UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: MIRAPEX PRODUCTS LIABILITY LITIGATION	MDL No. 07-1836 (JMR/FLN)
This document pertains to:	
BRIAN D. HEARN AND BETTIANNE HEARN, Plaintiffs, v.	Civil No.: 07 CV 973 (JMR/FLN)
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., a Delaware corporation, PFIZER INC., a Delaware corporation, PHARMACIA CORPORATION, a Delaware corporation and PHARMACIA & UPJOHN COMPANY LLC, Defendants.	**AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs Brian D. Hearn and Bettianne Hearn, for their causes of action against the above-named defendants, allege and state on information and belief as follows:

PARTIES, JURISDICTION & VENUE

1.

At all times material herein, plaintiffs Brian and Bettianne Hearn resided, and currently reside, in Phoenix, Arizona. Plaintiff Brian Hearn ("Plaintiff Hearn") developed a pathological gambling addiction and/or other compulsive behaviors caused by his use of Mirapex. Plaintiff Bettianne Hearn is the spouse of Plaintiff Hearn.

2.

Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation authorized to do business in the State of Minnesota and has appointed an agent for service of process in this State.

3.

Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer Ingelheim") is a Delaware corporation authorized to do business in the State of Minnesota and has appointed an agent for service of process in this State.

4.

Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation authorized to do business in the State of Minnesota and has appointed an agent for service of process in this State. Defendant Pharmacia is a wholly-owned subsidiary of defendant Pfizer. On information and belief, Pharmacia was acquired by Pfizer pursuant to an Agreement and Plan of Merger dated July 13, 2002.

5.

Defendant Pharmacia & Upjohn Company LLC ("Pharmacia & Upjohn") is a limited liability company whose sole member is Pharmacia & Upjohn LLC, whose sole member is Pharmacia, which is solely owned by Pfizer. Pharmacia & Upjohn is authorized to do business in the State of Minnesota and has appointed an agent for service of process in this State. On information and belief, in April 2000, Pharmacia & Upjohn completed a merger with Monsanto and Searle creating Pharmacia.

6.

Defendants Pfizer, Boehringer Ingelheim, Pharmacia and Pharmacia & Upjohn (collectively "defendants") are in the business of researching, testing, developing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly

through third parties or related entities, the pharmaceutical drug Mirapex, both in Minnesota and throughout the United States.

7.

This action is properly before the Court because there exists complete diversity of citizenship between Plaintiffs and Defendants. In addition, the amount in controversy claimed by each plaintiff exceeds $75,000. As a result, this Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a).

8.

Defendants are subject to the *in personam* jurisdiction of this Court, and venue is therefore proper herein pursuant to 28 U.S.C. § 1391, because defendants did and/or do business within and have continuous and systematic contacts with the State of Minnesota, have consented to jurisdiction in the State of Minnesota and/or committed a tort in whole or in part in the State of Minnesota against plaintiff, as more fully set forth herein. On information and belief, defendants also advertised in this district, made material omissions and representations in this district, and breached warranties in this district.

FACTUAL BACKGROUND

9.

Defendants jointly created, developed, designed, researched, manufactured, tested, labeled, packaged, launched, supplied, marketed, sold, advertised, promoted, and distributed in interstate commerce the pharmaceutical pramipexole dihydrochloride under the brand name Mirapex. Mirapex is indicated for treatment of the signs and symptoms of idiopathic Parkinson's Disease and of Restless Legs Syndrome. On information and belief, Mirapex is

promoted by defendants and/or commonly prescribed for treatment of the signs and symptoms of other movement disorders and depression.

10.

Parkinson's Disease is a chronic progressive neurological disease caused by degeneration of brain cells that produce the chemical messenger dopamine. Parkinson's Disease is marked especially by tremor of resting muscles, rigidity, slowness of movement, impaired balance, and a shuffling gait. RLS is also a neurological disorder believed to be caused by a dopamine imbalance in the brain. RLS is a condition in which one's limbs, particularly one's legs, feel extremely uncomfortable while sitting or lying down.

