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CW

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SUZANNE FRANKLIN,

Plaintiff,

vs.

WYETH PHARMACEUTICALS, INC.; WYETH-AYERST PHARMACEUTICALS, INC.; WYETH-AYERST INTERNATIONAL, INC.; WYETH LABORATORIES, INC.; WYETH PHARMACEUTICALS; WYETH, INC.; PHARMACIA & UPJOHN, INC.; PFIZER, INC.; BARR LABORATORIES, INC.; GREENSTONE LTD.; MICHELLE LUNA; and DOES 1 through 100, inclusive,

Defendants.

CASE NO._____

NOTICE OF REMOVAL OF ACTION UNDER 28 U.S.C. § 1441

KAYE SCHOLER LLP

TO: THE CLERK OF THE COURT:

Pursuant to 28 U.S.C. § 1441, defendants PFIZER INC., PHARMACIA & UPJOHN LLC (incorrectly named as Pharmacia & Upjohn, Inc.), and GREENSTONE LTD. (the "Removing Defendants") hereby remove this action, *Franklin v. Wyeth Pharmaceuticals, Inc., et al.* (Case No. CGC-05-441166, Superior Court, County of San Francisco, California) to the United States District Court for the Northern District of California, and allege as follows:

1. This action is brought by Plaintiff for injuries allegedly arising from treatment with hormone replacement therapy ("HRT") medications. Plaintiff seeks compensatory and punitive/exemplary damages. Specifically, Plaintiff alleges claims for fraudulent concealment, negligence, fraud, negligent misrepresentation, and breach of express warranty.

2. There is jurisdiction over this removed action pursuant to 28 U.S.C. § 1441 because this action originally could have been filed in this Court pursuant to 28 U.S.C. § 1332. Specifically, this Court has subject matter jurisdiction over this action because there is the requisite diversity of citizenship between the plaintiff and the defendants, and the amount in controversy exceeds $75,000, exclusive of interest and costs.

I. JURISDICTIONAL BASIS FOR REMOVAL

A. Diversity of Citizenship.

3. There is diversity of citizenship in this action because Wyeth (incorrectly named as "Wyeth, Inc."), Wyeth Pharmaceuticals Inc., Wyeth-Ayerst International, Inc. (collectively the "Wyeth Defendants")[1], Pharmacia & Upjohn LLC (incorrectly named as Pharmacia & Upjohn, Inc.), Pfizer Inc., Barr Laboratories, Inc., and Greenstone Ltd. are diverse from Plaintiff, and, as shown below, Michelle Luna is fraudulently joined.

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[1] Plaintiff also names Wyeth-Ayerst Pharmaceuticals Inc. (incorrectly named as Wyeth-Ayerst Pharmaceuticals, Inc.), Wyeth Laboratories Inc. (incorrectly named as Wyeth Laboratories, Inc.), and Wyeth Pharmaceuticals as defendants. Wyeth-Ayerst Pharmaceuticals Inc. and Wyeth Laboratories Inc. are predecessors to Wyeth Pharmaceuticals Inc. and no longer exist as separate corporate entities. On December 31, 1998, Wyeth Laboratories Inc. was merged into an entity that eventually became Wyeth Pharmaceuticals Inc. Wyeth-Ayerst Pharmaceuticals Inc. changed its name to Wyeth Pharmaceuticals Inc. on March 22, 2002. Wyeth Pharmaceuticals is an unincorporated division of Wyeth.

4. Plaintiff is, and at the time of the filing of this action was, a citizen of the State of California. [Complaint for Damages ("Compl."), attached as Exhibit A, ¶ 3.]

5. Defendant Wyeth Pharmaceuticals Inc. is, and at the time of filing of this action was, a corporation existing under the laws of the State of New York, having its principal place of business in the State of Pennsylvania.

6. Defendant Wyeth-Ayerst International, Inc. is, and at the time of filing of this action was, a corporation existing under the laws of the State of New York, having its principal place of business in the State of Pennsylvania.

7. Defendant Wyeth (incorrectly named as "Wyeth, Inc.") is, and at the time of filing of this action was, a corporation existing under the laws of the State of Delaware, having its principal place of business in the State of New Jersey.

8. Pharmacia & Upjohn LLC is, and at the time of the filing of this action was, a limited liability company whose sole member is, and at the time of the filing of this action was, Pharmacia Corporation. Thus, Pharmacia & Upjohn LLC has the same citizenship for purposes of federal diversity jurisdiction as Pharmacia Corporation. Pharmacia Corporation is, and at the time of the filing of the action was, a Delaware Corporation with its principal place of business in the State of New Jersey.

9. Defendant Pfizer Inc. is, and at the time of filing of this action was, a corporation existing under the laws of the State of Delaware, having its principal place of business in the State of New York.

10. Defendant Barr Laboratories, Inc. is, and at the time of filing of this action was, a corporation existing under the laws of the State of Delaware, having its principal place of business in the State of New Jersey.

11. Defendant Greenstone Ltd. is, and at the time of filing of this action was, a corporation existing under the laws of the State of Delaware, having its principal place of business in the State of New Jersey.

12. Pursuant to the allegations in the Complaint, Defendant Michelle Luna (the "Individual Defendant") is, and at the time of filing of this action was, a citizen of the State of

California. [Compl., ¶ 30.] However, the Individual Defendant is fraudulently joined. Thus, her citizenship must be disregarded in determining jurisdiction.

13. The Complaint purports to state claims against unnamed, fictitious defendants identified as "DOES 1 through 100." For purposes of removal, "the citizenship of defendants sued under fictitious names shall be disregarded." 28 U.S.C. § 1441(a).

14. Accordingly, the requisite complete diversity among the parties for federal jurisdiction is satisfied.

B. Applying the Fraudulent Joinder Doctrine, Complete Diversity Exists.

15. The doctrine of fraudulent joinder prevents Plaintiff from defeating federal diversity jurisdiction simply by naming in-state defendants. In determining whether there is complete diversity, a court must disregard the citizenship of those defendants where "plaintiff fails to state a cause of action against a resident defendant, and the failure is obvious according to the settled rules of the state. . . ." *McCabe v. General Foods Corp.*, 811 F.2d 1336, 1339 (9th Cir. 1987). As a leading California treatise explains, the standard to be applied in this Circuit in determining whether an in-state defendant is fraudulently joined is whether there is a "reasonable basis for imposing liability" against that defendant. *See 1 W. Schwarzer and A.W. Tashima, California Practice Guide: Federal Civil Procedure Before Trial (2003)* at ¶ 2:672.

