Case 0:07-cv-01795-PAM-JSM Document 1 Filed 04/06/2007 Page 1 of 9

# UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

RACHEL FLEEGER,	NO	
Plaintiff,	NO	
v. WYETH, and its division WYETH PHARMACEUTICALS, INC. and GREENSTONE LTD;  Defendants.	COMPLAINT FOR DAMAGES Personal Injury Action (28 U.S.C. §1332) [DEMAND FOR JURY TRIAL]	

# NATURE OF THE CASE

1. Plaintiff, RACHEL FLEEGER, developed breast cancer caused by her ingestion of prescription hormone replacement therapy medications, specifically Premarin, Prempro and Medroxyprogesterone, ("hormone therapy drugs" or "hormone therapy products"). This lawsuit asserts claims for negligence; strict product liability for design defect; strict product liability for failure to warn; and breach of implied warranty against the defendants responsible for the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of those hormone therapy products that caused her cancer.

# JURISDICTION AND VENUE

- 2. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §1332 (diversity of citizenship). The matter in controversy in this civil action exceeds the sum or value of \$75,000, exclusive of costs and interests, as to each defendant, and is between citizens of different states.
- 3. Venue is proper in this district under 28 U.S.C. §1391 because defendants transact business in this district.

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COMPLAINT FOR DAMAGES

# THE PARTIES

#### **Plaintiff**

4. At all material times, Plaintiff RACHEL FLEEGER has been resident and citizen of Venango County, Pennsylvania.

#### Defendant

- 5. Defendants as to Premarin and Prempro Plaintiff ingested:
- a. Defendant Wyeth, and its division, Wyeth Pharmaceuticals, Inc., is a New Jersey corporation with its principal place of business in Pennsylvania. Wyeth is licensed to do business in all states of the United States of America. At all relevant times, this defendant was engaged in the design, manufacturer, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and/or distribution of pharmaceutical products, including the hormone therapy drugs Premarin and Prempro, for ultimate sale and/or use in the United States of America, including but not limited to the state of Minnesota, as well as in various foreign jurisdictions.
  - 6. Defendants as to Medroxyprogesterone Plaintiff ingested:
- a. Defendant Greenstone, Ltd. is a Delaware corporation with its principal place of business in Kalamazoo, Michigan and may be served with process through its agent for service, to-wit: The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801. At all relevant times, this defendant was engaged in the design, manufacture, production, and/or distribution of pharmaceutical products, including the hormone therapy drug Medroxyprogesterone.

## **FACTUAL ALLEGATIONS**

#### Plaintiff's Injuries

- 7. Plaintiff RACHEL FLEEGER ingested Defendants' hormone therapy drugs, specifically Premarin, Prempro and Medroxyprogesterone. She first began ingesting the hormone therapy drugs in 1995. She stopped ingesting the hormone therapy drugs in April, 2001.
- 8. As a result of ingesting these hormone drugs, Plaintiff developed breast cancer, resulting in personal injuries and damages. Her breast cancer was diagnosed in April, 2001.

# Defendants' Misconduct

- 9. At all material times, each defendant was responsible for designing, manufacturing, producing, testing, studying, inspecting, mixing, labeling, marketing, advertising, selling, promoting, and/or distributing their hormone drugs described herein, which Plaintiff ingested.
- 10. Each defendant had an independent obligation to know, analyze, and disclose scientific and medical information about their hormone therapy drugs in a timely and adequate manner, and to provide warnings about risks and side effects as soon as it was aware of them. Each defendant failed to do so with respect to their hormone therapy drugs that Plaintiff ingested, including by failing to know, analyze, and/or disclose an increased incidence and risk of strokes, blood clots, heart attacks, breast cancers, and ovarian cancer from these drugs.
- 11. Each defendant made claims regarding the health benefits of ingesting their hormone drugs, and the risks and side effects of these drugs. Each defendant knew or should have known that these claims were false and misleading. They failed to adequately disclose the true health consequences, and the true risks and side effects from these drugs, including the increased incidence and risks of strokes, blood clots, heart attacks, breast cancers, and ovarian cancer.
- 12. Each defendant failed to conduct adequate pre-marketing clinical testing and research, and failed to conduct adequate post-marketing surveillance, to determine the safety of their hormone drugs, including with respect to the causal connection between their hormone therapy drugs and strokes, blood clots, heart attacks, breast cancers, and ovarian cancer.
- 13. Each defendant failed to disclose on their warning labels or elsewhere that adequate premarketing clinical testing and research, and adequate post-marketing surveillance, had not been done, thereby giving the false impression that their hormone therapy drugs had been sufficiently tested.

  Each defendant knew or should have known that, at all material times, its communications about the benefits, risks, and adverse effects of its hormone therapy drugs, including communications in labels, advertisements and promotional materials, were materially false and misleading. In the alternative, each defendants was ignorant of whether or not its communications about its hormone drugs were true in material ways.
- 14. Plaintiff would not have ingested the hormone therapy drugs described herein, or would have discontinued their use, or would have used safer alternative methods, had defendants disclosed the COMPLAINT FOR DAMAGES

true health consequences, risks, and adverse events, including the increased incidence and risk of strokes, blood clots, heart attacks, breast cancers, and ovarian cancer, among other illnesses, caused by their hormone drugs.