11.

Mirapex is within the class of drugs known as dopamine agonists. Dopamine agonists directly stimulate dopamine receptors and mimic the action of dopamine in the brain.

12.

There are at least five types of dopamine receptors in the brain, numbered D_1 to D_5. Dopamine agonists function by binding to those receptors. The function of any particular type of dopamine agonist is determined in part by its affinity or selectivity for particular receptors. Mirapex has the strongest affinity for D_3 dopamine receptors and also binds to the D_2 and D_4 receptors. The D_3 receptors are most highly concentrated in the brain's mesolimbic pathway, an area of the brain associated with pleasure, reward-seeking behavior and reinforcement systems.

13.

In December 1995, Pharmacia & Upjohn submitted an Application to Market a New Drug ("NDA") to the United States Food and Drug Administration ("FDA"). The application was resubmitted in January 1997. The applications sought approval to market Mirapex tablets

containing doses of 0.125 mg, 0.25 mg, 1.0 mg, 1.25 mg and 1.5 mg for the treatment of the signs and symptoms of Parkinson's Disease (NDA 20-667). In July 1997, the FDA approved Mirapex for treating adults with Parkinson's Disease.

14.

Defendants embarked upon a massive promotional campaign urging doctors to use Mirapex, but defendants have never warned that Mirapex causes pathological gambling addiction. Defendants have never sent out any "Dear Doctor" letters to inform doctors of this risk of Mirapex.

15.

Defendants changed the Mirapex label or prescribing information in March 2005 to reflect post-marketing reports associating Mirapex with pathological gambling and other compulsive behaviors. Prior to this change, the Mirapex label made no mention of the link between compulsive behaviors, like pathological gambling, and Mirapex. The March 2005 label change added a short paragraph at the end of the ADVERSE REACTIONS section entitled "post-Marketing Experience" that noted that "compulsive behaviors (including sexual and pathological gambling)" have been identified as adverse reactions to Mirapex. In February 2006, defendants added two short paragraphs in the PRECAUTIONS section of the Mirapex label or prescribing information entitled "Impulse Control/Compulsive Behaviors" and "Information for Patients," respectively. These revisions state that "impulse control disorders/compulsive behaviors can occur" while taking Mirapex, including "pathological gambling." The revised label or prescribing information also states that Mirapex-related compulsive behaviors "are generally reversible upon dose reduction or treatment discontinuation." To date, there is no

mention of compulsive behaviors in the "WARNINGS" section of the label or prescribing information.

16.

Defendants had, or should have had, knowledge that Mirapex can cause compulsive behaviors like pathological gambling addictions long before the labeling changes of March 2005 and February 2006.

17.

In August 2005, doctors from the Mayo Clinic published a report in the *Archives of Neurology* entitled "Pathological Gambling Caused by Drugs Used to Treat Parkinson's Disease." This study reported that eleven of the clinic's Parkinson's Disease patients, all of whom were on dopamine agonists, had recently developed pathological gambling addiction. Of the eleven, nine were taking Mirapex. For the eight patients with whom the doctors were able to follow up, all of these patients' gambling problems resolved after discontinuing the dopamine agonist. The Mayo doctors concluded that an association existed between pathological gambling and dopamine agonist therapy, that Mirapex was the agonist primarily implicated and that this may be related to the disproportionate stimulation of the D_3 dopamine receptor. The study concluded that dopamine agonists "appear to be *uniquely implicated* as a cause of pathological gambling and that disproportionate stimulation of dopamine receptors in the brain may be responsible."

18.

Since the Mayo study was published, the lead author, Dr. M. Leeann Dodd, has stated that fourteen other Mayo Clinic patients have since been found to have the same problem. According to Dr. Dodd in the American Psychiatric Association publication *Psychiatric News*,

affected patients are usually switched to different drugs or doses, and the result is often dramatic, "like a light switch being turned off when they stopped the drug."

19.

