

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re: MIRAPEX PRODUCTS LIABILITY

Civil No. 07-MD-1836  
(JMR/FLN)

LITIGATION

**ORDER**

RELATED CASES

GARY SELINSKY, <i>et al.</i>	Civil No. 06-873 JMR/FLN
ROBERT M. ZWAYER, <i>et al.</i>	Civil No. 06-874 JMR/FLN
MICHAEL A. DUBAICH, <i>et al.</i>	Civil No. 06-875 JMR/FLN
DONALD J. NELSEN	Civil No. 06-876 JMR/FLN
LARRY WEBB, <i>et al.</i>	Civil No. 06-898 JMR/FLN
TIMOTHY G. HARMS	Civil No. 06-899 JMR/FLN
TIMOTHY L. ESTEP	Civil No. 06-900 JMR/FLN
MARY CONWAY	Civil No. 06-901 JMR/FLN
DENNIS M. SCHARPEN, <i>et al.</i>	Civil No. 06-1206 JMR/FLN
GARY E. CHARBONNEAU, <i>et al.</i>	Civil No. 06-1215 JMR/FLN
TODD R. CAIN	Civil No. 06-1582 JMR/FLN
MANUEL A. QUINTELA, <i>et al.</i>	Civil No. 06-1675 JMR/FLN
THADDEUS R. FAYARD	Civil No. 06-2144 JMR/FLN
HYLTON H. DODD	Civil No. 06-2145 JMR/FLN
MICHAEL W. AVERITT, <i>et al.</i>	Civil No. 06-2194 JMR/FLN

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Tara D. Sutton, Gary L. Wilson for Plaintiffs  
Michael K. Brown, Joseph M. Price, for Defendant Pfizer  
Scott A. Smith, for Defendant BIPI

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**I. INTRODUCTION**

**THIS MATTER** came before the undersigned United States Magistrate Judge on September 10, 2007, on Plaintiffs' Motion to Amend the Complaint to Add Claims for Punitive Damages [#29] in the first fifteen cases to be tried. In this motion, Plaintiffs and Defendants have presented two vastly different interpretations of the events that have unfolded since 1990 when BIPI first filed an Investigational New Drug Application ("IND") for Mirapex.

Plaintiffs contend that the Defendants knew early on in the course of bringing this drug to the market that Mirapex could cause compulsive behaviors and they failed to properly investigate the issue in the clinical trials. Plaintiffs allege that once evidence emerged that the drug caused compulsive behaviors, Defendants first ignored it and then attempted to suppress it; and rather than warning patients in the United States of the possible side effect, the Defendants undertook misleading public relations campaigns, asserting that there was no relationship between Mirapex and compulsive behaviors.

Defendants put forth considerable evidence to rebut Plaintiffs' allegations. Defendants contend that they knew very little about the side effects of Mirapex when they began the process of bringing the drug to market (and to this day know very little) and that they took appropriate action when needed.

In the instant motion, the Court must first decide what law applies to each of the 15 cases and then determine which, if any, of the 15 Plaintiffs may amend their complaints to add a request for punitive damages. The Court expresses no opinion on whether any Plaintiff is entitled to be awarded punitive damages at trial.

## **II. CHOICE OF LAW**

The Plaintiffs contend that Minnesota Statute § 549.191 should apply to all cases because Minn. Stat. § 549.191 is considered "procedural" by Minnesota courts. They also contend that Minn. Stat. § 549.20 should apply to all cases because it provides for a remedy and the laws governing remedies are procedural. Because the laws are procedural, Plaintiffs argue that no choice of law analysis is necessary - Minnesota procedural law applies. Defendants, on the other hand, contend that punitive damages law is substantive. For the reasons set forth below, the Court finds that a choice of law analysis is required and concludes that the punitive damages law of the state in which each Plaintiff resides applies to his or her case.

In a diversity case such as this, federal courts apply the forum state's choice-of-law rules in order to achieve equal administration of justice in state and federal courts sitting in the same

state. *Klaxon Co. v. Stentor Electric Mfg. Co.* 313 U.S. 487 (1941) (citing *Erie R. Co. v. Tompkins*, 304 U.S. 64, 74 (1938)); see also *Walker v. Armco Steel Corp.*, 446 U.S. 740, 750 (1980) (in the absence of a conflicting Federal Rule of Civil Procedure, federal courts apply the forum's state law). As there is no conflicting Federal Rule of Civil Procedure, Minnesota choice-of-law principals dictate which state's punitive damages law applies in each case.

#### **A. The Laws Conflict**

Before applying the choice-of-law analysis, a court must determine whether or not the laws of the various states conflict. See *Jepson v. Gen. Cas. Co. of Wisconsin*, 513 N.W.2d 467, 469 (Minn.1994) (citing *Myers v. Gov't Employees Ins. Co.*, 302 Minn. 359, 225 N.W.2d 238, 241 (1974)). If there is a conflict, then the court applies Minnesota conflict-of-laws analysis. Minnesota law also requires us to consider whether the rule of each state may be constitutionally applied. See *Jepson*, 513 N.W.2d at 469 (cited in *Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.*, 590 N.W.2d 670, (Minn.Ct.App.1999)). In order for the law of each plaintiff's state of residence to be constitutionally applied, the state must have significant contacts or significant aggregation of contacts, creating a state interest, so that the choice of law is neither arbitrary nor fundamentally unfair. See *Nodak Mut.*, 590 N.W.2d at 672 (citing *Allstate Ins. Co. v. Hague*, 449 U.S. 302, 101 S.Ct. 633, 66 L.Ed.2d 521 (1981)).

As recognized by the court in *In re Baycol Prod. Litig.*, 218 F.R.D. 197, 207 (D. Minn. 2003), in a multi-district lawsuit involving plaintiffs from a number of states, there is a conflict of law between Minnesota punitive damages law and the punitive damages laws of the various states. State punitive damages laws vary significantly in that the procedures for alleging and awarding them are considerably different and the conduct and proof necessary for recovery differs significantly. *Id.* at 215. In addition, some states do not allow punitive damages in products liability cases; other states cap the amount of punitive damages allowed. As to the constitutionality issue, the Court finds that it would be constitutional to apply the punitive

damages laws of the plaintiffs' respective states as each state has an interest in enforcing its laws in a case where the injury happened in that state to one of its residents.

