UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: PROPULSID
PRODUCTS LIABILITY LITIGATION

MDL NO. 1355

SECTION L

JUDGE FALLON
MAG. JUDGE ROBY

THIS DOCUMENT RELATES TO ALL CASES

ORDER AND REASONS

Before the Court is plaintiff Virginia Gail Jones's motion filed in connection with her class action seeking certification of a nationwide class under Federal Rule of Civil Procedure 23(b)(2). For reasons set forth below the motion is DENIED.

I. *BACKGROUND*

A. *Introduction*

Propulsid is the trade name for a family of prescription drug products which contain the active pharmaceutical ingredient Cisapride. It was approved by the U.S. Food and Drug Administration (FDA) in 1993 to be used in treating the symptoms of nocturnal heartburn due to gastroesophageal reflux disease (GERD). Propulsid is manufactured by Janssen Pharmaceutica, Inc., which is a wholly owned subsidiary of Johnson & Johnson. Janssen Pharmaceutica's United

States headquarters is located in Titusville, New Jersey.

It is alleged that dangerous heartbeat irregularities develop when Propulsid is consumed by some individuals in certain circumstances and that as early as 1993 the defendants, through adverse drug reports, became aware of heart problems associated with the ingestion of Propulsid. Nevertheless, according to plaintiff, the defendants persisted in aggressively marketing Propulsid by misleading potential consumers, physicians, and other healthcare providers concerning the safety, efficacy and risks associated with the use of the drug.

On March 23, 2000 Janssen announced its decision to end general distribution of Propulsid in the United States as of July 14, 2000. The stated reason for the removal of the drug was that, despite clear label warnings regarding Propulsid's adverse effects when combined with contraindicated medicines and risk factors, the drug was being inappropriately prescribed by physicians. It is estimated that prior to its removal some thirty million U.S. residents had taken Propulsid. Following its removal, thousands of claimants began filing suits against Johnson & Johnson and Janssen Pharmaceutica in federal and state courts across the country.

On August 7, 2000, the Judicial Panel on Multidistrict Litigation (JPMDL) conferred multidistrict litigation status on the Propulsid suits filed in the federal courts, and pursuant to Title 28, United States Code, Section 1407, transferred all federal Propulsid suits to this Court to coordinate discovery and to consolidate pretrial matters. Shortly thereafter, this Court appointed committees of counsel to represent the parties, and the litigation commenced. This multidistrict litigation, designated MDL-1355 and captioned *In re Propulsid Products Liability Litigation,* involves hundreds, perhaps thousands of individual claimants including over thirty class actions from some fifteen states, all alleging various tort and products liability claims against the

manufacturers of Propulsid.

After a period of discovery, the Plaintiffs' Steering Committee filed the present motion for certification of a nationwide class under Federal Rule of Civil Procedure 23(b)(2). The pleadings allege various wrongful acts by the defendants and specify numerous theories of liability under both New Jersey law and the "laws of any state whose law may be found to be applicable to this case." These theories of liability include: negligence; fraud; failure to warn; strict products liability; defective design; breach of express warranty; breach of implied warranty; and knowing concealment, suppression or omission of a material fact.

Plaintiffs' Steering Committee requests equitable relief in the form of medical monitoring in addition to the establishment of a clinical study, the purpose of which is to examine the long-term effects of Propulsid. They also seek monetary reimbursement for the purchase of Propulsid.

The class representatives are Virginia Gail Jones and Patrick Luckman. Presently it is only the claims of Ms. Jones and those similarly situated that are the subject matter of this motion.[1] The putative class consists of all such persons in the United States who purchased and/or used Propulsid. Also included in the class are any other such persons asserting their right to sue the defendants independently or derivatively by reason of their personal relationship with persons who used Propulsid, including without limitation, spouses, parents, children, dependents,

[1] At this time the Plaintiffs' Steering Committee does not seek class certification of the claims of Patrick Luckman and others similarly situated seeking damages for personal injury resulting from the use of Propulsid. Plaintiffs' Steering Committee has reserved its right to pursue class certification of such claims at a later time. At present they seek class certification of only those claims typical of Virginia Gail Jones, namely those claimants who have not suffered a cardiac incident but nevertheless seek equitable relief in the form of the establishment of a clinical study and a medical monitoring program to determine whether they suffer from a lasting effect of Propulsid after discontinuing their use of the drug.

and other relatives or significant others.

B. ***Medical Background***

Prior to any legal analysis of the certifiability of plaintiff's claims as a class action, a discussion of the pharmacology of Propulsid as well as the anatomy and electrical behavior of the human heart is helpful in understanding the issues raised in this case.

