



**II.**

**JURISDICTION AND VENUE**

2.01 This Court has jurisdiction over the non-resident Defendants because they have done business in the State of Texas, have committed a tort in whole or in part in the State of Texas, and have continuing contacts with the State of Texas.

2.02 Venue of this case is proper in the Northern District of Texas because Defendants market and sell drugs there, and it is anticipated that the cause will be transferred to the MDL situated in the Eastern District of Arkansas, Western Division. At the conclusion of the MDL, venue would be properly remanded to the Northern District of Texas, as the Defendants market and sell drugs there.

2.03 Plaintiff's damages are in excess of the minimum jurisdictional limits of the Court.

**III.**

**PARTIES**

3.01 Victoria Gonzalez is an individual and a resident of Alvarado, Johnson County, Texas.

3.02 Defendant Wyeth LLC is a Delaware Limited Liability Company, with its principal places of business in New Jersey. On or about March 11, 2002, the name of American Home Products Corporation ("AHPC") changed to Wyeth. On or about March 22, 2002, Wyeth-Ayerst Pharmaceuticals, Inc. changed its name to Wyeth Pharmaceuticals, Inc. (hereafter called "Wyeth Pharmaceuticals"), a wholly owned subsidiary of Wyeth. On or about June 30, 2001, Wyeth-Ayerst Laboratories Company ("WALCo") was merged into AHP Subsidiary Holding Corporation ("AHPSHC") and ceased to exist as a separate entity. On or about January 31, 2007, AHPSHC was merged into Wyeth. On or about November 9, 2009, Wyeth converted from a Delaware Corporation

to a Delaware Limited Liability Company known as Wyeth LLC. Wyeth LLC is therefore the legal successor in interest to Wyeth, AHPC, AHPSHC and WALCo, and is fully liable for all the acts and omissions alleged herein committed by its various subsidiaries and predecessors in interest. At all times material hereto, Wyeth LLC and its various subsidiaries and predecessors in interest were 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 products. Defendant Wyeth may be served by serving its registered agent, C T Corporation System, 350 North St. Paul Street, Dallas, Texas 75201-0000. Plaintiff requests that Summons be issued.

3.03 Defendant Pfizer is a Delaware corporation, with its principal places of business in New York and Pennsylvania. Defendant Pfizer may be served by serving its registered agent, C T Corporation System, 350 North St. Paul Street, Dallas, Texas 75201-0000. Plaintiff requests that Summons be issued.

#### IV.

#### FACTS

##### **A. Plaintiff Acquired Breast Cancer after Ingesting Hormone Replacement Drugs**

4.01 Victoria Gonzalez is a 73-year-old woman who began hormone replacement therapy in 1994 for treatment of menopausal symptoms and discontinued that therapy in 1998. She was diagnosed with breast cancer. A biopsy taken on October 27, 1999 was later read to include infiltrating ductal carcinoma, with lobular hyperplasia. She has since undergone a mastectomy, chemotherapy and radiation. Her condition remains guarded. During her years of consumption, Ms. Gonzalez took Premarin (manufactured by Wyeth), Estrace and Provera (manufactured by Pfizer).

**B. The Creation of A Disease**

4.02 In 1942, Ayerst (the predecessor to Wyeth and Wyeth Pharmaceuticals) received approval to manufacture and market Premarin, a conjugated equine estrogen made from the urine of pregnant horses. Premarin has remained chemically unchanged from 1942 up until this day, and has been marketed as a hormone replacement product to replace the natural human female hormone, estrogen.

4.03 Since 1942, Defendant Wyeth (and later other Defendants) has continuously and vigorously promoted its menopausal hormone therapy products using a variety of marketing messages that emphasize the use of these medications for long-term relief of menopause symptoms. The marketing logo in the early to mid 1970's describes Premarin as a medication to “start her on, keep her on.” Even in the early 1990's, Defendant Wyeth continued to market its hormone therapy product as medicines that required continued use – “protection continued only as long as estrogen therapy continued.” The other Defendants joined in this marketing and advertising scheme, to a lesser extent. To distribute this message to both patients and doctors, Defendants have used numerous different marketing methods:

1. Sponsoring medical journal articles about the benefits of their products, oftentimes with questionable results drawn from doubtful scientific principles;
2. Sales representatives and “detail persons” calling on and encouraging physicians to prescribe these drugs;
3. Sponsoring continuing medical education programs to discuss the purported benefits of these products, often without appropriate description of the corresponding risks;
4. Hiring physicians in the field to speak to other physicians as an effort to market these medicines;
5. Press releases of audio, written and television advertising;
6. Direct-to-consumer advertising in addition to physician-directed advertising;

7. Medical journal and consumer journal advertising materials; and
8. Sponsoring medical and pseudo-medical organizations to provide “approval” or sponsoring support for the use of these products.