16. As set forth below, the Individual Defendant is fraudulently joined and should be disregarded in determining that there is federal diversity jurisdiction over this action.

C. The Allegations Against The Individual Defendant Does Not Support Any Causes Of Action Against Her.

17. The allegations directed toward the Individual Defendant does not support any causes of action against her. The Complaint alleges causes of action against the Individual Defendant for fraudulent concealment, fraud, and negligent misrepresentation. [Compl., ¶¶ 114-126, 175-198.]

18. However, the Complaint fails to plead the factual events supporting the causes of action for fraud and negligent misrepresentation with particularity.

Fraud and Fraudulent Concealment.

19. Claims for fraud and fraudulent concealment must be alleged with particularity in the

Complaint. As Professor Witkin explains in *California Procedure*, 4th ed. vol. 5, Pleadings, section 669:

> Fraud actions have been classed as "disfavored," and are subject to strict requirements of particularity in pleading. The idea seems to be that allegations of fraud involve a serious attack on character, and fairness to the defendant demands that he should receive the fullest possible details of the charge in order to prepare his defense. Accordingly, the rule is everywhere followed that fraud must be specifically pleaded. The effect of this rule is twofold: (1) General pleading of the legal conclusion of "fraud" is insufficient; the facts constituting the fraud must be alleged; (2) every element of the cause of action for fraud must be alleged in the proper manner (i.e., factually and specifically), and the policy of liberal construction of the pleadings will not ordinarily be invoked to sustain a pleading defective in any material respect. . . . F.R. Civ. P., Rule 9(b) also requires particularity. . .

20. Pleading with particularity means setting forth specific *facts*, not simply re-hashing boilerplate that is generic and identical to every complaint filed. As California's Supreme Court held in *Lazar v. Superior Court*, 12 Cal. 4th 631, 645 (1996), "[t]his particularity requirement necessitates pleading *facts* which show how, when, where, to whom, and by what means the representations were tendered." (Emphasis in original, citation and internal quotation marks omitted).

21. Indeed, MDL courts in other litigations concerning pharmaceutical products have denied remand where, as here, the Complaint asserts fraud claims against sales representatives but fail to allege the "time and place of particular representations." *In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 283 (S.D.N.Y. 2001) ("*Rezulin*"). Similarly, Judge Bartle in the Diet Drug MDL held that sales representatives were fraudulently joined where plaintiffs' allegations fell "far short of what is required under [Rule 9(b)]." *In re Diet Drugs*, 220 F. Supp. 2d 414, 424 (E.D. Pa. 2002).

22. The Complaint here fails to allege specific facts to support its conclusory allegations. Indeed, the Rezulin MDL judge has held that territory representatives were fraudulently joined where, as here, plaintiffs asserting claims against territory representatives failed to sufficiently allege the "time and place of particular representations." *Rezulin*, 133 F. Supp. 2d at 283. Those

"allegations do not meet the Rule 9(b) requirements." *Id.* at 284.

23. Moreover, the Complaint fails to allege "facts giving rise to a strong inference of scienter," as required for fraud claims. *See In re Rezulin*, PTO-156, 2003 WL 21396744, at *4 (emphasis in original) (denying remand in action naming in state representatives).

24. Accordingly, since this Complaint fails to allege fraud or fraudulent concealment against the Individual Defendant with particularity, it fails to state any such causes of action against them.

Negligent Misrepresentation.

25. The Complaint also fails to state a negligent misrepresentation claim against the Individual Defendant.

26. California's Supreme Court, in *Small v. Fritz Companies, Inc.*, 30 Cal. 4th 167, 184 (2003), stated that a claim for negligent misrepresentation must be alleged with particularity, as "implied in the reasoning of two decisions, *Committee on Children's Television, Inc. v. General Foods Corp.*, 35 Cal. 3d 197, 216 (1983), and *B.L.M. v. Sabo & Deitsch*, 55 Cal. App. 4th 823, 835-837 (1997)."

27. Just as this Complaint fails to allege the fraud claims against the Individual Defendant with particularity, it also fails to do so with respect to the negligent misrepresentation claims. Also, the allegations that the Individual Defendant "knew or should have known" (Compl. ¶ 190) are unsupported and wholly conclusory. As *TPS Utilicom Servs., Inc. v. AT&T Corp.*, 223 F. Supp. 2d 1089, 1102 (C.D. Cal. 2002), held, in evaluating whether a non-diverse defendant was fraudulently joined, the court only considers "non-conclusory factual allegations in the complaint as true."

28. Moreover, the Rezulin MDL court further held that a misrepresentation claim that in "substance . . . charge[s] fraud" (even if plaintiff has denominated such a claim as one for "negligent misrepresentation") is subject to the same pleading requirements. *Rezulin*, 133 F. Supp. 2d at 285.

29. Likewise, the Diet Drug MDL recently denied remand in actions naming sales representatives, where, as here, plaintiffs alleged "negligence and negligent/reckless misrepresentation by marketing the 'unreasonably dangerous subject drugs' as safe to the consuming public, 'including, but not limited to, plaintiffs and plaintiff's physicians.'" *In re Diet Drugs*, 294 F.

Supp. 2d at 677 (emphasis omitted).

D. Alternatively, This Court Could "Drop" The Non-Diverse Defendants Under Fed. R. Civ. P. 21 To Perfect Its Diversity Jurisdiction.

30. Removal is proper for another independent reason. Pursuant to Fed. R. Civ. P. 21, a federal court "may perfect diversity by dropping a non-diverse and dispensable party at any time." *Williams v. Knoll Pharms.*, No. 5:03CV8030, slip op. at 5 (N.D. Ohio, July 2003). This Court should "drop" the non-diverse defendants to perfect its diversity jurisdiction.