1. Pharmacology of Propulsid

Propulsid was developed to treat gastroesophageal reflux disease (GERD). GERD is the abnormal backflow (reflux) of stomach acids into the esophagus, the tube that leads from the throat to the stomach. This backflow occurs because the valve between the lower end of the esophagus and the stomach (the lower esophageal sphincter) does not close tightly enough. The main symptom of GERD is frequent heartburn. Some drugs treat this condition by neutralizing acid in the digestive tract or by decreasing the amount of acid produced by the stomach.

Propulsid is unique in that it is a prokinetic or motility agent. It treats GERD by increasing the rate at which the esophagus, stomach, and intestines move food during digestion. It also increases the rate at which the stomach empties into the intestines and increases the strength of the lower esophageal sphincter.

2. The Anatomy of the Heart

The human heart is a pear-shaped structure about the size of the possessor's fist. It lies obliquely within the chest cavity just left of center, with the apex pointing downward. The heart

is constructed of a special kind of muscle called myocardium and is enclosed in a double-layered, membranous sac known as the pericardium. A wall of muscle divides the heart into two cavities. The left cavity pumps blood throughout the body, while the right cavity pumps blood only through the lungs. Each cavity is in turn divided into two chambers, the upper ones are called atria, the lower ones, ventricles. Venous blood from the body, containing large amounts of carbon dioxide, returns to the right atrium. From there it enters the right ventricle, which contracts, pumping blood through the pulmonary artery to the lungs. Oxygenated blood returns from the lungs to the left atrium and enters the left ventricle, which contracts, forcing the blood into the aorta, from which it is distributed throughout the body.

3. *The Electrical System of the Heart*

In the normal heart, the heart beat (or heart contraction) originates in the natural pacemaker of the heart, the sinoatrial node (S.A. node) located high in the right atrium. The heart beat is caused by a special group of cells located in the S.A. node that have the ability to generate electrical activity by separating charged particles and leaking them into the extra-cellular space. The electrical impulses in the heart are created when the charged ions of sodium, potassium and other ions such as calcium pass via minute channels through the walls of the cardiac cells. This charge travels across the atria to another specialized group of cells called the atrioventricular node ("AVN"). Once there, the signal encounters a "delay" that allows both atria to contract which results in the filling of the larger ventricular cavities with blood. Under normal circumstances the signal then travels through the pathway in the septum (the wall between each ventricle) and then along each ventricles's bundle branches to the ventricles themselves which

respond by contracting and pumping the blood out to the lungs and the rest of the body.

Although the pacemaker cells create the electrical impulse that causes the heart to beat, numerous nerves regulate the rate at which the pacemaker cells fire and control how strongly the heart contracts. One of these nerves, the vagus nerve, starts at the brain and runs down as far as the stomach performing numerous tasks along the way, including the regulation of the heart rate. These nerves are part of the autonomic nervous system. This nervous system operates without conscious control and governs the function of glands and muscles. The autonomic nervous system has two parts—the sympathetic nervous system and the parasympathetic nervous system. The sympathetic nerves increase the heart rate and increase the force of contraction. The parasympathetic nerves do the opposite.

When the normal beating of the heart is disturbed, the heart can beat irregularly or erratically. This irregularity is known as an arrhythmia. Arrhythmias may be trivial and asymptomatic or severe and potentially life threatening.

4. *The Electrocardiogram*

The electrocardiogram (ECG or EKG) is a recording of the electrical waves produced by the above described electrical activity of the heart. The orderly progression of the electric impulses or waves associated with the heart beat are plotted on graph paper which allows for visualization of the heart's electrical activity along with a measurement of the heart rate. Each wave on the EKG is designated by a letter: P, Q, R, S, and T. The Q-wave is the beginning of the electrical discharge of the ventricles. The T-wave represents repolarization of the heart. The time lapse between the Q-wave and the T-wave is the QT interval. This interval represents the

time it takes for the ventricles to discharge (or contract) and recharge (or recover).

Because the QT interval varies with the heart rate, it must be corrected using one of several formulas available before a meaningful analysis may be made. The formula corrected measurement is referred to as QTc.

In perfectly healthy people, the QTc interval varies throughout the day by as much as 50 to 75 milliseconds. Individuals with a prolonged QTc interval are at risk for developing a condition known as "torsade de pointes" (twisting of the points) which is a form of ventricular tachycardia (abnormally fast heart rate) and is characterized by a long QTc interval and a short-long-short sequence in the beat preceding its outset.[2]

5. *Propulsid's Effect on the QTc Interval*

It is not contested that Propulsid can temporarily induce a prolongation of the QTc interval under certain circumstances. What is debated by the parties is whether Propulsid has a lasting or permanent prolonging effect on the QTc interval after cessation of use. Defendants suggest that there is no basis in science to support such a position.