4.04 These different message delivery systems were intended to be twofold: first to create the “disease” of menopause and thereafter to market the “solution” of hormone replacement drugs.

4.05 In 1977, the Food & Drug Administration issued a statement confirming that estrogen therapy should not be used to treat nervousness during menopause, and that there was no scientific support or any representation that estrogen could keep a woman feeling young or keep her skin soft. By the time of these reports, Premarin was the fifth most frequently prescribed drug in the United States.

4.06 The first truly scientific literature was published in 1975 in the *New England Journal of Medicine*. Two articles appeared that linked estrogen therapy to a significantly increased risk of women developing endometrial cancer. Estrogen sales plummeted, and Defendants were in search of a resurrection for their miracle pill.

4.07 In 1979, that miracle appeared in the form of an article written by Dr. Robert Greenblatt published in the *Journal of Geriatrics Society*. Dr. Greenblatt proposed that estrogen-related uterine cancer could be avoided if progesterone was added to the estrogen regimen. Immediately, Wyeth and the others began promoting this combination hormone therapy – Premarin with Provera as a hormone therapy combination. Pfizer, as the manufacturer of Provera, was delighted to join the “bandwagon.”

4.08 Once again, Dr. Greenblatt’s proposed remedy was bereft of scientific support, and there was no published scientific literature to even discuss the issue until the Women’s Health Initiative was begun in the late 1990’s.

4.09 By the mid 1990's, various governmental agencies began questioning the appropriateness of advertising estrogen and hormone replacement therapy as “cures” for all these various conditions caused by the “disease” of menopause. Seeking FDA approval for the use of these different medicines to “cure” these conditions, Defendant Wyeth agreed to participate in and sponsor various studies.

4.10 One of these studies (Heart and Estrogen/Progestin Replacement Study) was conducted in order to confirm that estrogen/progestin combination therapy did in fact reduce the risk of heart disease. This study began in 1994. The results of the study were published in 1998, when the investigators reported that hormone therapy did not reduce the rate of coronary heart disease, and in fact dramatically increased the risk of heart disease and heart attack in these women.

4.11 The Defendants immediately began distancing themselves from and minimizing the results of the HERS study.

4.12 The second study, called the Women’s Health Initiative, also began in the early 1990's. This study was conducted by the National Institute of Health, again with support by the Defendants; this study was designed to definitively answer questions about estrogen/progestin therapy’s benefits for heart health, osteoporosis and the other menopausal symptoms identified in Defendants’ advertising.

4.13 The Women’s Health Initiative was intended to run for 15 years; however, the National Institute of Health halted this study prematurely because the risks of taking hormone replacement therapy outweighed any potential benefits. The study concluded that “overall health risks exceeded benefits from use of combined estrogen plus progestin ...”

V.

**CAUSES OF ACTION**

**A. Negligence**

5.01 Defendants had a duty to exercise reasonable care in the design, testing, study, development, manufacture, promotion, sale, marketing and distribution of their hormone drugs. Defendants had a duty to assure that the products did not cause users to suffer from unreasonably dangerous side effects and serious health problems which were foreseeable to Defendants. Defendants also had a duty to warn of adverse drug reactions which they knew, or had reason to know, were inherent in the use of their hormone drugs.

5.02 Before Plaintiff ingested these drugs, Defendants knew or should have known that there had been many case reports, adverse event reports and public and private studies in the medical literature associating hormone drugs with a significantly increased risk of breast cancer. Defendants also knew or should have known that safer alternative medicines existed which would have provided equally efficacious treatment of the symptoms of menopause without any risk of breast cancer.

5.03 Defendants further had the duty to conduct appropriate clinical trials, tests and studies and review available literature to confirm the safety of their hormone drugs, particularly in light of their advertising efforts; to timely warn consumers of the known and foreseeable risks of hormone drugs; and to implement safer alternative delivery methods and/or medications to treat the symptoms of menopause.