15. Each defendant's nondisclosures and misrepresentations as alleged herein were material, and were substantial factors that contributed directly and causally, and naturally and necessarily, to the serious injuries and damages that Plaintiff has suffered.

#### FRAUDULENT CONCEALMENT

- 16. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to her pursuit of these claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing a complaint on her causes of action. Their fraudulent concealment did result in such delay. Plaintiff could not reasonably have discovered these claims until shortly before filing this complaint.
- 17. The Defendants are and were under a continuing duty to disclose the true character, quality, and nature of their hormone drugs that Plaintiff ingested, but instead they concealed them. As a result, Defendants are estopped from relying on any statute of limitations defense.

#### APPLICATION OF THE DISCOVERY RULE

18. At a minimum, before Defendants publicly disseminated information concerning the risks of hormone therapy drugs in July, 2002, Plaintiff did not discover, Plaintiff could not have discovered and Plaintiff should not have discovered, through the exercise of reasonable care and due diligence, the causal connection between Plaintiff's injuries and the hormone therapy drugs she ingested. Accordingly, the applicable discovery rule has tolled the commencement of the statute of limitations until July, 2002, at the earliest. Plaintiff's lawsuit is timely filed.

#### **CLAIMS FOR RELIEF**

#### First Claim Against All Defendant

#### (Negligence)

- 19. Plaintiff realleges all previous paragraphs.
- 20. Defendants introduced their hormone therapy drugs described herein into the stream of

  COMPLAINT FOR DAMAGES

commerce. At all material times, Defendants had a duty to Plaintiff and other consumers of their hormone therapy drugs to exercise reasonable care in order to properly design, manufacture, produce, test, study, inspect, mix, label, market, advertise, sell, promote, and distribute these products. This includes a duty to warn of side effects, and to warn of the risks, dangers, and adverse events associated with their hormone drugs.

- 21. Defendants knew, or in the exercise of reasonable care should have known, that their hormone therapy drugs were of such a nature that they were not properly designed, manufactured, produced, tested, studied, inspected, mixed, labeled, marketed, advertised, sold, promoted, and distributed, and they were likely to cause injury to those who ingested them.
- 22. Defendants were negligent in the design, manufacture, production, testing, study, inspection, mixture, labeling, marketing, advertising, sales, promotion, and distribution of their hormone therapy drugs, and breached duties they owed to Plaintiff. In particular, Defendants:
  - failed to use due care in the preparation of their hormone therapy drugs to prevent the aforementioned risks to women when the drugs were ingested;
  - failed to use due care in the design of their hormone therapy drugs to prevent the
     aforementioned risks to women when the drugs were ingested;
  - failed to conduct adequate pre-clinical testing and research to determine the safety
     of their hormone therapy drugs;
  - failed to conduct adequate post-marketing surveillance to determine the safety of their hormone therapy drugs;
  - failed to accompany their products with proper warnings regarding all possible
    adverse side effects associated with the use of their hormone therapy drugs and
    the comparative severity and duration of such adverse effects;
  - f. failed to use due care in the development of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
  - g. failed to use due care in the manufacture of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
  - h. failed to use due care in the inspection of their hormone therapy drugs to prevent

    -5
    COMPLAINT FOR DAMAGES

- the aforementioned risks to individuals when the drugs were ingested;
- failed to use due care in the labeling of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- failed to use due care in the marketing of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- k. failed to use due care in the promotion of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- 1. failed to use due care in the selling of their hormone therapy drugs to prevent the aforementioned risks to individuals when the drugs were ingested;
- failed to provide adequate information to healthcare providers for the appropriate
   use of their hormone therapy drugs;
- failed to adequately warn about the health consequences, risks, and adverse events
   caused by their hormone therapy drugs; and
- o. were otherwise careless and negligent.
- 23. Defendants knew or should have known that their hormone therapy drugs caused unreasonable harm and dangerous side effects that many users would be unable to remedy by any means. Despite this, Defendants continued to promote and market their hormone therapy drugs for use by consumers, including Plaintiff, when safer and more effective methods of countering the negative health effects of menopause were available.
- 24. It was foreseeable to Defendants that consumers, including Plaintiff, would suffer injury as a result of Defendants' failure to exercise ordinary care as described herein.
- 25. As a direct and proximate result of Defendants' conduct, Plaintiff suffered the injuries and damages specified herein.

# Second Claim Against All Defendants

(Strict Liability: Design Defect)

- 26. Plaintiff realleges all previous paragraphs.
- 27. Defendants manufactured, sold, and supplied the hormone therapy drugs described herein, and at all material times were in the business of doing so. They placed these drugs into the

  COMPLAINT FOR DAMAGES

stream of commerce. These drugs were expected to, and did, reach Plaintiff without substantial change in their condition. Plaintiff ingested these hormone therapy drugs.