As explained above, the heart beat is caused in large part by the movement of potassium, sodium and calcium ions in and out of heart cells through what are known as ion channels which are units of protein on the surface of the heart cells. Propulsid can cause a temporary prolongation of the QTc interval by chemically blocking the potassium ion channels. However, according to defendants' expert, these ion channels are very short lived and turn over constantly

[2] A QTc interval of greater than 0.46 seconds is generally considered by the cardiology community to indicate a high possibility for future cardiac arrhythmias.

in the heart. Furthermore, because Propulsid has a half-life[3] of less than one day in the body, within minutes the drug washes out of the potassium ion channels. Defendants' experts contend that the potassium ion channel is the only ion channel affected by Propulsid.

On the other hand, relying on the report of her expert, Dr. Joel Morganroth, plaintiff contends that there is empirical evidence that Propulsid has a lasting effect on the heart's electrical system so as to prolong the QTc interval well beyond the cessation of the use of the drug. In arriving at this conclusion, Dr. Morganroth considered all available medical literature concerning the effects of Propulsid on the QTc interval. Additionally, Dr. Morganroth relied on the study which he conducted along with William Shell, Elizabeth Charuvastra, Fernando DeMesa, and Michael Vincent. The study (referred to as the "Shell" study) examined individual ECG's obtained before, during and after Propulsid use in nine patients selected because of symptoms consistent with an arrhythmic event while on Cisapride.[4] From the data obtained in the study, Dr. Morganroth concludes that Propulsid has an enduring, post-cessation prolonging effect on the QTc interval. Plaintiff also suggests that the research report generated from the CIS-NED-32 on-going study supports the conclusions rendered by the plaintiff's experts. Defendants contest this conclusion.

[3] The period over which the concentration of a specified chemical or drug takes to fall to half its original concentration in the specified fluid or blood.

[4] Shell WE, Morganroth J, Charuvastra E, Demesa F, Vincent G, Sustained prolongation of the QTc interval following discontinuation of a drug that prolongs cardiac repolarization, Circulation 104:II-490, 2001.

In this study the mean duration of administration of Propulsid was 16 +/- 13.8 months. The mean time from the discontinuation of the drug to the last ECG available was 10.3 +/- 14 months. The mean QTc interval before Cisapride was 0.415, during was 0.484, and after was 0.492. The QTc interval fell toward baseline in three of the nine patients, while it remained elevated or increased in six of the nine patients.

In an effort to explain the biologic feasability of Propulsid's alleged enduring effect in light of Propulsid's short half-life and the fact that the potassium ion channels dissipate over time, plaintiff's expert, Dr. Dwain L. Eckberg, postulates that the alleged persistent prolonging effect of Propulsid on the QTc interval may be attributed to Propulsid's long-term, if not permanent, effects on the autonomic nervous system. Dr. Eckberg concludes that Propulsid acutely disturbs autonomic cardiovascular regulation and causes prolonged impairment of important vagus nerve mechanisms.

With these medical factors in mind, it is now appropriate to begin an analysis of the legal issues.

II. *ANALYSIS*

A. *Article III Standing*

The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing that she has standing under Article III of the U.S. Constitution to bring her claim. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559-60 (1992). This constitutional prerequisite must be met before a class certification inquiry can commence because it determines the Court's power to hear the case. *Rivera v. Wyeth-Ayerst Laboratories*, 283 F.3d 315, 318 (5th Cir. 2002); *see also Bertulli v. Indep. Ass'n of Cont'l Pilots*, 242 F.3d 290, 294 (5th Cir. 2001)(standing is an inherent prerequisite to the class certification inquiry). Article III standing requires that three elements be satisfied. *Defenders of Wildlife*, 504 U.S. at 560. Failure to establish any one of them deprives a federal court of jurisdiction to hear the suit. *Id.*

First, the plaintiff must have suffered an "injury-in-fact" which is defined as an invasion

of a legally protected interest that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. *Id.* (citations omitted). Furthermore, the injury-in-fact test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself among the injured. *Sierra Club v. Morton*, 405 U.S. 727 (1972).

Second, a causal connection must exist between the injury and the conduct complained of. In other words, the injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court. *Defenders of Wildlife,* 504 U.S. at 560.

Third, it must be likely that the injury will be redressed by a favorable court decision. *Defenders of Wildlife,* 504 U.S. at 561.

At the class certification stage, however, the question of whether the plaintiff has satisfied the elements of standing requires that the Court assume the truth of the facts alleged by the plaintiff. *See Defenders of Wildlife*, 504 U.S. at 561 (each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation); *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 178 (1974) (preliminary inquiry into the merits of the case is not proper at the class certification stage). Thus, the standard is similar to that used by a court in evaluating a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Utilizing this standard, it is appropriate to review these elements of standing.

First, with regard to the injury-in-fact element of standing, plaintiff alleges that her prior consumption of Propulsid has increased her risk of sustaining heart disease and/or related cardio-dysfunctions. Although the parties vigorously dispute whether Propulsid has a permanent or

long-term hazardous effect on the heart after discontinuance of the use of the drug, at this stage in the litigation plaintiff has satisfied her burden of establishing this element because the courts have long recognized that an increased risk of harm, which the plaintiff alleges, is an injury-in-fact. *See Friends For All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816 (D.C. Cir. 1984); *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990); *In re Orthopedic Bone Screw Products Liability Litigation*, 1999 WL 455667 (E.D. Pa.).