5.04 Defendants committed numerous acts of negligence in the design, manufacture, distribution, marketing and sale of their hormone drugs, including, but not limited to:

- (1) Failing to exercise reasonable care in the design, testing, study, development, manufacture, production, sale, marketing and/or distribution of their hormone drugs;

- (2) Failing to adequately and fully test their drugs to determine the true risks and benefits of consuming their hormone drugs, including the risk of heart disease;
- (3) Failing to properly warn consumers of the actual and reasonably knowable risks of consuming their hormone drugs, including the risk of developing breast cancer;
- (4) Failing to manufacture and distribute a safer delivery system for estrogen/progestin without the corresponding risk of breast cancer; and
- (5) Promoting the use of their hormone drugs in a fraudulent manner, despite evidence of their dangerousness.

5.05 As a proximate result of the Defendants' negligence, Plaintiff contracted breast cancer and has been seriously injured and damaged. Plaintiff seeks all damages to which she may be justly entitled.

**B. Negligence Per Se**

5.06 Defendants were negligent per se in their design, manufacture, marketing, distributing and placing into the stream of commerce products which they knew or should have known were not safe. As a direct, proximate and legal result, Plaintiff has suffered debilitating injuries for which she seeks all rights and remedies to which she is entitled.

5.07 Defendants were negligent per se in their pre- and post-marketing safety surveillance of the hormone drugs, and violated the following regulations:

- (1) The labeling lacked adequate information on the appropriate and safe use of and risks presented by hormone drugs, in violation of 21 C.F.R. § 201.56(a) and (d);
- (2) The labeling lacked adequate and accurate information of the appropriate kind, degree and duration of expected improvement, in violation of 21 C.F.R. § 201.57(c);
- (3) The labeling failed to state that there was a lack of evidence to support the common belief of the safety and efficacy of hormone drugs, in violation of 21 C.F.R. § 201.57(c);
- (4) The labeling failed to add a proper, complete and sufficient warning of the risks presented, in violation of 21 C.F.R. § 201.57(e);

- (5) There was inadequate information for patients regarding the safe and effective uses (and corresponding risks), in violation of 21 C.F.R. § 201.57(f);
- (6) There was inadequate information regarding the special care to be exercised in order for safe and effective use of hormone drugs, in violation of 21 C.F.R. § 201.57(f);
- (7) The labeling was not accurate, and instead was false, misleading and misrepresented the benefits of the hormone drugs, in violation of 21 C.F.R. § 201.56(b).

5.08 These and other violations of the Code of Federal Regulations are necessarily incorporated into violations of the United States Code, all of which were a proximate and producing cause of the injuries and damages suffered by Plaintiff.

**C. Gross Negligence/Malice**

5.09 The actions of Defendants were more than momentary thoughtlessness, error or inadvertence. In fact, Defendants acted knowingly and/or with reckless and conscious disregard for the rights, safety and welfare of the Plaintiff. The actions of the Defendants constitute more than mere negligence, and rise to the level of gross negligence/malice. Exemplary damages are, therefore, appropriate.

**D. Strict Liability**

5.10 Defendants had a duty to warn Plaintiff of the risks and/or defects that were known and reasonably knowable with respect to hormone drugs. Defendants never appropriately warned Plaintiff (or her physicians) of these risks. Plaintiff used and consumed the hormone drugs in a foreseeable manner, and as directed by Defendants.

5.11 The hormone drugs ingested by Plaintiff were defective and unreasonably dangerous when Defendants placed them into the stream of commerce because, among other things, they created an unreasonable risk of breast cancer without a corresponding benefit.

5.12 The hormone drugs were defective because they were not accompanied by proper, appropriate and adequate warnings of the significance and degree of the known and reasonably

knowable risks. In addition, the warnings given to Plaintiff (and her physicians) did not accurately reflect the scope and severity of the risks and possible side effects.

5.13 Plaintiff's consumption of hormone drugs as directed by Defendants involved a substantial danger that Plaintiff would contract breast cancer. This substantial danger was not readily recognizable to an ordinary consumer. Given the knowledge of Defendants when they manufactured, marketed and distributed hormone drugs, and their knowledge before Plaintiff began consuming hormone drugs, Defendants failed to adequately warn of the dangers involved.

