IN THE CIRCUIT COURT OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

EVA MARIE FELLNER,

Plaintiff,

v.

KAISER FOUNDATION HEALTH PLAN OF THE NORTHWEST, an Oregon non-profit corporation d.b.a. Kaiser Permanente; **NORTHWEST PERMANENTE P.C**., an Oregon professional corporation; **MARY L. KNOX, M.D.; WENDY JANE SMITH, M.D.**; and **SUSAN E. WAGNER, P.A.**,

Defendants.

Case No. _____

COMPLAINT
Civil Action for Personal Injuries based upon Professional Negligence
DEMAND FOR JURY TRIAL

(Case Not Subject to Mandatory Arbitration; Claim More than $10,000)

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Plaintiff alleges:

1.

Plaintiff Eva Fellner asserts claims of negligence against defendants Kaiser Foundation Health Plan of the Northwest, Norwest Permanente P.C., Mary L. Know, M.D., Wendy Jane Smith, M.D., and Susan E. Wagner, P.A. for failing to obtain her informed consent about the true risk of breast cancer from hormone replacement therapy when they prescribed this drug regimen to her for the treatment of menopausal symptoms.

JURISDICTION AND PARTIES

2.

This Court has jurisdiction because plaintiff is a citizen of Oregon, and defendants Kaiser Foundation Health Plan of the Northwest and Northwest Permanente, P.C. are citizens of Oregon.

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3.

Venue is proper in Multnomah County, Oregon because Kaiser defendants maintain several clinics in Multnomah County, and because plaintiff received cancer treatment at Kaiser's Interstate facility in Multnomah County.

The Plaintiff

4.

Plaintiff was at all relevant times a resident and citizen of Beaverton, Oregon.

5.

Beginning in July 1996 and continuing through December 2012, various physicians and nurse practitioners employed by Northwest Permanente, P.C. ("Kaiser") prescribed prescription hormone replacement therapy to plaintiff to treat her symptoms of menopause. This drug therapy consisted of Climara, a transdermal patch containing estradiol, and an oral synthetic progestin. From 1996 through 2010, the progestin component prescribed was generic medroxyprogesterone acetate ("MPA"). From 2010 through 2012, plaintiff's healthcare providers switched the progestin from MPA to generic norethindrone acetate ("NETA").

6.

As a result of taking Climara plus synthetic progestins, plaintiff developed hormone-receptor positive breast cancer, which means that hormones fueled the growth of her tumor. Plaintiff's breast cancer was first detected in a mammogram in November 2012, and she received her final diagnosis of breast cancer in December 2012.

7.

Plaintiff's exposure to Climara plus continuous synthetic progestins for 16 years resulted in permanent and ongoing injuries and lost income. As a consequence, she has incurred, and will continue to incur, significant economic and noneconomic damages, as described more fully below.

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8.

Plaintiff first learned that her condition was likely related to these hormone replacement therapy drugs in approximately December 2012, within two years of filing this lawsuit.

The Kaiser Defendants

9.

Defendant Kaiser Foundation Health Plan of the Northwest ("Kaiser FHP") is an Oregon corporation. At all relevant times, Kaiser FHP provided hospital and medical insurance benefits to its members and engaged in regular, sustained business activity in Multnomah County, Oregon.

10.

Defendant Northwest Permanente, P.C. ("Permanente") is an Oregon corporation. Its principal place of business is in Multnomah County. At all relevant times, Permanente employed physicians Wendy Smith, Mary Knox, and physician's assistant Susan Wagner.

11.

Defendant Wendy Smith, M.D. ("Smith") is an Oregon physician. At all relevant times, she was employed by defendant Northwest Permanente, P.C. and treated plaintiff at the Kaiser clinic in Beaverton.

12.

Defendant Susan Wagner, P.A. ("Wagner) is an Oregon licensed physician's assistant. At all relevant times, she was employed by defendant Northwest Permanente, P.C. and treated plaintiff at the Kaiser clinic in Beaverton.

13.