The second element of standing is causation. This element is satisfied when the injury alleged is fairly traceable to the challenged action of the defendant. In this case the drug which allegedly produces long-term harmful effects was manufactured by the defendants. Plaintiff traces her alleged injury to the defendants' failure to adequately test the drug and their failure to sufficiently warn of the dangers of the drug. A potential intermediary in the chain of events may be the physicians who prescribed Propulsid to their patients. *See In re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374 (5th Cir. 1999) (noting the applicability of the "learned intermediary doctrine"). However, this consideration, at least at the class certification stage, does not negate the fact that the alleged injury is fairly traceable to the alleged wrongful acts of the defendants.

The third and final consideration relative to Article III standing is that of redressability of the alleged injury by a favorable court decision. In this case plaintiff seeks equitable relief in the form of the creation of a medical monitoring program to provide testing, preventive screening and surveillance for conditions resulting from the consumption of Propulsid, as well as the establishment of a medical research and education fund and a medical/legal registry. Plaintiff also seeks restitution of all money acquired from the sale of Propulsid to plaintiff and members

of the putative class. The Court finds that such relief would redress the alleged injury suffered by the plaintiff and the putative class. Because plaintiffs have satisfied the elements of Article III standing at this stage of the proceeding, the Court may now proceed to an analysis of whether this action may be certified under Rule 23 of the Federal Rules of Civil Procedure.

B. *Choice of Law*

The plaintiff brings her claim under the diversity of citizenship jurisdiction of this Court pursuant to 28 U.S.C. § 1332. Accordingly, state substantive law will apply. *See Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938). At the outset the Court must determine which state's (or states') substantive law will govern the class.

It is a well established principle that a federal court sitting in diversity must apply the choice-of-law rules of the forum state in determining which state's substantive law to apply in the case. *Klaxon v. Stentor Elec. Mfg. Co., Inc.*, 313 U.S. 487 (1941). In the MDL setting, the forum state is usually the state in which the action was initially filed before it was transferred to the court presiding over the MDL proceedings. In the present case the plaintiff filed a master complaint in the MDL proceeding on October 5, 2001 and simultaneously filed a nearly identical complaint in the U.S. District Court for the Southern District of Indiana. The Indiana complaint was subsequently transferred to this Court pursuant to 28 U.S.C. § 1407 to be included in the MDL proceeding. The Plaintiffs' Steering Committee seeks to utilize the Indiana suit as the basis for a choice-of-law analysis. Defendants, on the other hand, argue that the MDL master complaint should be used. Thus, as a threshold matter this Court must decide which complaint—the master complaint filed in Louisiana or the complaint filed in Indiana—should be

used in the choice-of-law analysis.

Defendants note that although the master complaint and the Indiana suit were filed on October 5, 2001, the Indiana suit was not transferred to the MDL proceeding until December 31, 2001, nearly three months after plaintiff Jones's appearance in the master complaint. Defendants argue that since the master complaint was the first to be filed in the MDL proceeding, it should be used to determine the applicable choice-of-law rules. Accordingly, defendants urge this Court to apply Louisiana's choice-of-law rules in determining the substantive law applicable to the putative class action since the master complaint was filed in Louisiana.

Plaintiff correctly notes that the master complaint was filed pursuant to this Court's Pretrial Order No. 2. Plaintiff argues that the master complaint is nothing more than an administrative device used by the Court to streamline pleadings and motion practice. Therefore, as it is not a traditional complaint, according to plaintiff, Louisiana's choice-of-law rules do not come into play. Instead, plaintiff argues that Indiana's choice-of-law rules apply because that is where the true complaint was filed. The answer to this conundrum requires an analysis of the nature and origin of the master complaint in MDL proceedings.

1. The Legal Nature of a Master Class Action Complaint and the Rule of Lexecon

Master complaints are often used in complex litigation, although they are not specifically mentioned in either the Federal Rules of Civil Procedure or in any federal statute.[5] They seem to

[5] The use of a master class action complaint is documented in cases such as *In re Bridgestone/Firestone, Inc. Tires Products Liability Litigation*, 155 F.Supp.2d 1069 (S.D. Ind. 2001). However, in that case it was not necessary to address the nature of the master complaint as in this case.