5.14 As a direct, proximate and producing result of Defendants' failure to warn of the dangers, Plaintiff suffered debilitating injuries.

5.15 Defendants are liable under the theory of strict product liability as set forth in the Restatement (Second) of Torts. Defendants were at all times materially engaged in the business of designing, manufacturing, distributing, selling, marketing and advertising the hormone drugs in question. The hormone drugs in question reached Plaintiff without any substantial change in the condition in which they were sold.

**E. Misrepresentation and Fraud**

5.16 Defendants, through their advertising, labeling, marketing, sales and detail persons, made significant misrepresentations to the public and to physicians, both about the safety and efficacy of their hormone drugs. Physicians and their patients, including the Plaintiff, justifiably relied upon the misrepresentations by Defendants and Plaintiff was harmed as a result. Plaintiff is entitled to recover damages for her injuries caused by Defendants' misrepresentations pursuant to the Restatement (Second) of Torts, § 402(B).

5.17 Additionally, the representations made by Defendants were intentional, and Defendants knew or should have known that the representations made were false and misleading.

Defendants did nothing to correct or properly educate or instruct physicians or their patients, and Defendants failed to warn and failed to report the incidences of serious side effects associated with the drugs used.

5.18 As a result of this fraudulent conduct and these misrepresentations, Plaintiff was harmed. Plaintiff is entitled to recover her actual damages suffered as a result of these misrepresentations and fraud. Further, because the Defendants' conduct was willful, reckless, intentional and maliciously fraudulent, Plaintiff is entitled to an award of exemplary damages.

5.19 As a further result of this fraudulent conduct and these misrepresentations, the FDA and the Federal Government were never provided with a true understanding of the dangers presented by these drugs.

**F. Breach of Warranties**

5.20 Defendants designed, tested, manufactured, sold, distributed, marketed and promoted that their hormone drugs were safe and efficacious for their intended uses. The hormone drugs consumed by Plaintiff reached her without substantial change in their condition, and were used by Plaintiff as intended by Defendants. Defendants expressly and impliedly warranted that the hormone drugs were not unreasonably dangerous and instead were merchantable and fit for their intended use by Plaintiff. Further, Defendants expressly and impliedly warranted that the drugs had been fully and adequately tested for long-term use and were safe to use to treat the symptoms associated with menopause.

5.21 Defendants breached these warranties (both express and implied) as the hormone drugs were not merchantable, were unfit for their intended use and were unreasonably dangerous when comparing the benefits of the hormone drugs to the risks associated with their use. Plaintiff was injured as a result of these breaches of warranties.

VI.

**DAMAGES**

6.01 The conduct of Defendants as specifically identified above with respect to Plaintiff was a proximate and producing cause of substantial and permanent injuries and damages to Plaintiff. As a result of this conduct by Defendants, Plaintiff suffered severe and permanent physical, mental and emotional injuries. Plaintiff seeks all damages to which Plaintiff is entitled, both at law and in equity, from the Defendants. Plaintiff seeks recovery for past and future medical expenses, lost wages and lost earning capacity, physical pain and mental anguish, disfigurement and physical impairment. Plaintiff also seeks attorneys' fees and expenses incurred in litigating this cause of action, along with exemplary damages.

6.02 Plaintiff hereby requests a jury trial.

**FOR THESE REASONS**, Plaintiff requests that the Defendants be cited to answer and appear, and that upon final trial Plaintiff have judgment against the Defendants for Plaintiff's damages as set forth above, for attorneys' fees and expenses, for exemplary damages, for pre- and post-judgment interest at the maximum rate allowed by law, for costs of court, and for such other and further relief to which the Plaintiff may be justly entitled.

Respectfully submitted,

/s/William B. Curtis

**WILLIAM B. CURTIS**

Texas Bar No. 00783918

**LES WEISBROD**

Texas Bar No. 21104900

**MILLER CURTIS & WEISBROD, L.L.P.**

11551 Forest Central Drive, Suite 300

Dallas, Texas 75243

Telephone: (214) 987-0005

Fax: (214) 987-2545

E-Mail: [bcurtis@mcwlawfirm.com](mailto:bcurtis@mcwlawfirm.com)

**ATTORNEYS FOR PLAINTIFF**