**B. The Law is Substantive**

Having concluded that the laws conflict, the Court must next decide if the rule of law at issue is substantive or procedural. *Danielson v. Nat'l Suppy Co.*, 670 N.W.2d 1, 5 (Minn. Ct. App. 2003). If the law is substantive, then the court is to apply the five factor choice-of-law analysis to determine which state's law applies. *Id.* If, however, the law is procedural, then the court applies Minnesota law. *Id.* The issue in this case is whether the punitive damages statutes (Minn. Stat. § 549.191 and § 549.20) are substantive or procedural for choice of law purposes.

The Court concludes that Minnesota's entire statutory scheme for alleging punitive damages is substantive for choice of law purposes. This Court follows the court's conclusion in *Baycol* that punitive damages laws, including Minn. Stat. § 549.20, in multi-district litigation are substantive for choice of law purposes.

The classification of Minn. Stat. § 549.191 as substantive for choice of law purposes requires more explanation. The statute prohibits the pleading of punitive damages without first seeking permission of the court. The plaintiff must then establish a *prima facie* case for punitive damages before he is allowed to amend his complaint. The Plaintiffs point out that in *Thompson v. Hughart*, 664 N.W.2d 372, 377 (Minn. Ct. App. 2003), the Minnesota Court of Appeals referred to § 549.191 as a "*procedure* for screening out unmeritorious claims for punitive damages" (emphasis added). Plaintiffs contend that this Court should conclude the statute is procedural for choice of law purposes. For *Erie* purposes, federal courts are only bound to follow legal interpretations of the forum state's highest court. *United Fire & Cas. Ins. Co. v. Garvey*, 328 F.3d 411, 413 (8th Cir. 2003). Interpretations of intermediate appellate courts are only persuasive when they are the best evidence of what the state law is. *Id.*

The Court is unaware of any Minnesota Supreme Court case holding that Minnesota's statutory scheme for alleging punitive damages is procedural for the purposes of applying

Minnesota's choice of law principles. The Minnesota Court of Appeals opinion in *Hughart* sheds no light on the question. In *Hughart*, the court described Minnesota's statutory scheme as a "procedure" to explain why the trial court's decision allowing punitive damages to be pleaded did not compel the jury to award punitive damages. It was in no way addressing the question of whether the statutory scheme was substantive or procedural for choice of law purposes.

Plaintiff's reliance on the Eighth Circuit's opinion in *Porous Media v. Pall*, 173 F.3d 1109 (8th Cir. 1999) is also misplaced. The only issue there was whether the trial court had abused its discretion in denying the motion to add a punitive damages claim. The Eighth Circuit described Minnesota's statutory scheme as a "procedure for pursuing a punitive damages claim," sheds no light on the question of whether the scheme is substantive or procedural for choice of law purposes. Indeed, that the federal court is following the Minnesota statute in a diversity case reinforces the conclusion that the entire statutory scheme is substantive, not procedural.

The legislature's decision to implement a procedure for screening out unmeritorious punitive damages claims before trial is itself a policy choice that has the potential to be outcome determinative. That is, the heightened pleading standard has the potential to preclude recovery of punitive damages in cases where the facts are not fully developed until trial. Like state statutes of limitation, Minnesota's entire scheme for alleging punitive damages is substantive. *Cf. Danielson v. Nat. Supply Co.*, 670 N.W.2d 1, 6 (Minn. Ct. App. 2003) (classifying a statute of limitations as "substantive" rather than "procedural" because the law was outcome determinative). Indeed in this very case, in seven of the states at issue (California, Georgia, Ohio, Pennsylvania, Texas, Virginia and New Jersey), a plaintiff is not required to make a preliminary showing to allege punitive damages. In two states (Massachusetts and Louisiana), a plaintiff cannot collect punitive damages at all. For choice of law purposes, the Court concludes that Minnesota's entire statutory scheme for alleging punitive damages is substantive.

### **C. The Law of Each Plaintiff's Home State Applies to His or Her Action**

Because the Court concludes that the entire statutory scheme is substantive, it must apply the choice of law analysis. Minnesota has adopted a five factor analysis to determine which state's substantive law applies. Those factors are: (1) predictability of results; (2) maintenance of interstate order; (3) simplification of judicial task; (4) advancement of the forum's governmental interests; and (5) the better rule of law. *Milkovich v. Saari*, 203 N.W.2d 408 (Minn. 1973); *Nesdalek v. Ford Motor Co.*, 46 F.3d 734, 738 (8th Cir. 1995). The first and third factors, predictability of results and simplification of judicial task, have generally not been applied in tort cases. *Baycol*, 218 F.R.D. at 207 (citing *Hughes v. Wal-Mart Stores*, 250 F.3d 618, 620 (8th Cir. 2001); *Nodak Mutual Ins. Co. v. American Family Mutual Ins. Co.*, 604 N.W.2d 91, 94-95 (Minn. 2000)). In addition, Minnesota courts have not placed any emphasis on the fifth factor in twenty years. *Baycol*, 318 F.R.D. at 207. Thus, the Court will consider only the maintenance of interstate order and the advancement of the forum's governmental interests. *Id.*

“Maintenance of interstate order is concerned with whether the application of Minnesota law would manifest disrespect for [other state] sovereignty or impede the interstate movement of people and goods. An aspect of this concern is to maintain a coherent legal system in which the courts of different states strive to sustain, rather than subvert, each other's interests in areas where their own interests are less strong.” *Id.* (citing *Nodak*, 604 N.W.2d at 95).

In *Baycol*, the court held that the state law, including punitive damages law, in which the plaintiff resides was preferred under this factor because the drug was prescribed and ingested in the state of the plaintiff's residence and the alleged injury occurred in the state of the plaintiff's residence. *See also In re Telectronics*, 172 F.R.D. 271 (S.D. Ohio 1996) (holding that class certification of punitive damages was not proper because punitive damages are measured individually based on the facts and local law). The court in *Baycol* also recognized that state punitive damages laws vary significantly in that the procedures for alleging and awarding them

are considerably different. 218 F.R.D. at 215. Applying the punitive damages law of one state to plaintiffs from multiple states where individual state laws differ so significantly would not promote the maintenance of interstate order or a coherent legal system.

The facts of this case are remarkably similar to *Baycol*. The plaintiffs in the first fifteen cases are from eleven different states and each one alleges that Mirapex, a prescription drug, harmed them. The maintenance of interstate order factor favors applying the substantive punitive damages law and the pleading requirements of the plaintiff's residence because the alleged injuries occurred in the plaintiffs' home states.

The next factor, advancement of the forum's governmental interest, generally weighs in favor of application of the state law in which the plaintiff lives and in which the injury occurred. In *Baycol*, the court held that the substantive law of the state of the plaintiff's residence should apply because the injury occurred in that state. Likewise, in this case, the law of the state of the plaintiff's residence should apply because the injury occurred in that state. The Court finds that for each plaintiff, it will apply the punitive damages law of the state in which that plaintiff resides.