In *Bridgestone/Firestone* a master complaint asserting a nationwide class action was filed

be grounded instead in the general provisions of Rule 42(a) of the Federal Rules of Civil Procedure. Rule 42(a) broadly authorizes district courts to consolidate actions pending before the court and to make such orders "as may tend to avoid unnecessary costs or delay." Courts have interpreted Rule 42(a) to authorize the filing of a unified or master complaint in cases consolidated both for pretrial discovery and for trial. *See Katz v. Realty Equities Corp. of New York*, 521 F.2d 1354 (2d Cir. 1975); *In re Equity Funding Corp. of America Securities Litigation*, 416 F. Supp. 161, 175 (C.D. Cal. 1976); *see also* Hebert B. Newberg & Alba Conte, *Newberg on Class Actions* §9.27, at 269 (2d ed. 1985). In both situations, consolidation is not supposed to "merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another." *See* 9 Charles A. Wright and Arthur R. Miller, *Federal Practice and Procedure* §2382, at 255 (1971) (hereinafter "Wright & Miller"). Rather, consolidation is intended only as a procedural device used to promote judicial efficiency and economy. *See* Diana E. Murphy, *Unified and Consolidated Complaints in Multidistrict Litigation*, 132 F.R.D. 597 (1991) (hereinafter "Murphy").

Although the use of a consolidated or master complaint is mentioned as an option in a checklist found in the *Manual for Complex Litigation (Third),* the manual does not address the ramifications or effects of master complaints on the future course of the litigation. *See Manual for Complex Litigation (Third)* § 40.1(6), at 414 (1995). Some commentators have astutely

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in the Southern District of Indiana. In determining which state's choice-of-law rules would apply to the class, the court noted that "the parties agree that this Court should be treated as the forum court because Plaintiff filed their master complaint in this Court." Accordingly, the *Bridgestone/Firestone* court applied Indiana's choice-of-law rules. *In re Bridgestone/Firestone*, 155 F. Supp.2d at 1078. There is no such agreement in this case.

observed that master complaints in class actions may create substantive problems despite their intended purpose as an administrative vehicle to streamline the litigation. *See* Murphy, *supra*; Arnold Levin, *MDL/Class Actions in Mass Tort, Pharmaceutical, and Toxic Litigation*, Ann. 2001 ATLA-CLE 2793 (2001). These concerns are well founded.

If the master complaint in the present case were to be treated as a traditional complaint, many significant and perhaps unintended consequences would follow. First, it would make applicable Louisiana's choice-of-law rules even though the class action for which class certification is sought was filed in Indiana. Second, it would complicate the matter of the subsequent remand of the individual MDL actions back to the transferor court by introducing confusion as to which court is the transferor court in light of the fact that two substantive complaints---one in Louisiana and one in Indiana—have been filed. Indeed, taking this to the extreme, a master complaint, if given the status of a traditional complaint, could be used to circumvent the remand requirement of 28 U.S.C. § 1407 by substituting itself for all individual actions filed in the MDL and thereby frustrate the intended effect of that statute as recognized in the Supreme Court's decision in *Lexecon, Inc. v. Milbreg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 39 (1988).[6] In light of these concerns the master complaint should not be given the same effect as an ordinary complaint. Instead, it should be considered as only an administrative

[6] The *Lexecon* decision concerned the propriety of self-referrals of MDL consolidated cases to the MDL transferee court pursuant to 28 U.S.C. § 1404; however, the basis of the decision lies in the Court's resolution of the tension between a broad reading of the MDL court's pretrial authority and the Panel's remand obligation under § 1407(a) based on the statute's legislative history. In recognizing a limitation on the power of the transferee court to self-refer cases, *Lexecon's* message is relevant to the use of a master complaint insofar as a master complaint filed in the MDL court may be used to replace all § 1407 transferred actions such that the transferee court becomes the trial court for all cases.

device to aid efficiency and economy.

Having concluded that the master complaint filed in this case and in this Court is merely a procedural device, the Court looks to the specific action brought before the Court for class certification, namely the Indiana complaint, to determine which state's choice-of-law rules apply. Since Indiana is the forum state, the Court must look to the Indiana choice-of-law rules to determine which state's substantive law applies to the putative class.

2. Application of Indiana Choice-of-Law Rules

In this case the complaint asserts numerous claims based generally on common law negligence, fraud, and products liability theories. Because these claims are most closely associated with common law tort theories, they are subject to a tort-based choice-of-law analysis.

Indiana is a *lex loci delicti* state. In all but exceptional cases it applies the law of the place where the harm occurred. *In re Bridgestone/Firestone, Inc.*, 2002 WL 831990 at *2 (7th Cir.) (citing *Hubbard Manufacturing Co. v. Greeson*, 515 N.E.2d 1071 (Ind. 1987)).

In its choice-of-law analysis of tort cases, Indiana applies a two-step approach. *Land v. Yamaha Motor Corp.*, 272 F.3d 514, 516 (7th Cir. 2001). First, the court determines if the place of the injury is significant. *Id.* If it is, the law of that state applies. *Id.* Only if the court finds that the place of injury is insignificant does it move to step two which requires the court to consider "other factors such as: 1) the place where the conduct causing the injury occurred; 2) the residence or place of business of the parties; and 3) the place where the relationship is centered." *Id.* at 516-17 (citing *Hubbard*, 515 N.E.2d at 1073).