Defendant Mary Knox, M.D. ("Knox") is an Oregon physician. At all relevant times, she was employed by defendant Northwest Permanente, P.C. and treated plaintiff at the Kaiser clinic in Beaverton.

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FACTUAL BACKGROUND

14.

On July 22, 1996, and continuing through December 2012, defendants Smith, Knox and Wagner, all employed by Kaiser Northwest Permanente, P.C. ("Kaiser"), prescribed Climara, a transdermal estradiol patch, together with oral progestins, to plaintiff as hormone replacement therapy to treat her menopause symptoms. Kaiser defendants prescribed plaintiff a generic version of medroxyprogesterone acetate (MPA), and later, norethindrone acetate (NETA) as the progestin component to work in combination with the Climara patch. As a result of taking these combination hormone therapy drugs, plaintiff developed breast cancer, resulting in ongoing physical injury and pain. Her breast cancer was first detected in a mammogram on November 29, 2012. Her final pathological diagnosis was from a biopsy on December 19, 2012.

15.

Since the late 1970s, the most common form of hormone replacement therapy ("HRT") in the United States for women who had not had a hysterectomy was a two-pill regimen (and later, a single-pill or patch regimen) containing estrogen plus a synthetic imitation of progesterone. The two most popular of these artificial progestins were MPA and NETA. Both MPA and META have many biological actions similar to progesterone, but neither is chemically identical to progesterone. Both MPA and NETA have many biological effects that progesterone does not, and progesterone has biological effects that neither of these two imitation hormones has.

16.

MPA had the highest market share in the U.S., while NETA had the highest market share in Northern Europe. Either MPA or NETA was combined with estrogen because estrogen therapy alone causes a hormone-dependent form of uterine cancer known as endometrial cancer. Adding one of these imitation progesterone drugs to estrogen protected against endometrial cancer. But beginning in the early 2000s, published studies found that when combined with estrogen, these artificial progestins cause hormone-dependent breast cancer.

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17.

Bayer defendants market two forms of HRT. One is Climara Pro, a transdermal patch containing estradiol and levonorgestrel, another artificial progestin. The other is Climara, a transdermal patch containing estradiol alone. The form of HRT plaintiff used was Climara plus oral MPA, and later, Climara plus oral NETA.

18.

In the U.S., women with a uterus who were prescribed Climara to treat menopause symptoms took it in combination with a synthetic progestin (mainly MPA or NETA). Therefore, Bayer defendants knew that the financial success of Climara was largely dependent on its sales as the estrogen component of HRT.

19.

The estradiol contained in the Climara patch ("E2") is bio-identical to the human ovarian hormone estradiol. The synthetic progestins MPA and NETA prescribed to plaintiff are not bio-identical to the human hormone progesterone. Any drug that has progestational effects on the uterus is called a "progestagen." Progesterones and the artificial imitations of it are all progestagens. But there is only one molecule called "progesterone," namely, the natural, bio-identical human hormone. The artificial progestagens are called "progestins."

20.

When combined with estrogen, MPA and NETA disrupt the body's androgen receptor signaling and promote the growth of breast cancer cells. Thus, MPA and NETA fuel the growth of cancer cells that would otherwise lie dormant or grow very slowly.

21.

Prometrium (oral micronized progesterone, or "OMP") is an FDA-approved prescription bio-identical human progesterone. OMP has been on the market in the United States since 1998. In the body, OMP has the same effects as the body's natural progesterone. Unlike MPA and NETA, OMP does not promote the growth of breast tumors, and therefore, does not increase the risk of breast cancer when combined with estrogen.

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22.

Beginning in the mid- to late 1990s, published epidemiological studies from the U.S. and Europe found that combination HRT with artificial progestins increased the risk of breast cancer. Although these early observational studies did not specifically measure or compare the risks of different progestagen formulations of HRT, several *in vitro* and animal studies revealed that estrogen combined with either MPA or NETA increased proliferation and density of epithelial cells of breast tissue from postmenopausal women. Breast density is a known marker and risk factor for breast cancer.