- At time the hormone therapy drugs left defendants' hands, these drugs were in a 28. condition not contemplated by Plaintiff, and were unreasonably dangerous to her. These hormone therapy drugs were each dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased them. They were more dangerous than Plaintiff contemplated.
- The risks of each of these hormone therapy drugs outweigh its utility. There were 29. practicable and feasible safer alternatives to the defendants' hormone therapy drugs for treating menopause symptoms.
  - 30. Defendants' hormone drugs are defective and unreasonably dangerous.
- As a direct and proximate result of defendants' conduct, Plaintiff suffered the injuries 31. and damages specified herein.

# **Third Claim Against All Defendants**

(Strict Liability: Failure to Warn)

- 32. Plaintiff realleges all previous paragraphs.
- Defendants manufactured, sold, and supplied the hormone therapy drugs described 33. herein, and at all material times were in the business of doing so. They placed these drugs into the stream of commerce. These drugs were expected to, and did, reach Plaintiff without substantial change in their condition. Plaintiff ingested these hormone therapy drugs.
- When defendants placed their hormone therapy drugs into the stream of commerce, they 34. failed to accompany them with adequate warnings. They failed to warn of the true risks and dangers, and of the symptoms, scope and severity of the potential side effects of the hormone therapy products Plaintiff ingested. These risks, dangers, and side effects include, but are not limited to, strokes, blood clots, heart attacks, breast cancers, and ovarian cancer.
- Due to the inadequate warnings as alleged herein, at the time the hormone therapy drugs 35. left defendants' hands, these drugs were in a condition not contemplated by Plaintiff, and were unreasonably dangerous to her. They were dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased them. They were more dangerous than Plaintiff COMPLAINT FOR DAMAGES

contemplated. Furthermore, their risks outweighed their utility.

- 36. Defendants' hormone drugs described herein are defective and unreasonably dangerous.
- 37. Had defendants provided adequate warnings and instructions, Plaintiff would not have ingested these drugs, and would not have suffered the personal injuries she did.
- 38. As a direct and proximate result of defendants' conduct, Plaintiff suffered the injuries and damages specified herein.

#### Fourth Claim Against All Defendants

## (Breach of Implied Warranty)

- 39. Plaintiff realleges all previous paragraphs.
- 40. At the time defendants designed, manufactured, produced, tested, studied, inspected, mixed, labeled, marketed, advertised, sold, promoted, and distributed their hormone drugs for use by Plaintiff, they knew of the use for which their hormone drugs were intended, and impliedly warranted their products to be of merchantable quality and safe and fit for their intended use.
- 41. Contrary to such implied warranty, their hormone drugs were not of merchantable quality or safe or fit for their intended use because they were and are unreasonably dangerous and unfit for the ordinary purposes for which they were used, as alleged herein.
- 42. As a direct and proximate result of defendants' conduct, Plaintiff suffered the injuries and damages specified herein.

#### PRAYER FOR RELIEF

- 43. WHEREFORE, Plaintiff seeks judgment in Plaintiff's favor against the defendants, jointly and severally, as follows:
  - a. economic and non-economic damages in an amount in excess of \$75,000 as to each as provided by law and to be supported by the evidence at trial;
  - b. an award of attorneys' fees and costs of suit, as provided by law;
  - c. such other legal and equitable relief as this Court deems just and proper.

# JURY DEMAND

Plaintiff requests trial by jury.

DATED this 5<sup>th</sup> day of April, 2007.

# RACHEL FLEEGER, PLAINTIFF

"/s David M. Langevin"
David M. Langevin
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CV

# U.S. District Court District of Minnesota (DMN) CIVIL DOCKET FOR CASE #: 0:07-cv-01795-PAM-JSM

Fleeger v. Wyeth et al

Assigned to: Senior Judge Paul A. Magnuson Referred to: Magistrate Judge Janie S. Mayeron

Demand: \$75,000

Cause: 28:1332-pip-Diversity-Personal Injury, Product

Liability

Date Filed: 04/06/2007 Jury Demand: Plaintiff

Nature of Suit: 365 Personal Inj. Prod.

Liability

Jurisdiction: Diversity

#### **Plaintiff**

**Rachel Fleeger** 

# represented by David M Langevin

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V.

# **Defendant**

# Wyeth

and its division Wyeth Pharmaceuticals, Inc.

# **Defendant**

#### Greenstone, Ltd.

Date Filed	#	Docket Text	
04/06/2007	1	COMPLAINT with Jury Demand against Wyeth, Greenstone, Ltd.	

	(Filing fee \$350 receipt number 4012240) assigned to Senior Judge Paul A. Magnuson per Master List referred to Magistrate Judge Janie S. Mayeron, filed by Rachel Fleeger.(jc) (Entered: 04/06/2007)
04/06/2007	Summons Issued as to Wyeth, Greenstone, Ltd. (jc) (Entered: 04/06/2007)

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