E. Amount In Controversy.

31. The amount in controversy in this case exceeds $75,000, excluding interest and costs. A defendant can establish the amount in controversy by the allegations of a complaint. *See Conrad Associates v. Hartford Accident & Indemnity Company*, 994 F. Supp. 1196, 1198 (N.D. Cal. 1998). The Complaint alleges injuries caused by breast cancer. [Compl., ¶ 111.] Reported verdicts and settlements in cases where the alleged injury is breast cancer indicate that damages in such cases exceed $75,000. *See, e.g., Rozar v. Kaiser Foundation Healthcare*, 21 No. 8 Verdict Settlement & Tactics ("VST") 348 (Westlaw 2000) ($842,680 arbitration award for delay in diagnosing breast cancer); *Howstow v. Rosenburg*, 21 No. 2 VST 65 (Westlaw 2000) ($750,000 verdict in suit alleging failure to diagnose breast cancer); *Mathews v. Bloy*, 19 No. 4 VST 141 (Westlaw 1999) ($400,000 awarded in suit alleging failure to diagnose breast cancer); *Ruffin v. Medical Ctr. Radiology Group*, 15 No. 7 VST 238 (Westlaw 1995) ($2.6 million awarded to plaintiff in suit alleging failure to diagnose breast cancer); *Greeley v. Slepian*, 12 No. 8 VST 280 (Westlaw 1992) ($1.4 million arbitration award for failure to diagnose breast cancer).

32. Moreover, federal courts have held that requisite amounts in controversy can be established from "other evidence in the record," including similar complaints that have been removed and transferred to an MDL. *Rezulin I* at 296 (defendants met burden of establishing amount in controversy because other complaints in that MDL alleged sufficient damages for similar injuries); *In re Norplant Contraceptive Products Liability Litigation*, 918 F. Supp. 178, 180 (E.D. Tex. 1996) (damages exceeded the requisite amount because, in part, the case involved injuries alleged in numerous other Norplant cases currently pending in the court under MDL).

Several similarly pleaded complaints alleging similar injuries from HRT medications have been removed to this District Court. *See, e.g., Karen Erdman v. Wyeth Pharmaceuticals, et al.*, Case No. SACV-03-1736 JVS (MLGx) (C.D. Cal. Dec. 3, 2003); *Sally Hamilton v. Wyeth Pharmaceuticals, et al.*, Case No. SACV-03-1737 AHS (ANx) (C.D. Cal. Dec. 3, 2003); *Arnold Klein, Individually and as Personal Representative of the Estate of Yvette Klein, deceased v. Wyeth, et al.*, Case No. CV-04-1920 DT (AJWx) (C.D. Cal. Mar. 19, 2004); *Margaret Rosen v. Wyeth Pharmaceuticals, Inc., et al.*, Case No. CV-04-7182 DT (MANx) (C.D. Cal. Aug. 27, 2004); *Mildred Rimmer v. Wyeth Pharmaceuticals, Inc., et al.*, Case No. CV-04-3822 RS (ADR) (N.D. Cal. Sept. 10, 2004).

33. Furthermore, the Complaint includes a prayer for punitive and exemplary damages. [*Id.*, Prayer.] Federal courts "routinely have held that unspecified claims for punitive damage sufficiently serve to bring the amount in controversy over the requisite jurisdictional threshold set out in 28 U.S.C. § 1332." *Ross v. First Family Fin. Servs.,Inc.*, 2002 U.S. Dist. LEXIS 23212 at *27 (N.D. Miss. Aug. 29, 2002) (citations omitted). For this additional reason, the requisite amount in controversy for diversity jurisdiction is satisfied.

II. PROCEDURAL REQUIREMENTS FOR REMOVAL

34. On May 10, 2005, Plaintiff filed her Complaint, a copy of which is attached as Exhibit A. The Removing Defendants were served with the Complaint on May 25, 2005. Upon information and belief, the Wyeth Defendants were served with the Complaint on May 25, 2005. Upon information and belief, Barr Laboratories was served with the Complaint on June 1, 2005. This Notice of Removal is timely under 28 U.S.C. § 1446(b).

35. Copies of other process and pleadings are attached to this Notice of Removal as Exhibit B.

36. As reflected in Exhibit C, the Wyeth Defendants and Defendant Barr Laboratories consent to the removal of this action. The Individual Defendant, as shown above, is fraudulently joined. Moreover, upon information and belief, the Individual Defendant has not been served. Accordingly, the Individual Defendant's consent is not required.

37. The United States District Court for the Northern District of California embraces the

county in which the state court action is now pending, and thus, this Court is a proper venue for this action pursuant to 28 U.S.C. § 84. This case is assigned to this Division pursuant to Civil Local Rule 3-2.

38. In the United States District Court for the Eastern District of Arkansas there is a multidistrict litigation ("MDL") established by the Judicial Panel on Multidistrict Litigation (the "Panel") for the efficient handling of actions arising from the treatment with HRT medication. *In re Prempro Prods. Liab. Litig.*, 254 F. Supp. 2d 1366 (J.P.M.L. 2003). The Honorable William Wilson, United States District Judge for the Eastern District of Arkansas, was designated the transferee judge by the Panel for this MDL proceeding. The Panel will be notified, pursuant to 28 U.S.C. § 1407, that this action is a "tag-along" case that should be transferred to the MDL proceeding.

39. The Removing Defendants are filing written notice of this removal with the Clerk of the State Court in which the action is currently pending pursuant to 28 U.S.C. § 1446(d). Copies of Notice to Adverse Party of Removal to Federal Court, together with this Notice of Removal, are being served upon Plaintiff's counsel pursuant to 28 U.S.C. § 1446(d).

WHEREFORE, the Removing Defendants respectfully remove this action from the Superior Court of the State of California, County of San Francisco, to this Court, pursuant to 28 U.S.C. § 1441.

Dated: June 15, 2005

Respectfully submitted,

KAYE SCHOLER LLP

By: _____
Betsy Katz
Attorneys for Defendants
PFIZER INC., PHARMACIA & UPJOHN LLC
and GREENSTONE LTD.

KAYE SCHOLER LLP

EXHIBIT A

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF SAN FRANCISCO

SUZANNE FRANKLIN,

Plaintiff,

v.

WYETH PHARMACEUTICALS, INC.; WYETH-AYERST PHARMACEUTICALS, INC.; WYETH-AYERST INTERNATIONAL, INC.; WYETH LABORATORIES, INC.; WYETH PHARMACEUTICALS; WYETH, INC.; PHARMACIA & UPJOHN, INC.; PFIZER, INC.; BARR LABORATORIES, INC.; GREENSTONE LTD.; MICHELLE LUNA; and DOES 1 through 100, inclusive,

Defendants.