In 2003, two years before the Mayo study, Dr. Mark Stacy and his colleagues at the Muhammad Ali Parkinson Research Center at the Barrow Neurological Institute in Phoenix published a study linking dopamine agonists with pathological gambling. In this retrospective database review of 1,884 Parkinson's patients, Dr. Stacy and his colleagues reported the correlation of Mirapex with pathological gambling. The authors found that the overall incidence of pathological gambling in their patients with Parkinson's was .05%, regardless of therapy, but the incidence of pathological gambling for patients on Mirapex was 1.5%. The authors noted that their patients' excessive gambling seemed to begin with an increase in dopamine agonist therapy and resolve with dosage reduction. The authors concluded with a statement on the appropriateness of informing patients of a potential risk of pathological gambling while on dopaminergic therapy, especially Mirapex.

20.

As of March 2005, the FDA's Adverse Event Reporting System contained 39 reports of Mirapex users with pathological gambling addiction. An analysis led by Dr. Ana Szarfman of the FDA and reprinted in the February 2006 *Archives of Neurology* reported that this incidence of gambling is "380 times greater than expected."

21.

Even when faced with evidence that showed Mirapex was causing compulsive behaviors like pathological gambling, and in the face of calls from the medical establishment to conduct further research and warn patients about this possible effect of Mirapex, defendants have either

failed to investigate or conduct any studies on the possible compulsive behavior side effects of Mirapex or have failed to make public the results of any studies or investigations that they might have done.

FIRST CAUSE OF ACTION
(Strict Liability – Design, Manufacturing and Warning – in Tort against all Defendants)

22.

Plaintiff Hearn incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

23.

Defendants had a duty to provide adequate warnings and instructions for Mirapex, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately test their product.

24.

The Mirapex manufactured and/or supplied to Plaintiff Hearn by defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, it was in an unreasonably dangerous and defective condition for its intended use and posed a risk of serious compulsive behaviors and harm to Plaintiff Hearn and other consumers which could have been reduced or avoided, *inter alia*, by the adoption of a reasonable alternative design.

25.

The Mirapex manufactured and/or supplied to Plaintiff Hearn by defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or supplier, Mirapex had not been adequately tested, was in an unreasonably dangerous and

defective condition, and posed a risk of serious compulsive behaviors and harm to Plaintiff Hearn and other consumers.

26.

The Mirapex manufactured and/or supplied to Plaintiff Hearn by defendants was defective due to inadequate warnings or instructions because the defendants knew, or should have known, through testing, scientific knowledge, advances in the field or otherwise, that the product created a risk of compulsive behaviors, injury and serious harm and was unreasonably dangerous to Plaintiff Hearn and other consumers, about which defendants failed to warn.

27.

The Mirapex manufactured and/or supplied to Plaintiff Hearn by defendants was defective, dangerous, and had inadequate warnings or instructions at the time it was sold, and defendants thereafter acquired additional knowledge and information confirming the defective and dangerous nature of Mirapex. Despite this knowledge and information, defendants failed and neglected to issue adequate warnings or post-sale warnings that Mirapex causes compulsive behaviors, especially pathological gambling addictions, including failure to warn about the severity and duration of such compulsive behaviors. Defendants failed to provide adequate warnings to users, purchasers, or prescribers of Mirapex, including Plaintiff Hearn and his physicians, and instead continued to sell Mirapex in an unreasonably dangerous form without adequate warnings or instructions.

28.

As a direct and proximate result of defendants' conduct, including the inadequate warnings, lack of adequate testing, and the defective and dangerous nature of Mirapex, Plaintiff

Hearn has suffered, and will continue to suffer, physical injury, emotional distress, harm, and economic loss as alleged herein.

SECOND CAUSE OF ACTION
(Breach of Express Warranty by Defendants)

29.

Plaintiff Hearn incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

30.

Defendants expressly warranted to physicians and consumers, including Plaintiff Hearn and/or his physicians, that Mirapex was safe and/or well-tolerated.

31.