23.

The findings of the early epidemiological, *in vitro*, and animal studies led researchers to investigate whether combination HRT containing MPA and NETA posed a higher risk of breast cancer in women than other formulations.

24.

Beginning in 2002, published epidemiological studies found that HRT with MPA more than doubled the risk of breast cancer, and HRT containing NETA at both high and low doses more than tripled women's breast cancer risk.

25.

In northern Europe, where both NETA and OMP (as well as dydrogesterone, a racemic cousin of human progesterone) were commonly used in HRT, investigators were able to compare the risks of different HRT regimens. They found that OMP and/or dydrogesterone posed little or no risk of breast cancer, while the breast cancer risk from MPA and NETA was much higher, regardless of the type or route of administration of estrogen.

26.

In early 2005, the first of several published reports from E3N, a large prospective epidemiological cohort study from France, found that HRT containing the natural progesterone OMP appeared to have little or no risk of breast cancer, but HRT with synthetic progestins

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significantly increased breast cancer risk. Because most of the women in this study were either teachers or spouses of teachers, the study is commonly known as the French Teachers Study.

27.

CLAIM FOR RELIEF

(Professional Negligence against Kaiser Defendants)

28.

Plaintiff realleges paragraphs 1 through 27.

29.

Defendants Kaiser FHP and Permanente are vicariously liable for the negligence of their employees, defendants Knox, Smith and Wagner.

30.

Kaiser defendants failed to obtain plaintiff's informed consent to the use of the Climara patch in combination with MPA and NETA.

31.

In order to obtain the proper informed consent of a patient, a physician must explain that there may be alternative procedures or methods of treatment. Where these alternative forms of treatment provide the same benefits as the one the physician is recommending but have a safer risk profile, the physician must ask the patient if the patient wants a more detailed explanation. If the patient requests further explanation, the physician must disclose in substantial detail the viable alternatives and the material risks of both treatments unless to do so would be materially detrimental to the patient.

32.

Providing material and detailed information about the lower breast cancer risk of OMP compared to MPA and NETA would not have been detrimental to plaintiff. Kaiser defendants should have explained to plaintiff that there was a large body of published scientific data finding that using OMP instead of MPA or NETA as the progestagen companion drug to estradiol was safer with respect to the risk of blood clots and cardiovascular effects, and carried a lower breast

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cancer risk than MPA and NETA. This failure to obtain informed consent was repeated every time defendant prescribed NETA to plaintiff beginning in 2005.

33.

Specifically, Kaiser defendants violated ORS 677.097 (1)(b) because they never told plaintiff there was a potentially safer alternative progestagen; and they violated ORS 677-097 (2) because they never asked plaintiff if she wanted to know more details about alternatives to using MPA or NETA as the progestagen companion to estradiol. Had they done so, plaintiff would have told Kaiser defendants she did want additional information concerning any potentially safer progestagens.

34.

Had Kaiser defendants told plaintiff there was evidence that OMP was potentially safer for cardiovascular risk and/or, posed a lower risk of breast cancer risk, and was equally as effective for preventing uterine cancer as MPA or NETA, she would have chosen to take OMP instead of MPA or NETA, and she would not have developed breast cancer.

35.

As a result of the Kaiser defendants' failure to obtain informed consent, plaintiff developed breast cancer and suffered all of the damages alleged above.

PRAYER

WHEREFORE, plaintiff prays for judgment against defendants, and each of them, as follows:

1. On her Claim for Relief, plaintiff prays for judgment against each defendant in a reasonable amount to be determined by a jury at trial, but not expected to exceed $700,000 in economic damages for past and future medical expenses; six million dollars in non-economic damages, as well as past and future diminished earning capacity, and for her reasonable costs and disbursement incurred herein, not including the attorney fees she incurs in prosecuting this action;

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2. Plaintiff prays for such other and further relief as justice requires; and

3. Plaintiff requests trial by jury.

DATED: November 19, 2014.

WILLIAMS O'LEARY, LLC

s/ Michael L. Williams

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