CASE NO. 505441166

COMPLAINT FOR DAMAGES:

1. **Fraudulent Concealment;**
2. **Fraudulent Concealment;**
3. **Negligence;**
4. **Negligence;**
5. **Fraud;**
6. **Fraud;**
7. **Fraud;**
8. **Negligent Misrepresentation;**
9. **Breach of Express Warranty; and**
10. **Breach of Express Warranty**

DEMAND FOR JURY TRIAL

COMES NOW Plaintiff, Suzanne Franklin, and for causes of action against the defendants, and each of them, complains and alleges as follows:

I.

GENERAL ALLEGATIONS

1. The true names and/or capacities, whether individual, corporate, associate,

governmental or otherwise of Defendants DOES 1 through 100, inclusive, and each of them, are unknown to Plaintiff, who therefore sues said Defendants by such fictitious names and will amend this Complaint to show their true names and/or capacities when the same has been ascertained. The Plaintiff is informed and believes, and thereupon alleges, that each Defendant designated herein as a DOE was responsible, negligently or in some other actionable manner for the events and happenings referred to herein which legally caused the injuries and damages to Plaintiff as hereinafter alleged.

2. Plaintiff is informed and believes and thereupon alleges that at all times mentioned herein, Defendants, and each of them, were the agents, servants, employees and/or consultants of their co-Defendants and were, as such, acting within the course, scope and authority of said agency and/or employment, and that each and every Defendant as aforesaid, when acting as the principal, was negligent in the selection and hiring of each and every other Defendant as an agent, servant, employee and/or assistant.

3. All times mentioned herein, Plaintiff was and now is a citizen of the State of California and was and now is a resident of the County of San Mateo.

4. Plaintiff brings this action to recover damages for personal injuries against Defendants Wyeth Pharmaceuticals, Inc., Wyeth-Ayerst Pharmaceuticals, Inc., Wyeth-Ayerst Pharmaceuticals, Inc., Wyeth-Ayerst International, Inc., Wyeth Laboratories, Inc., Wyeth Pharmaceuticals, Wyeth, Inc., and DOES 51 through 75, inclusive, and each fo them, which tested, manufactured, marketed, labeled, distributed, promoted, and sold Premarin, Prempro, Premphase, and medroxyprogesterone acetate (a synthetic equivalent of the hormone progestin). These defendants shall herein be referred to collectively as the "Wyeth Defendants."

5. Plaintiff also brings this action against Defendants Pharmacia & Upjohn, Inc., Pfizer, Inc., Barr Laboratories, Inc., Greenstone Ltd., and DOES 76 through 100, inclusive, and each of them, which tested, manufactured, marketed, labeled, distributed, promoted, and sold medroxyprogesterone acetate. These defendants shall herein be referred to collectively as the "Medroxyprogesterone Acetate Defendants" or "MPA Defendants."

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6. Plaintiff also brings this action against Defendants Michelle Luna and DOES 1 through 50, inclusive, and each of them, who, the Plaintiff is informed and believes and therefore alleges, were responsible for the solicitation, marketing, and promotion of Premarin, Prempro, Premphase, and medroxyprogesterone acetate to to Plaintiff and her physicians. These defendants shall herein be referred to collectively as the "Individual Defendants."

7. Among the most prescribed hormone therapy drugs for post-menopausal women is the Wyeth Defendants' product, Prempro, which is also known by its pharmaceutical name, conjugated equine estrogens/medroxyprogesterone acetate (progestin). Prempro is considered a combination hormone therapy because it contains a combination of two hormones, estrogen and progestin. The Wyeth Defendants' product, Premphase, is very similar to Prempro, containing a combination of estrogen and progestin. However, instead of providing estrogen and progestin every day, as the Prempro tablet does, Premphase provides estrogen every day while the progestin is added to the pill only for the last two weeks of the menstrual cycle. This is done so that Premphase hormone regime resembles the normal menstrual cycle.

8. Estrogen therapy refers to use of estrogen alone for hormone therapy. Among the most prescribed brands of estrogen is the Wyeth Defendants' product, Premarin, which is also known by its pharmaceutical name, conjugated equine estrogens.

9. In addition to manufacturing the hormone therapy drugs, Premarin, Premarin, and Premphase, the Wyeth Defendants along with the MPA Defendants manufactured and distributed another hormone drug, medroxyprogesterone acetate, which is a synthetic progestin that when taken concurrently with Premarin constitutes a form of combination hormone therapy that is pharmaceutically equivalent to the Prempro tablet.

10. On July 9, 2002, the National Heart, Lung and Blood Institute ("NHLBI"), a federal agency and part of the National Institutes of Health ("NIH"), halted a major clinical trial studying the risks and benefits of hormone therapy involving estrogen and progestin in healthy post-menopausal women. The drug used during the trial was Prempro, which

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was supplied by the Wyeth Defendants. The 16,600-patient study was abruptly halted after researchers said the risks of taking Prempro outweighed its benefits.

11. The July 2002 Prempro study came after decades of marketing efforts by the Wyeth Defendants to promote the notion that long-term use of hormone therapy-either as combination estrogen and progestin therapy (e.g., Prempro) or estrogen alone (e.g., Premarin)-could provide cardiovascular benefits to women and make women look and feel "feminine forever." The study revealed that long-term use of hormone therapy *increased* the risk of cardiovascular disease as well as the risk of invasive breast cancer, pulmonary embolism, blood clots, stroke, and heart attack.

12. Almost simultaneously, another significant study from researchers at the National Cancer Institute ("NCI") reported that women who use long-term estrogen therapy (e.g., Premarin) are at a significantly increased risk of developing ovarian cancer.

13. Immediately following the announcement of the findings of both studies, sales of Prempro and Premarin plummeted as physicians and patients alike learned that the marketing message - promoted by the Wyeth Defendants, the MPA Defendants and DOES 51 through 100 - extolling the safety and efficacy of hormone therapy was false. In particular, these studies finally exposed the true nature of the Wyeth Defendants decades-long marketing effort to promote hormone therapy as a safe and effective long-term drug regimen for post-menopausal women: for decades the Wyeth Defendants have been profiting from a misguided and fraudulent campaign that endangered the health and lives of millions of American women.

II.

PARTIES

14. Defendant Wyeth Pharmaceuticals, Inc., is a New York corporation with a principal place of business at 555 East Lancaster Avenue, St. Davids, Pennsylvania. At all times relevant hereto, Wyeth Pharmaceuticals, Inc., was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including Premarin, Prempro, Premphase, and

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medroxyprogesterone acetate. Plaintiff alleges on information and belief that Wyeth Pharmaceuticals, Inc., does business in the State of California and in Los Angeles County, and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drugs Premarin, Prempro, Premphase, and medroxyprogesterone acetate.