### **1. States Where Punitive Damages not Allowed**

The plaintiffs from Louisiana (Thaddeus Fayard) and Massachusetts (Manuel and Nancy Quintela) may not amend their complaints to allege punitive damages because these two states do not allow punitive damages in a products liability action. *See Brookshire Bros. Holding, Inc. v. Total Containment, Inc.*, 455 F.Supp. 2d 541, 543 (D. La. 2006) (citing La.R.S. §§ 9:2800.51-9:2800.59); *Freeman v. World Airways, Inc.*, 596 F.Supp. 841, 844 (D. Mass. 1984) (noting that the legislature has not authorized punitive damages in personal injury cases).

### **2. States Where No *Prima Facie* Showing is Required**

In the cases in which the plaintiff resides in California (Mary Conway), Georgia (Timothy Harms), Ohio (Larry and Elizabeth Webb), Pennsylvania (Michael Dubaich, et al.), Texas (Hylton Dodd and Michael Averitt), Virginia (Timothy Estep), or New Jersey (Todd

Cain), the Plaintiffs may amend their complaints to include punitive damages and are not required to establish a *prima facie* case before doing so. In these states, a plaintiff may allege punitive damages without establishing a *prima facie* case. For California law, see *Cyrus v. Haveson*, 65 Cal. App. 3d 306 (1976) (allowing plaintiff to allege punitive damages without leave of court); for Georgia law, see Ga. Code Ann., § 51-12-5.1(d)(1) (statute provides that “[a]n award of punitive damages must be specifically prayed for in a complaint” and does not require leave of court); for Ohio law, see *Brookridge Party Center, Inc. v. Fisher Foods, Inc.*, 12 Ohio App.3d 130, 131 (1984) (“Punitive damages need not be specially pleaded or claimed.); for Pennsylvania law, see *Wagner v. McNeil*, 1992 WL 573015, \*2 (Pa. Com. Pl. 1992) (allowing plaintiff to allege punitive damages without leave of court); for Texas law, see *Scurlock Oil Co. v. Joffrion*, 390 S.W.2d 526 (Tex.Civ.App.1965) (“In order to recover exemplary damages, plaintiff must not only plead, but he must prove that defendant acted with malice.”); for Virginia law, see *Neurology Services, Inc. v. Fairfax Medical PWH, LLC*, 2005 WL 832160, \*12 (Va. Cir. Ct. 2005) (allowing plaintiff to allege punitive damages without leave of court); for New Jersey law, see N.J. Stat. Ann. §2A:15-5.11 (requires punitive damages be specifically prayed for in complaint but does not require leave of court to do so).

### **3. States Where *Prima Facie* Showing Required**

Under Minnesota, Wisconsin and Florida laws, a plaintiff must seek leave of court and must make an appropriate showing before the court will allow a punitive damages claim. These pleading requirements apply to Minnesota Plaintiffs Gary Selinsky, Donald Nelson and Dennis Scharpen, Wisconsin Plaintiffs Gary Charbonneau, et al. and Florida Plaintiffs Robert Zwayer, et al. Whether these Plaintiffs have met the heightened pleading standard will be addressed in Part III of this ORDER.

## **III. Plaintiffs in Minnesota, Wisconsin and Florida Have Met the Heightened Pleading Requirements of Their Respective States**

### **A. Each State’s Pleading Requirements**

## **1. Minnesota Pleading Requirements**

Under Minnesota law, a plaintiff must make a *prima facie* showing of entitlement to punitive damages. Minn. Stat. § 549.191. *Prima facie* evidence is that which “if unrebutted would support a judgment in that party’s favor.” *Olson v. Snap Products, Inc.*, 29 F.Supp.2d 1027, 1034 (D. Minn. 1998) (citations omitted). Therefore, in this case, in order to allege punitive damages, the Minnesota Plaintiffs must set forth that the Defendants acted with “deliberate disregard for the rights or safety of others.” Minn. Stat. § 549.20. “A defendant has acted with deliberate disregard for the rights and safety of others if the defendant has knowledge of facts or intentionally disregards facts that create a high probability of injury to the rights and safety of others and: (1) deliberately proceeds to act in conscious or intentional disregard of the high degree of probability of injury to the rights or safety of others; or (2) deliberately proceeds to act with indifference to the high probability of injury to the rights or safety of others.” *Id.*

Under Minnesota law, in the products liability context, punitive damages are warranted where “manufacturers abuse their control over safety information and market defective products in flagrant disregard for public safety.” *Gryc v. Dayton-Hudson Corp.*, 297 N.W.2d 727 (Minn. 1980).

## **2. Wisconsin Pleading Requirements**

Under Wisconsin law, the court must determine whether the evidence submitted by the plaintiff, if believed by the jury, is sufficient “so that a reasonable jury could find that the plaintiffs had proved by the middle burden of proof, ‘clear and convincing evidence,’ that [the defendant] was aware that its conduct was substantially certain to result in the plaintiffs’ rights being disregarded.” *Wischer v. Mitsubishi Heavy Industries America, Inc.*, 694 N.W.2d 320, 330 (Wis. 2005). Even though the language of the statute requires that plaintiff establish the defendant acted with “intentional disregard” for the rights of the plaintiff, Wis. Stat. § 895.85(3), the Wisconsin Supreme Court has interpreted this language to mean that the defendant “act with a purpose to disregard the plaintiff’s rights or be aware that his or her conduct is substantially

certain to result in the plaintiff's rights being disregarded." *Strenke v. Hogner*, 694 N.W.2d 296, 304 (Wis. 2005).

### **3. Florida Pleading Requirements**

Under Florida law, the plaintiff must establish that the defendant is guilty of either "intentional misconduct" or "gross negligence." Fl. Stat. § 768.72(2). Gross negligence means "the defendant's conduct was so reckless or wanting in care that it constituted conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct." Fl. Stat. § 768.72(2)(b). As for the pleading requirement, Florida Statute § 768.72(1) provides that:

In any civil action, no claim for punitive damages shall be permitted unless there is a reasonable showing by evidence in the record or proffered by the claimant which would provide a reasonable basis for recovery of such damages. The claimant may move to amend her or his complaint to assert a claim for punitive damages as allowed by the rules of civil procedure. The rules of civil procedure shall be liberally construed so as to allow the claimant discovery of evidence which appears reasonably calculated to lead to admissible evidence on the issue of punitive damages. No discovery of financial worth shall proceed until after the pleading concerning punitive damages is permitted.