In this case the alleged injury suffered by the putative class members is the increased risk

of experiencing a cardiac event as a result of QTc prolongation caused by the ingestion of Propulsid. The ingestion of Propulsid is the last event that relates to liability. Putting aside the question of whether the alleged injury resulted from long-term use of the drug or from limited or one-time use, it is clear that the injury or harm occurred in the states in which the drug was ingested. Since the putative class consists of individuals from virtually every jurisdiction of the United States, Indiana's choice-of-law rules would make applicable the substantive law of every state in which a putative class member ingested Propulsid unless the fact that the drug was ingested in a particular place is considered insignificant in terms of liability.

Plaintiff argues that this Court in applying Indiana's choice-of-law rules should consider the last event, namely ingestion of the drug, as insignificant and proceed to step two of the analysis thereby applying the other factors mentioned above. In this regard, plaintiff notes that the defendants are headquartered in New Jersey; the wrongful acts occurred in New Jersey; the drug was manufactured in New Jersey; corporate decisions regarding the marketing of the drug were made in New Jersey; the sales and marketing materials were developed and approved in New Jersey; the drug warning labels were developed and approved in New Jersey; and finally the decision to maintain the drug on the market despite the rising death and injury toll was made in New Jersey. Plaintiff also relies on the district court opinion in *Bridgestone/Firestone* wherein the district court held that because each plaintiff would have suffered the identical injury wherever he or she purchased or used the defective tire or vehicle, the place where the tort manifests itself other than the point of manufacture and marketing has little connection to the tort claims and is, therefore, insignificant. *In re Bridgestone/Firestone, Inc. Tires Products Liability Litigation*, 155 F.Supp.2d 1069, 1081 (S.D. Ind. 2001).

The *Bridgestone/Firestone* case arose out of the abnormally high failure rate of Firestone tires installed on Ford Explorer sport utility vehicles. In *Bridgestone/Firestone*, buyers and lessees of sport utility vehicles that were equipped with Firestone tires brought several class action complaints against the tire manufacturer and the vehicle manufacturer. In the master complaint filed in that litigation, plaintiffs asserted claims for breach of warranty and consumer fraud against Ford (a Delaware corporation with its principal place of business in Michigan) and Firestone (an Ohio corporation with its principal place of business in Tennessee). In applying Indiana's choice-of-law analysis, the district court concluded that Indiana would select the law of Michigan as to the claims asserted against Ford and the law of Tennessee as to the claims asserted against Firestone, regardless of the residences of the plaintiffs and regardless of where the plaintiffs purchased the defective tires or vehicle. The district court reasoned that the place of purchase or place of injury was insignificant and that the only locations of importance were the headquarters of the defendants because (1) the defendants sold their products in every state in the nation and (2) each plaintiff would have suffered the identical injury regardless of where the products were purchased or where the plaintiff resided. *Id.* at 1081. Finding that the place of injury was insignificant, the court considered the factors set forth in *Hubbard Manufacturing Co. v. Greeson* and concluded that the laws of Tennessee and Michigan should be applied because the products were designed there and important decisions about disclosures and sales were made there.

The United States Court of Appeals for the Seventh Circuit reversed the decision of the district court. *In re Bridgestone/Firestone, Inc.*, 2002 WL 831990 (7th Cir.). Noting that Indiana is a *lex loci delicti* state in all but exceptional cases, the appeals court observed that not once

since the Indiana Supreme Court's 1987 decision in *Hubbard* has Indiana applied the law of a state where a product was designed, or promotional materials drafted, to a suit arising out of an injury in Indiana although the court has had many opportunities to do so. *Id.* at *2. According to the appeals court, "Indiana and this court have routinely applied Indiana law when injury caused by a defective product occurred in Indiana to Indiana residents." *Id.* (citing *Land v Yamaha Motor Corp.*, 272 F.3d 514, 517 (7th Cir. 2001) and *Morgen v. Ford Motor Co.*, 762 N.E.2d 137 (Ind. App. 2002)). Finding that the Indiana *lex loci delicti* analysis would select the substantive laws of every state in the nation, the appeals court decertified the class on the grounds that a single nationwide class would not be manageable.

