff and her physicians that the hormone therapy drugs were safe when Defendants did not believe it to be true and had no reasonable grounds for believing it to be true.

105. At all times herein mentioned, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the aforementioned drug products and willfully deceived Plaintiff, her physicians, and the general public as to the health risks and consequences of the use of the aforementioned products. Defendants, and each of them, were aware of the foregoing and that the aforementioned products were not safe, fit, and effective for human consumption, the use of said products was hazardous to health, and said products had a serious propensity to cause serious injuries to users including, but not limited to, the injuries suffered by Plaintiff as delineated herein.

106. Defendants, with the intent to defraud and mislead, intentionally concealed and suppressed the true facts concerning the hormone therapy drugs. Defendants knew that Plaintiff's physicians would not prescribe the subject products, and Plaintiff would not have used the subject products, if they were aware of the true facts concerning the dangers of said products.

107. As a result of the foregoing fraudulent and deceitful conduct by Defendants, and each of them, Plaintiff suffered injuries and damages as alleged herein. Therefore, Plaintiff has a cause of action against Defendants in an amount in excess of Seventy Five Thousand Dollars (\$75,000.00).

COUNT SIX

MISREPRESENTATION

108. Plaintiff incorporates by reference herein all paragraphs and allegations of this Complaint as though fully set forth herein:

109. Defendants, and each of them, made false representations, as previously set forth herein, to Plaintiff, Plaintiff's physicians, and the general public, including, but not limited to, the misrepresentation that the hormone therapy drugs were safe, fit and effective for human consumption. At all times herein mentioned, Defendants, and each of them, conducted a sales and marketing campaign to promote the sale of the aforementioned drug products and willfully deceived Plaintiff, Plaintiff's physicians, and the general public as to the health risks and consequences of using the hormone therapy drugs.

110. Defendants made the foregoing representations without any reasonable grounds for believing them to be true. These representations were made directly by Defendants to physicians, medical patients and the public with the intention of inducing reliance and the prescription, purchase, and use of the hormone therapy drugs.

111. The foregoing representations by Defendants, and each of them, were in fact false in that the hormone therapy drugs were not safe, fit, and effective for human consumption, the use of said products was hazardous to health, and said products had a serious propensity to cause serious injuries to users, including, but not limited to, the injuries which ultimately caused Plaintiff's injuries as delineated herein.

112. The foregoing misrepresentations by Defendants, and each of them, were made with the intention of inducing reliance and the prescription, purchase, and use of the subject products by the public, including Plaintiff.

113. In reliance on the misrepresentations by Defendants, and each of them, Plaintiff

was induced to purchase and use the aforementioned products. If Plaintiff had known of the true facts and the facts concealed by Defendants, she would not have used the subject products. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

114. As a result of the foregoing negligent misrepresentation by Defendants, and each of them, Plaintiff suffered injuries and damages as alleged herein. Therefore, Plaintiff has a cause of action against Defendants in amount substantially in excess of Seventy Five Thousand Dollars (\$75,000.00).

COUNT SEVEN

VIOLATION OF THE FALSE AND MISLEADING ADVERTISING ACT, THE MINNESOTA PREVENTION OF CONSUMER FRAUD ACT AND THE UNIFORM DECEPTIVE TRADE PRACTICES ACT

115. Plaintiff incorporates by reference herein all paragraphs and allegations of this Complaint as though fully set forth herein:

116. By reason of the conduct as alleged herein, Defendants violated the provisions of Minnesota Statutes sections 325D.44, 325F.67 and 325F.69 by knowingly and intentionally inducing Plaintiff to use the hormone therapy drugs through the use of false and/or misleading advertising, representations and statements. The products failed to perform as represented and advertised, and in fact were unsafe.

117. As a direct and proximate result of Defendants' statutory violations, Plaintiff used the hormone therapy drugs as a means of hormone replacement therapy, which Plaintiff would not have used had Defendants not issued false and/or misleading advertising, representations and

statements.

118. By reason of such violations and pursuant to Minnesota Statutes section 8.31 subdivision 3a, section 325D.44, section, section 325F.67 and sections 325F.68-70, Plaintiff is entitled to recover all of the monies paid for the products; to be compensated for the cost of medical care arising out of the use of the products; together with any and all other consequential damages recoverable under the law including, but not limited to, past medical expenses, past wage loss, past pain, suffering, disability and emotional distress.

119. In addition, pursuant to Minnesota Statutes section 8.31, Plaintiff is entitled to recover costs and disbursements, including costs of investigation, reasonable attorneys' fees, and any other equitable relief as determined by this Court.

A TRIAL BY JURY IS HEREBY DEMANDED.

Dated: 8/5/09

Ted G. Meadows

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ATTORNEY FOR PLAINTIFF

ACKNOWLEDGEMENT

The allegations in this Complaint are well grounded in fact and are warranted by existing law or a good faith argument for its extension, modification or reversal. Plaintiff brings this Complaint in good faith and not for any improper purposes. Plaintiff acknowledges that the costs, disbursements and reasonable attorney and witness fees may be awarded to Defendants pursuant to Minn. Stat. Sec. 549.21, Subd 2, and the Rules of Civil Procedure if there is an affirmative finding by the Court to the contrary.

Dated: 8/5/09

Ted G. Meadows

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