### **4. The Pleading Requirements are Similar**

The law of the three states requires the court to look at the evidence presented by the plaintiff and to determine whether, if believed by the jury, the evidence establishes that the defendant acted with disregard for the high probability of injury to the rights or safety of others. In all three states the claim must be proven by clear and convincing evidence at trial. *See* Minn. Stat. § 549.20, subd. 1; Fla. Stat. § 768.725; *Strenke v. Hogner*, 694 N.W.2d 296, 305 (Wis. 2005). Because the pleading requirements in Minnesota, Wisconsin and Florida are so similar, if the requirements are met for one state, they are met for all three.

### **B. Plaintiff's Evidence of Each Company's Involvement with Mirapex**

On May 14, 1990, BIPI submitted an IND to the FDA. BIPI transferred the IND to Upjohn on February 16, 1993. Three months after BIPI transferred the IND to Upjohn, Upjohn and BI Germany entered into a co-development agreement regarding Mirapex. On December

26, 1995, Upjohn submitted the Mirapex New Drug Application (“NDA”) to the FDA. Upjohn transferred the Mirapex NDA to Pharmacia & Upjohn on June 26, 1996. On July 2, 1997, BIPI entered into a Co-Promotion agreement with Pharmacia & Upjohn for marketing Mirapex. Pharmacia was acquired by Pfizer on April 16, 2003. On January 1, 2004, Pfizer transferred the Mirapex NDA to BIPI. On May 1, 2005, the Co-Promotion Agreement between BIPI and Pharmacia & Upjohn ended.

### **1. Plaintiffs’ Evidence Against BIPI**

The Plaintiffs allege that BIPI knew all along that Mirapex could cause compulsive behaviors and failed to properly research the issue and to warn patients. In the IND for Parkinson’s disease filed in 1990, BIPI describes Mirapex as having “pronounced” activity in the mesolimbic dopaminergic pathway which is involved in emotional function and control. (Pl. Ex. 7.) In the same application, BIPI stated that animals that had been treated with Mirapex exhibited stereotypic climbing and compulsive gnawing. (*Id.* at 5194-95.) BIPI noted that “[b]oth from a theoretical standpoint, and based on results of controlled clinical trials with other DA agonist drugs,” the product might “cause and/or exacerbate pre-existing states of confusion, hallucinations, or mental disturbances.” (*Id.* at 5251.) Similarly, in its Investigational New Drug Application for schizophrenia, BIPI anticipated that Mirapex would “reinforc[e] behavior that . . . seeks pleasure.” (Pl. Ex. 1, Tr. Gordon Dep. at 129.) Even though BIPI was aware of the pathway the drug targeted and was aware of the possible effects of the drug, Dr. Gordon, BIPI’s 30(b)(6) pharmacology representative testified that clinical trial investigators never asked study participants any questions about gambling or other impulse control disorders. Instead, investigators were simply asking a “general open question about any changes, problems, side effects” at each visit. (*Id.* at 260-61.)

Plaintiffs contend that the numerous reports of compulsive gambling from the clinical trials should have induced BIPI to research the issue further and to warn patients about the

possible side effect. BI, BIPI and Upjohn were studying and developing Mirapex between February 16, 1993 and December 26, 1995. During that time, the following reports were made in the clinical trials:

- In May 1994, three clinical trial patients reported “increased sexual function” and increased libido. (Pl. Ex. 34 at 2806, 2768); (Pl. Ex. 35 at 5488, 5436); (Pl. Ex. 36 at 7978.)
- In July 1994, a patient reported “increased sex drive.” (Pl. Ex. 37 at 2885.)
- In December 1994, a patient trial developed hypersexuality. Pl. Ex. 38 at 4346. This condition continued until 1999, when the investigator noted it had “become chronic.” (*Id.* at 4515.)
- In May 1995, patient 1213 in the open-label M/2730/0011 PD trial developed “compulsive behavior.” (Pl. Ex. 20 at 7911.) The investigator determined that there was a reasonable probability that this compulsive behavior was caused by Mirapex. (*Id.*)
- In September 1995, patient 1144 in the M/2730/0011 trial developed “increased libido” and “abnormal sexual behavior,” both judged by the investigator to be severe and reasonably likely to be caused by the study drug. (Pl. Ex. 21 at 3470.) The investigator stated that “Patient’s libido became overwhelming, resulting in obsessive/compulsive extreme behavior. Dosage was reduced.” (*Id.*) In January 1996, this patient was recorded as suffering “compulsive behavior,” again judged as severe and possibly drug-related. (*Id.* at 3542.)
- In November 1995, patient 2185 in open-label PD trial M/2730/0002 trial was recorded as having suffered “compulsive behavior” since June 1995. (Pl. Ex. 22 at 1682, 1687.) The investigator again determined that there was a reasonable probability that this compulsive behavior was caused by Mirapex. (*Id.* at 1687.)

On July 2, 1997, BIPI entered into a Co-Promotion agreement with Pharmacia and Upjohn for marketing of Mirapex and both companies jointly marketed Mirapex until May 1, 2005. During this time period, the following reports of compulsive behaviors were made:

- In March of 1998, patient 16071 in the M/2730/0016 trial developed “loss of ability to control impulsive behavior” which the investigator concluded was Mirapex-related. (Pl. Ex. 30 at 6736.) The case report form reveals that this loss of ability to control impulsive behavior related to “depression and gambling problem” which was “now revealed to be severe.” (*Id.* at 6751.)
- In June 1998, patient 213 in the 248.332 clinical trial developed “anxiety due to gambling” due to being “[a]ddicted to gambling” since an unrecorded date (Pl. Ex. 31 at 1198.)
- In November 1998, patient 39 in the M/2730/0103 trial developed “impulsive behavior” and “excitability.” (Pl. Ex. 32 at 8972.) The investigator attributed both events to Mirapex. (*Id.*)

- In November 2000, patient 291 in the M/2730/0072 trial developed “compulsive gambling.” (Pl. Ex. 33 at 5265.)