As mentioned above, the place of injury in the instant case is each state in which the individual class members ingested Propulsid. Considering the fact that Propulsid is a prescription drug which necessitates the involvement of a physician, the place of injury is significant. Indeed, the behavior and knowledge of the treating physicians may be of great importance to this case. Furthermore, there are other issues of legal significance which are location specific such as the effect (and effectiveness) of the warnings issued by the defendants as well as the legal significance of the defendants' practice of direct marketing of Propulsid to users. Therefore, to the extent that the geographic location of the injury matters in the *lex loci delicti* analysis, it can not be said in this case that the locations fixed by the ingestion of Propulsid are insignificant. Accordingly, the Court concludes that Indiana would select the law of the states in which the drug was ingested as the law applicable to the class members' claims. More likely than not this would be the law of the state in which each putative class member resides or is domiciled. Since the putative class members in this case hail from virtually every

state in the nation, the Court must decide whether a nationwide class action brought under Rule 23(b)(2) is certifiable as a class action when the laws of virtually every jurisdiction are applicable.[7] Clearly certification would be unlikely if it were sought under Rule 23(b)(3) in light of the "predominance" requirement. Indeed, the Fifth Circuit in *Castano v. American Tobacco Co.* observed that in multistate class actions, "variations in state law may swamp any common issues and defeat predominance." 84 F.3d 734, 741 (5th Cir. 1996). The present case, however, is brought for certification under Rule 23(b)(2). The question is whether this changes matters.

C. *Certifiability of the Nationwide Class Action under Rule 23(b)(2)*

In determining whether the instant action may be certified as a class action under Rule 23(b)(2) it is necessary to consider the following issues: (1) whether the monetary relief sought by the putative class predominates over the injunctive relief sought and (2) whether this class action would be manageable in light of the applicability of the laws of multiple jurisdictions.

1. Whether Monetary Relief Predominates over the Injunctive Relief Sought

In this case plaintiff seeks the creation of a court-supervised trust fund to finance a medical monitoring program (including a nationwide clinical study of the long-term effects of Propulsid) as well as restitution of all monies acquired from the sale of Propulsid to the class members, compensatory and punitive damages in an amount to be proven at trial, and pre-judgment and post-judgment interest. Plaintiff further seeks an award of costs and expenses of

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[7] Having concluded that the law of New Jersey is not the only law applicable to the nationwide putative class, the Court need not address whether the application of one state's substantive law to the entire class would be constitutional.

this litigation, including attorneys fees.

In *Allison v. Citgo Petroleum Corp.*, 151 F.3d 402 (1998), the Fifth Circuit recognized that monetary relief may be sought in addition to injunctive relief in class actions certified under Rule 23(b)(2) provided that the injunctive relief is the predominant form of relief sought for the class.[8] There is little discussion by the Fifth Circuit or any appellate court as to what it means for a particular form of relief to be predominant. The court in *Allison* looked to the Federal Rules Advisory Committee Notes for guidance but found that the notes "make no effort to define or explain the concept." *Id.* at 411. After consulting dictionaries and commentators to no avail, the *Allison* court turned to "the principles and assumptions" underlying the (b)(2) class action and reached the following conclusions:

> [M]onetary relief predominates in (b)(2) class actions unless it is incidental to requested injunctive or declaratory relief. By incidental, we mean damages that flow directly from liability to the class as a whole on the claims forming the basis of the injunctive or declaratory relief. Ideally, incidental damages should be only those to which class members automatically would be entitled once liability to the class (or subclass) as a whole is established. ...[S]uch damages should at least be capable of computation by means of objective standards and not dependent in any significant way on the intangible, subjective differences of each class member's circumstances. Liability for incidental damages should not require additional hearings to resolve the disparate merits of each individual's case; it should neither introduce new and substantial legal or factual issues, nor entail complex individualized determinations. Thus, incidental damages will, by definition, be more in the nature of a group remedy,

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[8] Rule 23(b)(2) is silent as to whether monetary remedies may be sought in conjunction with injunctive or declaratory relief. The Advisory Committee Notes on Rule 23 state that class certification under (b)(2) "does not extend to cases in which the appropriate final relief relates exclusively or predominantly to money damages." Fed. R. Civ. P. 23 advisory committee notes. This commentary implies that the drafters of Rule 23 believed that at least some form or amount of monetary relief would be permissible in a (b)(2) class action. *Allison*, 151 F.3d at 411.

consistent with the forms of relief intended for (b)(2) class actions.

Allison, 151 F.3d at 415 (citations omitted).

In the present case the monetary claims are "dependent in a significant way on differences of each class member's circumstances." They will require additional hearings to resolve the "disparate merits of each individual's case." There are likely to be "new and substantial legal issues" presented because each state's law will have to be analyzed to determine whether such monetary awards are allowed and, if so, under which legal theory, and also whether the claims are subject to any legal defenses. Applying the principles annunciated in *Allison,* it is clear that the monetary claims asserted by plaintiff "predominate." Consequently they are not recoverable under 23(b)(2) and must be stricken.

Perhaps in anticipation of the complications caused by seeking monetary relief, plaintiff indicates that she is willing to abandon her claim for monetary relief if it presents an obstacle to class certification under Rule 23(b)(2). For reasons discussed below, the Court finds that even if plaintiff's claim for monetary relief is set aside, there are other issues which make certification problematic.