Mirapex does not conform to these express representations because it is not safe and/or well-tolerated because it causes pathological gambling addictions that can lead to financial ruin, job loss, familial devastation and suicide attempts. Also, Mirapex does not conform to defendants' representations that scientific studies had shown that Mirapex was safe and/or well-tolerated.

32.

As a direct and proximate result of the breach of defendants' warranties, Plaintiff Hearn suffered, and will continue to suffer, physical injury, emotional distress, harm, and economic loss as alleged herein.

THIRD CAUSE OF ACTION
(Breach of Implied Warranty)

33.

Plaintiff Hearn incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

34.

At the time defendants marketed, sold, and distributed Mirapex, defendants knew of the use for which Mirapex was intended and impliedly warranted Mirapex to be of merchantable quality, safe, and fit for such use.

35.

Defendants knew, or had reason to know, that Plaintiff Hearn and his physicians would rely on the defendants' judgment and skill in providing Mirapex for its intended use.

36.

Plaintiff Hearn and his physicians reasonably relied upon the skill and judgment of defendants as to whether Mirapex was of merchantable quality, safe, and fit for its intended use.

37.

Contrary to such implied warranty, Mirapex was not of merchantable quality or safe or fit for its intended use, because the product was, and is, unreasonably dangerous, defective and unfit for the ordinary purposes for which Mirapex was used.

38.

As a direct and proximate result of the breach of implied warranty, Plaintiff Hearn suffered, and will continue to suffer, physical injury, emotional distress, harm, and economic loss as alleged herein.

FOURTH CAUSE OF ACTION
(Negligence)

39.

Plaintiff Hearn incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

40.

At all times material herein, defendants had a duty to exercise reasonable care and the duty of an expert in all aspects of the design, formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, promotion, advertising, sale, warning and post-sale warning to assure the safety of the product when used as intended or in a way that defendants could reasonably have anticipated, and to assure that the consuming public, including the Plaintiff Hearn and his physicians, obtained accurate information and adequate instructions for the safe use or non-use of Mirapex. Defendants had a duty to warn plaintiff, his physicians, and the public in general of Mirapex's dangers and serious side effects, including serious compulsive behaviors like pathological gambling addictions, since it was reasonably foreseeable that an injury could occur because of Mirapex's use.

41.

At all times material herein, defendants failed to exercise reasonable care and the duty of an expert and knew, or in the exercise of reasonable care should have known, that Mirapex was not properly manufactured, designed, compounded, tested, inspected, packaged, labeled, warned about, distributed, marketed, advertised, formulated, promoted, examined, maintained, sold, and/or prepared.

42.

Each of the following acts and omissions herein alleged was negligently and carelessly performed by defendants, resulting in a breach of the duties set forth above. These acts and omissions include, but are not restricted to, negligence and careless research and testing of Mirapex; negligent and careless design or formulation of Mirapex; negligent and careless failure to give adequate warnings that would attract the attention of Plaintiff Hearn, his physicians, and the public in general of the potentially dangerous, defective, unsafe, and deleterious propensity of Mirapex and of the risks associated with its use; negligent and careless failure to provide instructions on ways to safely use Mirapex to avoid injury; negligent and careless failure to explain the mechanism, mode, and types of adverse events associated with Mirapex; negligent representations that Mirapex was safe and/or well-tolerated; and negligent and careless failure to issue adequate post-sale warnings that Mirapex causes an increased risk of compulsive behaviors, including pathological gambling.

43.

As a direct and proximate result of defendants' negligence, Plaintiff Hearn suffered, and will continue to suffer, physical injury, emotional distress, harm, and economic loss as alleged herein.

FIFTH CAUSE OF ACTION
(Negligence Per Se)
(Violation of 21 U.S.C. §§ 331, 352 and 21 C.F.R. §§ 201.56, 201.57, 202.1)

44.

Plaintiff Hearn incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

45.

At all times herein mentioned, defendants had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, promotion, advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting, sale, warning, and post-sale warning of the risks and dangers of Mirapex.

46.