Plaintiffs also allege that BIPI’s failure to warn patients in the U.S. about gambling as a possible side effect when BI, its parent company, was warning patients in the rest of the world constitutes a disregard for the rights and safety of others. On September 10, 2004, BI Germany, the parent company of BIPI issued a Clinical Expert Statement on the topic of pathological gambling and whether warnings were needed. (Pl. Ex. 82.) The authors of the Statement reviewed reports of pathological gambling both from the clinical trials and from spontaneous reports. (*Id.* at 2822-23.) Based on the review of these reports, the authors concluded that the data “strongly suggest a pharmacodynamic effect of pramipexole on pathological gambling.” (*Id.* at 2824.) They recommended that: “Pathological gambling should be listed as a side effect of Pramipexole. In addition, a statement should be added that these events occurred at higher doses and improved upon drug discontinuation.” (*Id.* at 2825.) The authors based their conclusions, in part, on the fact that a large percentage of patients who had a pathological gambling problem ceased to have the problem when they stopped taking Mirapex. (*Id.* at 2824.) BI Germany changed the Basic Product Information sheet in August of 2004 to list pathological gambling as a possible side effect of Mirapex that was generally reversible on treatment discontinuation. (Pl. Ex. 123 at 5865.)

The Basic Product Information sheet “reflects the full knowledge of the BI company, including all relevant sources of information, and the Company’s evaluation of these data.” (Pl. Ex. 83 at 0891.) According to BI’s Standard Operating Procedures, side effects of a drug are listed only when “sufficient evidence for a causal association is given.” (Pl. Ex. 84 at 5988.) The Basic Product Information sheet was circulated to BIPI and the rest of BI’s operating companies in September 2004 for incorporation into Mirapex product labeling worldwide. (Pl. Ex. 85.) BIPI did not put a warning on the product label in the United States indicating that pathological gambling symptoms subside upon treatment discontinuation. Rather, BIPI added

only “pathological gambling” to the “post-marketing experience” section of the label. (Pl. Ex. 86 at 7166-72.) The text stated that: “[b]ecause these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.” (Pl. Ex. 90 at 7170-71.)

Plaintiffs allege that BIPI then publicly denied that there was a causal link between Mirapex and compulsive behaviors, in the face of contrary conclusions from its parent company and with the knowledge that there had been reports of compulsive gambling in the clinical trials. On November 30, 2004, Dr. Kirk Shepard appeared on CBS News in Cedar Rapids, Iowa and communicated that “[t]here is no evidence of a causal effect between pramipexole and compulsive behavior such as gambling” and that “[i]n the trials . . . there were no cases of compulsive behavior.” (Pl. Ex. 91.) Plaintiff’s Exhibit 91 is an internal email summarizing Dr. Shepard’s “key points.” (*Id.*) On December 16, 2004, Dr. Zerban, with BI Germany, sent an email to Dr. Shepard and Dr. Corsico (BIPI’s Director of Drug Safety), stating that:

the attached document (CBS Q&A Final) addresses the question: Is Mirapex causing the compulsive gambling? We do have indication of a causal relationship. This is why we recommend a discontinuation of Pramipexole in our corporate label, if pathological gambling is observed. I have already send a copy of the report dealing with the issue of pathological gambling to Kirk. (Pl. Ex. 93.)

BIPI’s statement that there was no evidence of a causal relationship between Mirapex and gambling was also reported on Good Morning America on December 23, 2004 where it was reported that “[t]he manufacturer of Mirapex told ABC News in a written statement that . . . it does not believe there is proof of a causal relationship between the product and gambling.” (Pl. Ex. 94.) BIPI’s position that there is no link was reported in numerous other outlets, including NBC News Baltimore (February 10, 2005), Associated Press (July 12, 2005). BIPI also emailed a statement to the Wall Street Journal in July of 2005 stating that “there is no scientific evidence of a causal effect between pramipexole and compulsive behavior[.]” (Pl. Ex. 98.)

Plaintiffs allege that BIPI also failed to report important information to the FDA in July 2005. At that time, the FDA requested information about reports of gambling that BIPI had

received. (Pl. Ex. 113.) In the letter sent to the FDA in response to their request, BIPI did not mention BI's Clinical Expert Statement which concluded that there was a clear pharmacodynamic effect of Pramipexole on pathological gambling. (Pl. Ex. 78.) BIPI did not disclose that BI had added a warning to labels outside the United States indicating that pathological gambling was a possible side effect that was reversible upon discontinuation of the treatment. (*Id.*) BIPI also failed to report three cases of compulsive gambling from the clinical trials. (Bray Aff. ¶¶ 5-8.)

Plaintiffs contend that BIPI delayed conducting a study. In October of 2003, a panel of expert consultants recommended that a study should be conducted on impulse control behaviors in Parkinson's Disease patients. (Pl. Ex. 72.) The panel explained that "such a study could document the broad range of compulsive disorders in these patients and help determine if the disorders are disease or treatment-related. *Id.* In April 2004, another expert panel made the same recommendation. (Pl. Ex. 73.) Representatives from Pfizer and BIPI were present at this meeting. (*Id.*) In May 2005, one expert, Dr. Olanow, was concerned that BIPI "had not taken action steps on the issue despite advice [sic] provided by consultants." (Pl. Ex. 75.) In June 2005, Dr. Olanow voiced his concern again, indicating that the study was "twelve months overdue as it is." (Pl. Ex. 76.) BIPI convened another expert meeting in July 2005. (Pl. Ex. 77.) BIPI did not finalize the protocol for the study until July 2006, (Pl. Ex. 80), and BIPI will not have the study completed and the report on it issued until March 2009. (Pl. Ex. 81.)

Plaintiffs' allegations and the evidence presented in support constitute a *prima facie* case that BIPI acted with deliberate or conscious disregard for the rights or safety of others. Therefore, the Court finds that Plaintiffs may allege punitive damages against BIPI.

## **2. Plaintiff's Evidence Against, Pharmacia & Upjohn, LLC, Pharmacia and Pfizer**

### **a. Pharmacia & Upjohn, LLC**

Plaintiffs allege that Pharmacia and Upjohn knew all along that Mirapex caused compulsive behaviors and failed to research the issue or warn patients about the possible side

effect. Plaintiff has presented evidence that Upjohn filed Mirapex Investigational New Drug application for the treatment of depression where it acknowledged that Mirapex targeted the dopamine function and the mesolimbic pathways involved with motivation and reward resulting in mood enhancement and reduced depression. (Pl. Ex. 4.) Upjohn noted that dopamine agonists caused compulsive behaviors in animals such as compulsive gnawing, licking, biting and sniffing. (*Id.* at 8729.)