15. Defendant Wyeth-Ayerst Pharmaceuticals, Inc. is a New York corporation with a principal place of business at 555 East Lancaster Avenue, St. Davids, Pennsylvania. At all times relevant hereto, Wyeth-Ayerst Pharmaceuticals Inc. was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including Premarin, Prempro, Premphase, and medroxyprogesterone acetate. Plaintiff alleges on information and belief that Wyeth-Ayerst Pharmaceuticals Inc. does business in the State of California and in Los Angeles County, and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drugs Premarin, Prempro, Premphase, and medroxyprogesterone acetate.

16. Defendant Wyeth Ayerst International Inc. is a New York corporation with a principal place of business at Philadelphia, Pennsylvania. At all times relevant hereto, Wyeth Ayerst International, Inc., was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including Premarin, Prempro, Premphase, and medroxyprogesterone acetate. Plaintiff alleges on information and belief that Wyeth Ayerst International, Inc. does business in the State of California and in Los Angeles County, and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drugs Premarin, Prempro, Premphase, and medroxyprogesterone acetate.

17. Defendant Wyeth Laboratories, Inc. is a New York corporation with a principal place of business at 1300 Wolf Street, Philadelphia, Pennsylvania. At all times relevant hereto, Wyeth Laboratories, Inc. was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy

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drugs, including Premarin, Prempro, Premphase, and medroxyprogesterone acetate. Plaintiff alleges on information and belief that Wyeth Laboratories, Inc., does business in the State of California and in Los Angeles County, and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drugs Premarin, Prempro, Premphase, and medroxyprogesterone acetate.

18. Defendant Wyeth Pharmaceuticals is a Pennsylvania corporation headquartered and with a principal place of business at 500 Arcola Drive, Collegeville, Pennsylvania. At all times relevant hereto, Wyeth Pharmaceuticals was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including Premarin, Prempro, Premphase, and medroxyprogesterone acetate. Plaintiff alleges on information and belief that Wyeth Pharmaceuticals does business in the State of California and in Los Angeles County, and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drugs Premarin, Prempro, Premphase, and medroxyprogesterone acetate.

19. Defendant Wyeth, Inc., is a Delaware corporation headquartered and with a principal place of business at 5 Giralda Farms, Madison, New Jersey. At all times relevant hereto, Wyeth, Inc., was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including Premarin, Prempro, Premphase, and medroxyprogesterone acetate. Plaintiff alleges on information and belief that Wyeth, Inc., does business in the State of California and in Los Angeles County, and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drugs Premarin, Prempro, Premphase, and medroxyprogesterone acetate.

20. MPA Defendant Pharmacia & Upjohn, Inc., is a Delaware corporation headquartered and with a principal place of business at 100 Route 206 North, Peapack, New Jersey. At all times relevant hereto, Pharmacia & Upjohn, Inc., was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting,

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and selling hormone therapy drugs, including medroxyprogesterone acetate. Plaintiff alleges on information and belief that Pharmacia & Upjohn, Inc., does business in the State of California and in Los Angeles County, and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drug medroxyprogesterone acetate.

21. MPA Defendant Pfizer Inc. is a Delaware corporation headquartered and with a principal place of business at 235 East 42d Street, New York, New York. At all times relevant hereto, Pfizer Inc. was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including medroxyprogesterone acetate. Plaintiff alleges on information and belief that Pfizer Inc. does business in Pennsylvania and in Philadelphia County and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drug medroxyprogesterone acetate.

22. MPA Defendant Barr Laboratories, Inc., is a New York corporation headquartered and with a principal place of business at 2 Quaker Road, Pomona, New York. At all times relevant hereto, Barr Laboratories, Inc., was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including medroxyprogesterone acetate. Plaintiff alleges on information and belief that Barr Laboratories, Inc., does business in Pennsylvania and in Philadelphia County and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drug medroxyprogesterone acetate.

23. MPA Defendant Greenstone Ltd. is a Delaware corporation headquartered and with a principal place of business at 7000 Portage Road, Kalamazoo, Michigan. At all times relevant hereto, Greenstone Ltd. was engaged in, inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including medroxyprogesterone acetate. Plaintiff alleges on information and belief that Greenstone Ltd. does business in Pennsylvania and in Philadelphia County and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted,

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and sold the drug medroxyprogesterone acetate.

24. Plaintiff alleges on information and belief that the following companies and others not yet identified manufactured and/or distributed and/or promoted medroxy-progesterone acetate and other progestins and that Plaintiff may have ingested the progestin manufactured and/or distributed by one or more of them: Apotheca Inc.; Barr Laboratories Inc., Compumed; DRX Pharmaceutical Consultants Inc.; Duramed Pharmaceuticals Inc.; Carnrick Laboratories Inc.; Fielding Pharmaceutical Company; Greenstone Ltd.; Kaiser FDN. Hospital, a California entity located in Livermore, California; Major Pharmaceuticals; Martec Pharmaceuticals Inc.; Mylan Laboratories Inc.; Nucare Pharmaceuticals Inc. located in Orange, California; Parmed Pharmaceuticals Inc.; PD-RX Pharmaceuticals Inc.; Pharma Pac; Pharmedix, located in Hayward, California; Physicians Total Care Inc.; Qualitest Pharmaceuticals Inc.; Quality Care Pharmaceuticals Inc.; Quality Care Products LLC; R.I.D. Inc.; Rosemont Pharmaceutical Corporation; Rugby Laboratories Inc.; Southwood Pharmaceuticals Inc.; Talbert Medical Management Corp. located in Costa Mesa, California; United Research Laboratories, Inc.; Upsher-Smith Laboratories Inc.; Veratex Corp.; Warner Chilcott Inc.; and Watson Pharmaceuticals Inc., a California Corporation, located in Corona, California.

The above list is intended to include each company's subsidiaries, divisions, franchises, partners, joint venturers, organizational units of any kind, their predecessors, their successors and assigns, and their present officers, directors, employees, agents, representatives and other persons acting on their behalf.

Plaintiff will amend the Complaint and/or seek leave of the Court to amend the Complaint to name as DOES any or all of these or other companies, once Plaintiff has discovered which company/companies manufactured and/or distributed the generic progestins she ingested.