By reason of its conduct as alleged herein, defendants violated provisions of statutes and regulations, including, but not limited to, the following:

a. Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding Mirapex;

b. Defendants failed to follow the "[g]eneral requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.56;

c. Defendants failed to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.57; and

d. Defendants advertised and promoted Mirapex in violation of 21 C.F.R. § 202.1.

These statutes and regulations impose a standard of conduct designed to protect consumers of drugs, including plaintiff. Defendants' violations of these statutes and regulations constitute negligence per se.

47.

As a direct and proximate result of defendants' statutory and regulatory violations, Plaintiff Hearn, a member of the class of persons protected by the above-mentioned statutes, suffered, and will continue to suffer, physical injury, emotional distress, harm, and economic loss as alleged herein.

SIXTH CAUSE OF ACTION
(Negligent Misrepresentation)

48.

Plaintiff Hearn incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:

49.

Defendants misrepresented to consumers and physicians, including plaintiff and/or his physicians and the public in general, that Mirapex was safe and/or well-tolerated when used as instructed, and that Mirapex showed that Mirapex was safe and/or well-tolerated, when, in fact, Mirapex was dangerous to the well-being of patients.

50.

At the time defendants promoted Mirapex as safe and/or well-tolerated, they did not have adequate proof upon which to base such representations, and, in fact, knew or should have known that Mirapex was dangerous to the well-being of Plaintiff Hearn and others.

51.

Defendants failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of Mirapex and otherwise failed to exercise reasonable care in transmitting information to Plaintiff Hearn, his physicians, and the public in general.

52.

Defendants made the aforesaid representations in the course of defendants' business as designers, manufacturers, and distributors of Mirapex despite having no reasonable basis for their assertion that these representations were true and/or without having accurate or sufficient information concerning the aforesaid representations. Defendants were aware that without such information they could not accurately make the aforesaid representations.

53.

At the time the aforesaid representations were made, defendants intended to induce Plaintiff Hearn and/or his physicians to rely upon such representations.

54.

At the time the aforesaid representations were made by defendants, and at the time Plaintiff Hearn received Mirapex, Plaintiff Hearn and/or his physicians, and the public in general reasonably believed them to be true. In reasonable and justified reliance upon said representations by plaintiff and/or his physicians, plaintiff used Mirapex.

55.

As a direct and proximate result of reliance upon defendants' misrepresentations, Plaintiff Hearn suffered, and will continue to suffer, physical injury, emotional distress, harm, and economic loss as alleged herein.

SEVENTH CAUSE OF ACTION
(Loss of Consortium)

56.

Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows:

57.

As a further direct result of defendants' breach of duties as described and alleged above, Plaintiff Bettianne Hearn has lost, and will in the future lose, her husband's companionship, aid, comfort, society, services, protection and consortium, all to her damage in an amount far greater than $75,000.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs seek judgment in their favor as follows:

1. Awarding actual damages to Plaintiffs incidental to the purchase and ingestion of Mirapex in an amount to be determined at trial;
2. Awarding the costs of treatment for Plaintiffs' injuries caused by Mirapex;
3. Awarding injunctive relief, including disgorgement of all profits made from and monies paid for Mirapex;
4. Awarding damages for Plaintiffs' physical pain and suffering;
5. Awarding damages for Plaintiffs' mental and emotional anguish;
6. Awarding pre-judgment and post-judgment interest to Plaintiffs;
7. Awarding the costs and expenses of this litigation to Plaintiffs;
8. Awarding reasonable attorneys' fees and costs to Plaintiffs as provided by law;
9. Awarding punitive damages and other exemplary relief pursuant to the Order filed November 27, 2007, in *In re: Mirapex Products Liability Litigation*, MDL No. 1836; and
10. For such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiffs hereby request a trial by jury, pursuant to Rule 38 of the Federal Rules of Civil Procedure, on all claims and issues so triable.

Dated: January 17, 2008

ROBINS, KAPLAN, MILLER & CIRESI L.L.P.

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