Plaintiffs have also presented evidence that Upjohn was also part of an effort to suppress Mirapex studies. In February 1994, individuals on the BI/Upjohn Development team agreed that “no [pramipexole] will be sent to the NIDA [National Institute on Drug Abuse] as we would not wish to be confronted with this data regarding addiction models[.]” (Pl. Ex. 10 at 9165.) BI and Upjohn representatives also decided not to give a sample of pramipexole to researcher Torben Kling-Peterson, who was conducting an intracranial self-stimulation model, because they did not want to risk pramipexole being associated in any way with “addiction.” (Pl. Ex. 14.) They also agreed that Mirapex should not be provided to external investigators “for models associated with addiction.” (*Id.*) Plaintiffs allege that BI and Upjohn then worked together to suppress mention of the terms “addiction” and “positive reinforcement” from a proposed abstract and presentation about Mirapex. (Pl. Ex. 17.) The researcher eventually agreed to delete the terms from his abstract and the discussion from his presentation and BI then agreed to release the abstract for publication. (*Id.* at 7648.)

Plaintiffs also contend that the numerous reports of compulsive gambling from the clinical trials should have induced Upjohn and BIPI to research the issue further and to warn patients about the possible side effect. BI, BIPI and Upjohn were studying and developing Mirapex between February 16, 1993 and December 26, 1995, during which time a number of cases of compulsive behavior were reported. *See* Section III.B *supra*. According to Defendant’s chart, on July 2, 1997, BIPI entered into a Co-Promotion agreement with Pharmacia and Upjohn for marketing of Mirapex and both companies jointly marketed Mirapex until May 1, 2005.

During this time, there were also a number of cases of compulsive behavior reported. *See* Section III.B.1 *supra*.

Plaintiffs have presented *prima facie* evidence that Pharmacia and Upjohn failed to properly study possible side effects, failed to warn and attempted to suppress studies of Mirapex as it relates to addiction. This evidence, if un rebutted, could be relied upon at trial to find that Pharmacia and Upjohn disregarded the high probability of injury to the rights or safety of others.

### **b. Pharmacia**

Plaintiffs allege that Pharmacia remained silent about compulsive gambling as a side effect of Mirapex despite receiving many reports of gambling from patients and doctors.

Pharmacia received the following reports:

- In early September, 1996, patient 2421 in the M/2730/0002 trial developed “compulsive behavior” and was hospitalized. (Ex. 25, BIPI-SELINSKY01147027 at 7152.) The patient was hospitalized for “depression with suicidal ideation,” because she “had been having an ongoing problem with gambling and has again spent money she didn’t have and overdrawn her bank account again.” The records describe the patient as suffering “what she felt is a gambling addiction.” (Ex. 26, BIPI-PFIZER-SELINSKY0042987.) But when Pharmacia reported the event to the FDA nearly two years after her hospitalization, they failed to disclose the true nature of the adverse event—gambling addiction—instead reporting only that she suffered from “anxiety” and “stress.” (Ex. 27, BIPI-PFIZER-SELINSKY00199704 at 9812.) In fact, her gambling addiction has never been reported to the FDA. (Ex. 28, Tr. Reidies Dep. at 109-115.)
- In August 2002, Pharmacia received a report that a woman taking Mirapex had developed “compulsive gambling.” (Pl. Ex. 51 at 6819-20.)
- In September 2002, Pharmacia received a report that a woman and her husband on Mirapex developed gambling addiction and were “in financial ruin.” (*Id.* at 6825-28.) The woman also reported that she knew four other people taking Mirapex who developed gambling addictions. (*Id.* at 6829-30.)
- In March 2003, Pharmacia received a report that a man who was on Mirapex had developed a problem with gambling, and was “putting that activity before business, paying bills, [or] gathering information for taxes[.]” (*Id.* at 6859-60.)
- In May 2003, Pharmacia received a report that a woman had been taking Mirapex and had developed “a serious gambling compulsion, which caused her complete financial ruin.” (Ex. 52 at 5345.) “After she was off the product for one month

she returned to normal and did not have a gambling compulsion any longer.”  
(*Id.*)

Pharmacia did report this last event to the FDA but did not take any steps to warn patients or doctors that compulsive behavior may be linked to Mirapex. Plaintiffs also allege, that Pharmacia, along with the rest of the Defendants failed to properly study compulsive behaviors as a possible side effect of Mirapex. These allegations and the evidence presented in support establish a *prima facie* case that Pharmacia acted with disregard for the high probability of injury to the rights or safety of others.

### **c. Pfizer**

Plaintiffs allege that Pfizer learned in August of 2003 that three doctors who were prescribing Mirapex, Dr. Stern, Dr. Ravin and Dr. Lieberman had patients develop gambling addictions. (Pl. Ex. 61; Pl. Ex. 64) Pfizer did not report these cases to the FDA. (Pl. Ex. 42, Tr. Castro Dep. at 239-50; Ex. 59 Tr. Taylor Dep. at 149.) On January 30, 2004, after BI took over reporting responsibilities from Pfizer, it concluded that Pfizer’s failure to report these cases “placed BI in a non-compliance situation” because these reports were not made when Pfizer first learned of them. (Pl. Ex. 111.) Even though Pfizer did not report Dr. Lieberman or Dr. Ravin’s cases to the FDA, in November 2003, it did share the existence of those cases with its “communications team for . . . planning purposes.” (Pl. Ex. 70.) When Pfizer shared this information with its public relations consultant, Weber Shandwick, the consultant’s crisis management proposal identified the doctors as “threats.” (Pl. Ex. 71.) That Pfizer failed to timely report to the FDA what it had learned from Doctors Stern, Ravin and Lieberman, but instead treated the information as a public relations issue constitutes *prima facie* evidence that Pfizer acted with deliberate disregard for the rights and safety of others.

### **C. Defendants’ Response to Plaintiffs’ Allegations**

Defendants make three broad responding arguments. (Def. Br. at 3.) First, Defendants point out that the FDA has concluded that, based on the information available, there is not

enough evidence to conclude that Mirapex causes compulsive gambling. (*Id.*) Second, contrary to Plaintiffs' assertions, Defendants contend there is no general consensus among researchers and doctors that Mirapex causes compulsive gambling. (*Id.*) Third, Defendants argue they appropriately reported information to the FDA; that they have worked under its close supervision; and, the FDA has never found the Defendants conduct to be "irresponsible, punishable or illegal." (*Id.*)

### **1. BIPI's Response**

Plaintiffs allege that BIPI knew all along that Mirapex could cause compulsive behaviors in part because "animals treated with Mirapex exhibited stereotypic climbing and compulsive gnawing." (Pl. Ex. 7.) Plaintiffs' Exhibit 7 is BIPI's IND sent to the FDA on May 14, 1990. In the application, BIPI actually concluded that Mirapex did not induce stereotypic behavior in animals except at very high dosages. (*Id.*) The report in the application also states that this type of behavior in animals is simply an indication that the drug is working as intended. (*Id.*) BIPI's 30(b)(6) pharmacology witness stated in his deposition that the information learned in these studies was too preliminary to give any indication as to how the drug would affect humans. (Def. Ex. B at 90-91.)