25. Plaintiff alleges on information and belief that the following companies and others not yet identified manufactured and/or distributed conjugated estrogens, and that Plaintiff may have ingested conjugated estrogens manufactured and/or distributed by them:

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Barr Laboratories Inc.; Comprehensive Consultant Services; DRX Pharmaceutical Consultants Inc.; Duramed Pharmaceuticals Inc.; Pharmedix, located in Hayward, California; and Talbert Medical Management Corp. located in Costa Mesa, California.

The above list is intended to include each company's subsidiaries, divisions, franchises, partners, joint venturers, organizational units of any kind, their predecessors, their successors and assigns, and their present officers, directors, employees, agents, representatives and other persons acting on their behalf.

Plaintiff will amend the Complaint or will seek leave of the Court to amend the Complaint to name as DOES any or all of these or other companies, once Plaintiff has discovered which company/companies manufactured and/or distributed the Hormones she ingested.

26. Plaintiff alleges on information and belief that the following companies and others not yet identified manufactured and/or distributed esterified estrogens, and that Plaintiff may have ingested esterified estrogens manufactured and/or distributed by them: Allscripts Healthcare Solutions; Apotheca Incorporated; Compumed; Direct Dispensing Inc.; DRX Pharmaceutical Consultants Inc.; King Pharmaceuticals™, Inc.; Med Pro Inc.; Monarch Pharmaceuticals; Murfreesboro Pharmaceutical Nursing Supply; Parke-Davis (Wyeth); PD-RX Pharmaceuticals Inc.; Physicians Total Care; and Quality Care.

The above list is intended to include each company's subsidiaries, divisions, franchises, partners, joint venturers, organizational units of any kind, their predecessors, their successors and assigns, and their present officers, directors, employees, agents, representatives and other persons acting on their behalf.

Plaintiff will amend the Complaint or seek leave of the Court to amend the Complaint to name as DOES any or all of these or other companies, once Plaintiff has discovered which company/companies manufactured and/or distributed the Hormones she ingested.

27. Plaintiff alleges on information and belief that the following companies and others not yet identified manufactured and/or distributed estradiol, and that Plaintiff may have ingested estradiol manufactured and/or distributed by them: 3M Pharmaceuticals Inc.;

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Aaipharma Inc.; Allscripts Healthcare Solutions; Amerisource Health Services Corp. DBA American Health Packaging AH; Apotheca Inc.; Apothecon; Barr Laboratories Inc.; Bristol Meyers Squibb Laboratories Co.; Cheshire Pharmaceutical Systems; Compumed; Direct Dispensing Inc.; DRx - The Doctor's Dispensing Network; DRX Pharmaceutical Consultants Inc.; Duramed Pharmaceuticals Inc.; ESI Lederle Generics & Pharma; Fielding; Galen; Geneva; Haines Pharmaceuticals; Kaiser FDN. Hospital, Livermore, California; Major Pharmaceuticals Inc.; Martec Pharmaceuticals Inc.; Mylan Laboratories Inc.; National Pharmpak Services Inc.; PD-Rx Pharmaceuticals Inc.; Pharma Pac; Physician's Total Care Inc.; Prestige Packaging Inc.; Qualitest Pharmaceuticals Inc.; Quality Care Pharmaceuticals Inc.; Repackaging Co. of America; Rugby Laboratories Inc.; Rugby Lab Inc.; RX Pak Div. of McKesson HBOC; Sandoz; Teva Pharmaceuticals USA Inc.; Watson Pharmaceuticals Inc. a California Corporation located in Corona, California; and Zenith Goldline Pharmaceuticals.

The above list is intended to include each company's subsidiaries, divisions, franchises, partners, joint venturers, organizational units of any kind, their predecessors, their successors and assigns, and their present officers, directors, employees, agents, representatives and other persons acting on their behalf.

Plaintiff will amend the Complaint or seek leave of the Court to amend the Complaint to name as DOES any or all of these or other companies, once Plaintiff has discovered which company/companies manufactured and/or distributed the Hormones she ingested.

28. Plaintiff alleges on information and belief that the following companies and others not yet identified manufactured and/or distributed estropipate, and that Plaintiff may have taken estropipate manufactured and/or distributed by them: Barr Labs Inc.; Duramed Pharmaceuticals Inc.; Mylan Laboratories Inc.; Noramco Inc.; Ortho-McNeil Pharmaceutical; Qualitest Pharmaceuticals Inc.; United Research Laboratories Inc.; Watson Pharmaceuticals Inc. a California Corporation, located in Corona California; and Women First HealthCare Inc.

The above list is intended to include each company's subsidiaries, divisions,

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franchises, partners, joint venturers, organizational units of any kind, their predecessors, their successors and assigns, and their present officers, directors, employees, agents, representatives and other persons acting on their behalf.

Plaintiff will amend the Complaint or seek leave of the Court to amend the Complaint to name as DOES any or all of these or other companies, once Plaintiff has discovered which company/companies manufactured and/or distributed the Hormones she ingested.

29. Plaintiff also alleges on information and belief that one or more chain pharmacies and/or large health care providers and/or health insurance companies, some of which are named above, may have manufactured and/or repackaged and distributed generic hormones. Plaintiff will seek leave of the Court to amend the Complaint to include any or all of these companies, once Plaintiff has discovered which company/companies manufactured and/or distributed the drugs she ingested.

30. Plaintiff is informed and believes, and thereupon alleges, that at all times mentioned herein and at the time of filing of this action, the Individual Defendants (Defendants Michelle Luna and DOES 1 through 50, inclusive, and each of them) were and now are citizens of the State of California and residents of the County of San Francisco, State of California, were and now are employees, servants or ostensible agent, agents, of the Wyeth Defendants, the MPA Defendants, and Defendant DOES 51 through 100, inclusive, and each of them, and were and now are operating out of the County of San Francisco, State of California and the County of San Mateo, State of California.

III.

FACTUAL BACKGROUND

A. The Marketing of Hormone Therapy

31. Hormone "Replacement" Therapy or "HT" most commonly refers to the combination of both conjugated estrogens (estrogen) and progesterone (progestin). Estrogen used alone is sometimes known as Estrogen "Replacement" Therapy, "ET," estrogen alone, or estrogen unopposed. HT and ET are prescription therapies provided to women during and after menopause. HT is prescribed to women who have made the

natural transition to menopause through the aging process. ET is prescribed to women who have had a surgical menopause through hysterectomy.[1] In general, hormone therapy is an umbrella term that is used to refer to either the use of combination hormone therapy (that is, estrogen and progesterone) or to the use of estrogen alone.