Plaintiffs argue that because the report stated that the drug might "cause and/or exacerbate pre-existing states of confusion, hallucinations, or mental disturbances," Defendants knew the drug could cause compulsive behaviors (Pl. Ex. 7 at 5251.) Defendants contend that these types of disturbances are clearly distinguishable from the impulse control disorders alleged in this litigation. Defendants point to Pfizer's pharmacology witness, Dr. McCall's testimony that all dopamine agonists have well known side effects, including hallucinations, orthostatic hypotension and somnolence, all of which are different from impulse control disorders (Def. Ex. C (McCall Dep.) at 100-01.)

In response to Plaintiffs' argument that Defendants knew the drug caused compulsive behaviors because of the adverse events reported in the clinical trials, Defendants contend that

they properly reported all events to the FDA. They further contend that no gambling adverse events were reported in three pivotal placebo-controlled clinical trials used to support the Mirapex NDA. (Def. Ex. H; Def. Ex. I (Davidai Dep.) at 143-44.); Def. Ex. J (Reidies Dep. at 157-58.); Def. Ex. B (Gordon Dep.) at 258; Def. Ex. K (Tomczyk Dep.) at 176.

Plaintiffs contend that BIPI failed to appropriately warn patients and physicians in the United States about compulsive gambling as a possible side effect. Defendants contend the BIPI and BI are separate legal entities which operated differently and these differences are a reflection of the different legal and regulatory environments in which they reside and legitimate scientific disagreement between scientists at BIPI and BI (Def. Br. at 5.) BIPI witnesses testified that they evaluated BI's warning and disagreed with it because the data was mainly spontaneous data insufficient to support the statements in BI's warning. These witnesses further testified that the data relied upon by BI does not indicate that Mirapex *causes* compulsive behaviors. (Def. Ex. P (Keating Dep.) at 102; Def. Ex. B (Gordon Dep.) at 256-59; Def. Ex. J (Reidies Dep.) at 221-22, 223-24; Def. Ex. E (Corsico Dep.) at 181-82, 192-96; Def. Ex. I (Davidai Dep.) at 112-13, 139-141, 288-89.) These witnesses also stated because a patient's symptoms subside upon discontinuation of the drug does not by itself establish a causal connection. *Id.*

Plaintiffs contend that BIPI publicly denied causation. Defendants assert that there has been no evidence of a cause and effect relationship between Mirapex use and pathological gambling. Dr. Davidai testified that the scientific evidence to date has shown merely an association between Mirapex and impulse control disorders. (Def. Ex. I (Davidai Dep.) at 155-56.) There is also no evidence that Mirapex causes "addiction." (Pl. Ex. 92 (letter from Department of Health and Human Services to BIPI stating "the available information does not constitute proof of a cause and effect relationship"); Def. Ex. B (Gordon Dep.) at 83; Def. Ex. O (Wohlberg Dep.) at 346-47).

Plaintiffs focus on a news segment where Dr. Shepard, who was affiliated with BIPI, stated that there was no causal connection between Mirapex and gambling. In response,

Defendants contend that Plaintiffs' evidence for this attribution is an email from Ann Davin to a number of BIPI employees and purports to summarize the "key messages" that were conveyed in the news story. (Pl. Ex. 91.) Defendants contend that it contains only four items in quotes, two of which are directly attributed to the Parkinson's disease patient profiled in the story. (Def. Br. at 23 fn.6.) Also, the email does not quote Dr. Shepard or specifically identify what he said during the program. Dr. Shepard did say: "[t]here is no clear answer at this time whether a causal relationship exists between Mirapex and the compulsive gambling. On occasion compulsive behavior among Parkinson's disease patients has been reported in conjunction with numerous drug therapies." (Def. Ex. Z.)

Plaintiffs also contend that BIPI omitted important information in its July 2005 report responding to the FDA's request for information about reports of gambling that BIPI had received. Specifically Plaintiffs argue that BIPI should have mentioned the Clinical Expert Report of two BI doctors which concluded there was a clear pharmacodynamic effect of pramipexole on pathological gambling and BI's decision to include in the rest of the world pathological gambling as a side effect. (Pl. Ex. 78.) Plaintiffs also contend that BIPI omitted three patients who suffered from compulsive behavior in correspondence to the FDA dated September 22, 2005.

Defendants contend that the July 2005 correspondence to the FDA was in response to very specific requests. (Def. Br. at 25.) The FDA was requesting information to help them determine whether reports of impulse control disorders might have been missed in the pivotal Mirapex clinical trials due to coding issues. (Pl. Ex. 113; Ex. E (Corsico Dep.) at 215-16.) The FDA requested that BIPI provide files of all the "verbatim terms" in the case report forms and their associated "coded terms" used in the pivotal trials used to support the Mirapex NDA. (Def. Ex. J (Reidies Dep.) at 248-49.) There were no gambling events reports in the three pivotal trials.

As for the three patients who were not included in the September 22, 2005 correspondence, Dr. Corsico explained that they were not included because either: (1) the coded terms used for these adverse events did not match the list of 75 preferred terms that BIPI used to run the search; or (2) the patient participated in a clinical trial that was not included in the search. (Def. Ex. E (Corsico Dep.) at 274-75.) The Defendant further contends that the September 22, 2005 response to the FDA was based on the FDA's request that BIPI search its long-term Mirapex clinical trials for reports of impulse control disorders. The FDA requested that it use 22 preferred search terms provided by the FDA which it used in addition to 50 or so more terms used in reports of impulse control disorders. (Pl. Ex. 14; Def. Ex. E (Corsico Dep.) at 211-12.) Defendants contend that BIPI responded in good faith to the FDA's requests.

In response to Plaintiffs' contention that BIPI delayed in conducting a study, BIPI argued that it convened a number of expert panels on whether Mirapex caused gambling and once the experts determined that a study was necessary, both BIPI and Pfizer began planning a study. Defendants argue that in spite of Plaintiffs' contention that studies can be "unfolded like a puppet," one of BIPI's 30(b)(6) witnesses, Christopher Wohlberg, testified that "designing a study is . . . a massive undertaking and it involves a lot of different groups of people . . . That's why it takes a long time to design a study[.]" (Def. Ex. O (Wohlberg Dep.) at 358-59; Def. Br. at 18). Defendants also take issue with Plaintiffs' contention that Defendants remained silent about the alleged risks of Mirapex. (Pl. Ex. 86.) The experts on the various panels convened disagreed on whether a warning should be issued before the matter was completely understood. (Pl. Ex. 73 at 1881-82.) In November 2004, BIPI did change its label to include a warning in the product information. (Pl. Ex. 86.)

## **2. Response to Allegations Against, Pharmacia & Upjohn, LLC, Pharmacia and Pfizer**

### **a. Pharmacia & Upjohn**

Plaintiffs allege that Upjohn knew early on that Mirapex induced compulsive behaviors in animals. Defendants contend, as they do with respect to BIPI, that the types of disturbances anticipated in the IND applications are clearly distinguishable from the impulse control disorders alleged in this litigation. Defendants point to Pfizer's pharmacology witness, Dr. McCall's testimony that all dopamine agonists have well known side effects, including hallucinations, orthostatic hypotension and somnolence, all of which are different from impulse control disorders. (Def. Ex. C (McCall Dep.) at 100-01.)

Defendants contend that Plaintiffs' allegation that defendants "intentionally suppressed" study of addiction is baseless. (D. Br. at 11.) Upjohn conducted "a rat study about cocaine seeking . . . [involving] motivation and reward." (Def. Ex. N.) Defendants contend that Plaintiffs misconstrue Defendants' conduct in connection with an animal study proposed by Torben Kling-Peterson and an abstract and presentation by Kjell Svensson. Plaintiffs do not mention that these researchers sought to show that D3 agonists have the ability to *block* reward mechanisms not stimulate them. (Pl. Ex. 12 (McCall Dep.) at 201.) Defendants argue that Plaintiffs point to no evidence that Mirapex is addictive and contend that no such evidence exists. (Def. Br. at 13.) They also contend that none of the patients alleges that he or she is addicted to Mirapex. (*Id.*)

#### **b. Pharmacia**

Plaintiffs contend that Pharmacia did not report instances of compulsive gambling and remained silent about the risks of Mirapex. Defendants contend that Pharmacia, as well as the other Defendants, properly reported cases to the FDA and that a study on Mirapex and gambling is underway. (Def. Br. at 6-8, 18.)

#### **c. Pfizer**

Plaintiffs contend that Pfizer failed to report to the FDA the cases of compulsive behavior reported to them by Drs. Stern, Ravin and Lieberman. Pfizer claims that it appropriately followed up with Dr. Lieberman and that he sent them an abstract reporting his findings. (Pl. Ex.

67 at 0721.) Pfizer claims that it also contacted Dr. Lieberman to investigate an internet survey but that federal law governing patient privacy (HIPAA) prevented Dr. Lieberman from sharing the information. (Pl. Ex. 42 at 242-43.) Pfizer claims that it urged Dr. Lieberman to report any adverse events to the FDA himself. (*Id.* at 246-48.) Pfizer claims that this conduct is hardly that of a company trying to suppress or cover up adverse information.

In response to the allegation that Pfizer viewed Drs. Ravin, Stern and Lieberman as “threats,” Pfizer contends that it never viewed them as such. The Plaintiffs take that term from a public relations proposal from an outside consultant, Weber Shandwick, which Pfizer rejected. (Def. Br. at 24, n.8.)

As to the allegations that Pfizer and BIPI delayed in conducting a study, Pfizer notes that it co-sponsored three scientific advisory panels to address the issue and to determine whether a study was needed. (Pl. Ex. 72, 73; Def. Ex. T.) Pfizer also contends that its predecessors and BIPI conducted nearly 50 clinical trials, during which time adverse events of all kinds were gathered and evaluated. (Def. Br. at 38.)

### **3. Analysis of Defendants’ Response**

Defendants have presented substantial evidence to rebut the *prima facie* evidence relied upon by Plaintiffs. At trial, in order to be awarded punitive damages, these Plaintiffs will need to prove by clear and convincing evidence that Defendants’ conduct violated the standards established by the law of their respective states. At this stage of the proceeding, however, Plaintiffs from Minnesota, Wisconsin and Florida, must be permitted to amend their complaints to allege punitive damages if they present *prima facie* evidence that the standards were violated. They have. *Prima facie* evidence is, by definition, evidence that, if unrebutted would support a judgment in the plaintiff’s favor. *Olson v. Snap Products, Inc.*, 29 F.Supp.2d 1027, 1034 (D. Minn. 1998); *Wischer v. Mitsubishi Heavy Industries America, Inc.*, 694 N.W.2d 320, 330 (Wis. 2005); Florida Statute § 768.72(1). Whether the rebuttal evidence relied upon by Defendants is sufficient to defeat Plaintiffs’ claims for punitive damages, is an issue for the fact finder at trial.

That we have concluded that Plaintiffs in Minnesota, Wisconsin and Florida may amend their complaints does not compel the awarding of punitive damages. *See Hugart*, 664 N.W.2d at 377.

Based on all the files, records and proceedings herein, **IT IS HEREBY ORDERED** that Plaintiffs' Motion to Amend the Complaint to Add Claims for Punitive Damages [#29] is

**GRANTED in part** and **DENIED in part**, as follows:

1. To the extent that Plaintiffs seek to amend the complaints in cases where the Plaintiffs are from Massachusetts (Plaintiff Manuel A. Quintela, *et al.*) or Louisiana (Plaintiff Thaddeus R. Fayard), the motion is **DENIED**.
2. To the extent that Plaintiffs seek to amend the complaints in cases where the Plaintiffs are from California (Plaintiff Mary Conway), Georgia (Plaintiff Timothy G. Harms), New Jersey (Plaintiff Todd R. Cain), Ohio (Plaintiff Larry Webb, *et al.*), Pennsylvania (Plaintiff Michael A. Dubaich, *et al.*), Texas (Plaintiffs Hylton H. Dodd, *et al.* and Michael W. Averitt, *et al.*), Virginia (Plaintiff Timothy L. Estep), without regard to whether they could meet a heightened pleading standard, the motion is **GRANTED**.
3. To the extent that Plaintiffs seek to amend the complaints in cases where the Plaintiffs are from Florida (Plaintiff Robert M. Zwyer, *et al.*), Minnesota (Plaintiffs Gary Selinsky, Dennis M. Scharpen *et al.*, and Donald J. Nelson), and Wisconsin (Plaintiff Gary E. Charbonneau, *et al.*), the Court finds the Plaintiffs have met the heightened pleading standard of their respective states and the motion is **GRANTED**.

DATED: November 26, 2007

*s/ Franklin L. Noel*  
FRANKLIN L. NOEL  
United States Magistrate Judge