32. In the average female reproductive life, the period of menopause can occur from age 51 until death. During menopause, a woman's estrogen level drops sharply. Hot flashes-which for some women are just a vague feeling of warmth, for others, the skin suddenly flushes and beads with sweat, while the pulse races-are a very common symptom of menopause. When estrogen levels drop off, so does calcium in the skeleton. As a result, the risk of osteoporosis and spine, hip, and other fractures goes up.

33. Menopause is a major issue in the lives of millions of women. Natural menopause comes at a time when women are relatively young, usually between 46 and 62, when most American women live to an average age of 80. As a result, the consequences of menopause are felt for years after the menopause begins.

34. Menopause has been described in scientific literature since the late 1800s. By the turn of the 20th century, the search for an aid to maintaining the youth, health, sex, and vitality of women was widely pursued. The increasing awareness of the effects of menopause made a drug to "cure" menopause a blockbuster drug waiting to happen. In 1942, Ayerst, the predecessor to the Wyeth Defendants, received approval for the patent of that blockbuster, Premarin, a mix of estrogens extracted from the urine of pregnant mares.

35. The same year the predecessor to the Wyeth Defendants patented Premarin it also received FDA approval. Premarin was marketed early on as "Replacement" therapy because it "replaced" the estrogens that began to disappear from a woman's body.

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[1] Estrogen therapy is prescribed to women who have any one of three types of hysterectomy: *subtotal* (where only the uterus is removed and the ovaries and cervix remain intact); *total* (where both the uterus and cervix are removed but the ovaries remain), or *total plus oopherectomy* (where at least one ovary is removed along with the uterus and cervix).

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36. The Wyeth Defendants have vigorously promoted its hormone therapy products - using marketing efforts directed to physicians and programs intended to reach consumers directly (i.e., "direct-to-consumer" or "DTC" marketing). The intention of Wyeth's marketing efforts was to create a lifelong demand for its hormone therapy drugs and a willingness by physicians to prescribed these drugs to their post-menopausal patients.

37. There are an estimated 50 million post-menopausal women in the United States. Menopause is a natural condition and process and not a disease. In July 2002, approximately 38% of postmenopausal women in the United States used estrogen or hormone replacement therapy, including approximately six million American women who were taking Prempro.

38. The Wyeth Defendants' DTC 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 speakespersons. In 1999, the Wyeth Defendants spend $34.7 million on DTC advertising for Prempro, one of its hormone therapy drugs. In 2000, Wyeth spent $37.4 million on Prempro DTC advertising.

39. Wyeth's hormone therapy drugs, Prempro and Premarin, were designed and have been approved by the FDA only to relieve menopausal symptoms, such as hot flasks and vaginal atropy, and osteoporisis. The Wyeth Defendants, however, have long touted additional benefits for their hormone therapy drugs, beyond these FDA-approved uses.

40. Wyeth marketing hormone therapy marketing efforts have a long history. In 1962, a Brooklyn, New York, gynecologist, Dr. Robert Wilson, wrote an article, also appearing in the Journal of the American Medical Association (JAMA), that claimed taking estrogen during menopause reduces breast and genital cancers. Then, in 1966, Dr. Wilson wrote his bestseller entitled Feminine Forever. In it, Dr. Wilson recommended estrogen as the "cure" for "the tragedy of menopause." He argued that women who use the drugs "will

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be much more pleasant to live with and will not become dull and unattractive." In writing about the menopause condition, which he termed the "deficiency disease," 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." Dr. Wilson asserted that estrogen prevents breast and genital cancers, such as endometrial cancer (i.e., cancer of the uterine lining).

41. The FDA later said that Dr. Wilson's recommendations went beyond approved use for hormone therapy and that it would no longer accept his data. However, soon after the publication of Dr. Wilson's book, the Wyeth Defendants' sales force began to distribute the book to physicians throughout the country. The Wyeth Defendants poured thousands of dollars into Dr. Wilson's research. The Wyeth Defendants ran ads in medical journals that read: "Treat her with Premarin. Keep her on Premarin." Following Dr. Wilson's publications, sales of Premarin quadrupled. 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.

42. In 1973, an article appearing 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."

43. In a print advertisement that the Wyeth Defendants published in the October 13, 1975, edition of JAMA, the Wyeth Defendants claimed that "tension, irritability, headaches, undue fatigue, depression and insomnia," when caused by declining menopausal estrogen levels, may be relieved with Premarin. Additionally, at the top of the advertisement, in large print, Wyeth advised doctors, "Almost any tranquilizer might calm her down ... but at her age, estrogen maybe what she really needs."

44. But, by the mid-70s it also became evident that women using estrogen began

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to show a significant increase of endometrial cancer. In 1976, the first study showing a link between menopausal estrogen and endometrial cancer appeared in the New England Journal of Medicine. Consequently, physicians stopped prescribing Premarin for women, except for those who had hysterectomies and therefore were not at risk for endrometrial cancer. Estrogen sales plummeted and by 1979, the only approved use of estrogen was for treatment of hot flashes and vaginal dryness. The Wyeth Defendants therefore had to come up with a new justification for menopausal women without hysterectomies to continue taking Premarin. In 1980, an article by Dr. Don Gambrell that appeared in the journal, Obstetrics and Gynecology, reported that adding progestin to estrogen led to a decline in endometrial cancer. This progestin (i.e., synthetic progesterone or medroxyprogesterone acetate) was therefore added to the estrogen hormone therapy regimen to protect the uterus.

45. The Wyeth Defendants, as well as the MPA Defendants and DOES 51 through 100, have 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.

46. In 1985, the Wyeth Defendants developed another spin on the marketing of hormone therapy drugs, claiming that the drugs could help prevent bone loss. The Wyeth Defendants hired a public relations firm to create public awareness of osteoporosis and learned that 77% of women never heard of osteoporosis. As a result, the Wyeth Defendants' public relations campaign sought to tell women that osteoporosis is a devastating disease and that its estrogen drug, Premarin, could treat it. Soon, their public relations campaign created support for a National Osteoporosis Week and eventually, a National Osteoporosis Foundation (to which the Wyeth Defendants contributed).

47. The Wyeth Defendants also sought to claim that hormone therapy drugs, such as Premarin, could prevent cardiovascular disease. By claiming as the Wyeth Defendants did that hormone therapy drugs prevent the biggest killer of all, cardiovascular disease, Premarin could be promoted as recommended treatment for all women. In 1985,

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the Nurses Health Study was released and the Wyeth Defendants asserted that the study proved this very assertion-hormone therapy prevented cardiovascular disease.

48. The Nurses Health Study, which was based on questionnaires of almost 122,000 female nurses, including 32,300 post-menopausal women, suggested that women using hormone therapy were at a lesser risk of developing coronary heart disease. Soon enough, researchers were producing many studies championing the use of hormone therapy to prevent heart disease and bone loss, without the risk of cancer, stroke or blood clots. As a result of the Wyeth Defendants efforts to generate and promote research that supported the conclusion that hormone therapy protected women's cardiovascular system, between 1990 and 1995 Premarin became the most frequently dispensed prescription drug in the United States.

49. The Wyeth Defendants' hormone therapy promotion and marketing efforts overstated the conclusions of the Nurses Study. Researchers were still uncertain of the final assessment of the benefits and risks of hormone therapy. For instance, the Nurses Study was significant in size, but it was not a randomized study where participant results are compared between drug users and participants using placebo, the type of study considered the gold standard in medical research. Moreover, the participants in The Nurses' Study were educated and compliant "patients"-actually nurses-who were more keenly aware of their health conditions and at a lower risk for heart disease regardless of hormone therapy.

50. In addition to Wyeth's research efforts to support its overreaching claims its hormone therapy drugs, the drug maker's marketing juggernaut sailed forward, unimpeded by the lack of scientific support for its claims. For instance, in March of 1998, Wyeth offered a free magazine subscription (to "Seasons" magazine) to women taking its hormone therapy drugs in exchange for submitting personal information to Wyeth on a postcard or by calling a toll-free phone number. Beginning in early 1999, Wyeth also distributed a brochure to women through the waiting rooms of physicians' offices, that claimed, "Menopause isn't gone in a flash - its debilitating consequences can affect the rest

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of your life." The promotional brochure also directed women to "Take a few minutes to think about the rest of your life" and listed a number of conditions 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.

51. 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 1 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."

52. A cornerstone of the marketing Wyeth program was promotion of hormone therapy for long-term use of indefinite duration. Specifically, *JAMA* reported that:

> In 2000, 46 million prescriptions were written for Premarin (conjugated estrogens), making it the second most frequently prescribed medication in the United States and accounting for more that $ 1 billion in sales, and 22.3 million prescriptions were written for Prempro (conjugated estrogents plus medroxyprogestrone acetate). While US Food and Drug Administration-approved indications for hormone therapy include relief of menopausal symptoms and prevention of osteoporosis, *long-term use has been in vogue to prevent a range of chronic conditions, especially heart disease.*

(Emphasis added.)

53. In or around 1993, Wyeth distributed a videotape to consumers entitled, "What every woman should know about estrogen." This videotape claimed to be a "seminar for women" and depicted a female doctor advising women about menopause and hormone therapy. Wyeth's video "seminar" warned of a wide variety of illnesses and

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ailments purportedly associated with menopause. Among other things, Wyeth represented that estrogen loss causes bones to become "brittle," skin to become "dryer," and sexual intercourse to become "painful and irritating." While Wyeth's video "seminar" was exhaustive in its warnings about menopause, it glossed over the dangers and risks associated with hormone therapy.

54. In its "What every woman should know about estrogen" video seminar, Wyeth also represented to women that estrogen provided "long term health protection" and should be continued indefinitely, even after short term menopausal symphony, 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, through its video "seminar" that the benefits of taking estrogen "far outweigh[ed]" the risks for women unless they faced a particularly high risk of breast cancer.

55. Faced with the threat of a shrinking market for Premarin because of the end of its patent protection in 1995, the Wyeth Defendants began to develop a combination therapy pill that would combine its super pill, Premarin, with progestin. In 1995, the Wyeth Defendants introduced Prempro, one of the first estrogen-plus-progestin hormone therapy pills approved by the FDA.

56. Soon after introduction of Prempro, the Wyeth Defendants began funding a four year heart disease prevention trial, called HERS: Heart and Estrogen/Progestin Replacement Study. The Wyeth Defendants had high hopes that HERS would show that hormone therapy prevents heart disease in high-risk women and that, as a result, Prempro would become an FDA-approved drug for heart disease. But in 1998, the HERS investigators reported that hormone therapy did not reduce the rate of coronary heart disease events in women with heart disease. The Wyeth Defendants' hopes were left to a very important study underway known as the WHI study or Women's Health Initiative Study.

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57. While the Wyeth Defendants waited for the WHI study researchers to collect their data and reach their conclusions, the drug maker's overzealous hormone therapy marketing effort continued. At least until mid-2002, the Wyeth Defendants distributed a hormone therapy promotional brochure targeted for women consumers. Wyeth emblazoned across the front cover of its brochure the words "Starting your Hormone Replacement Therapy (HRT)." At the bottom of the cover and at the bottom of nine of its seventeen pages of text, the following words appear: "Say yes to PREMPRO." The brochure contains testimonial statements from women taking Prempro, such as, "I wanted an HRT that was established, time tested, and had a successful track record. I'm delighted with PREMPRO" and "With PREMPRO, I know I've taken action to protect my health - and that's truly empowering." The unbalanced nature of Wyeth's marketing efforts is typified by the inadequate warnings contained in the "Side Effects" section of Wyeth's "Say yes to PREMPRO" brochure. In the section, the Wyeth Defendants warn about uterine cancer (associated with estrogen-only therapy), worsening diabetes, nausea, abdominal pain, irregular bleeding, headache, hair loss, and breast tenderness.

58. The 2001 Annual Report of the Wyeth Defendants contains a similarly testimonial statement from a Philadelphia woman: "I started taking Premarin after a hysterectomy, and it made an immediate difference in getting me back to normal. *Now, more than 15 years later*, I continue to lead an active life." (Emphasis added.)

B. <u>The WHI and NCI Studies</u>

59. For years estrogen and progestin hormone therapy were thought to be drugs of prevention. It was originally thought that the prevention of osteoporosis and heart disease were two of the main long-term benefits for taking hormone therapy. The WHI and NCI studies released in July 2002 changed the way doctors and scientists viewed estrogen-not only does estrogen hormone therapy fail to prevent disease, it substantially increases the risk of *causing* disease.

60. There are two studies that form the foundation for the new conclusion that the risks of hormone therapy outweigh the benefits for most women given the present

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