2. Whether this Class Action is Manageable in Light of the Applicability of the Laws of Multiple Jurisdictions

A class action may be certified under Rule 23(b)(2) when the opposing party "has acted or refused to act on grounds generally applicable to the class, thereby making final injunctive relief or corresponding declaratory relief appropriate with respect to the class as a whole." Fed. R. Civ. P. 23(b)(2). In the present case, plaintiff argues that the defendants' conduct is generally applicable to the class. Plaintiff explains that the defendants marketed, promoted, and distributed

Propulsid on a nationwide scale while at the same time suppressing and hiding the harmful effects of the drug and in this way acted on grounds generally applicable to the class of Propulsid users. On this basis, plaintiff seeks injunctive relief in the form of the establishment of a nationwide medical monitoring program, including a nationwide clinical study of all former Propulsid users.

Viewed from a purely practical perspective the creation of a nationwide class in the present case would seem to be an appropriate if not a necessary vehicle for achieving the remedy sought by the plaintiff. To have any statistical meaning a medical monitoring program, which includes a clinical study of former Propulsid users, would have to be carried out on a national scale. Any smaller or regionally based group would jeopardize the accuracy of the results and the efficiency of the program. But practicality alone is not sufficient to justify a court ruling. The remedy sought must be both manageable and timely for judicial action.

In *Castano*, the Fifth Circuit held that in multistate class actions, variations in state law may swamp any common issues and defeat predominance. 84 F.3d at 741. Of course, the *Castano* court confronted the issue of the certifiability of a nationwide class under Rule 23(b)(3), whereas the present case involves a claim under (b)(2). Unlike Rule 23(b)(3), Rule 23(b)(2) does not expressly require that issues of law or fact common to the members of the class *predominate* over any questions affecting only individual members. Rather, what is required under (b)(2), in addition to satisfying the prerequisites of Rule 23(a), is a finding that the "opposing party has acted or refused to act on grounds *generally applicable* to the class. . . ." Fed. R. Civ. P. 23(b)(2) (emphasis added). The statute and case law are silent as to whether grounds which are generally

applicable to the class must involve common legal rights as well as common facts.[9] According to one noted authority, "[w]hat is necessary is that the challenged conduct or lack of conduct be premised on a *ground* that is applicable to the entire class." *See* 7A Wright & Miller, *Federal Practice and Procedure* § 1775, at 456 (2d ed. 1986) (emphasis added). The question posed by the present case is whether the defendant's conduct can be "generally applicable" to the class when the legal rights asserted by the class members derive from various and different state laws.[10]

The answer to this question lies in the purpose or *raison d'etre* of the general applicability requirement. The requisite of generally applicability has significance not only in defining the

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[9] In determining whether to certify a class seeking injunctive or declaratory relief under (b)(2), the courts often speak in terms of homogeneity and cohesiveness of the claims and interests of the class. *See Allison v. Citgo Petroleum Corp.*, 151 F.2d 402, 412 (5th Cir. 1998). The underlying premise of the (b)(2) class is that its members suffer from a common injury properly addressed by class-wide relief. *Id.* at 413. The very nature of a (b)(2) class is that it is homogenous without any conflicting interests between the members of the class. *Holmes v. Continental Can Co.*, 706 F.2d 1144, 1155 (11th Cir. 1983).

Defendants suggest that three factors must be considered in determining whether there is cohesiveness. First, whether the plaintiff can establish entitlement to injunctive relief with respect to the class as a whole in a single unitary trial. Second, whether the case would be manageable at such a unitary trial. Third, whether or not there are significant individual interests that could counsel against certification as a class action.

The Court finds that these considerations are helpful in determining whether the (b)(2) class is cohesive.

[10] In this case, having determined that the law of virtually every jurisdiction will apply, it is very unlikely that the state law claims of the putative class members will be the same. Indeed, some states may allow for medical monitoring while others may not. Some states may provide an affirmative defense to the defendants in this case, such as a learned intermediary defense. Furthermore, considering the array of laws applicable to the putative class, it is quite possible that in some circumstances individual issues will be of such significance that the action would not be manageable in a unitary trial. Therefore, a crucial issue in this case is to what extent if any does the claim for medical monitoring depend upon individual issues. *Barnes v. American Tobacco Co.*, 161 F.3d 127, 138 (3d Cir. 1998).

involved group but also ensuring the manageability of a unified trial. The need for manageability at trial which has been clearly recognized by the Fifth Circuit and other circuits in (b)(3) actions also exists in (b)(2) actions. The application of multiple state laws to a class makes manageability more difficult in both (b)(3) and (b)(2) class actions.

Historically, the Rule 23 (b)(2) class action has been utilized by aggrieved societal classes in seeking classswide relief from various forms of discrimination and other civil rights violations. *See generally* 7A Wright & Miller, *Federal Practice and Procedure* § 1775 (2d ed. 1986). Typically, these class actions have asserted claims under the U.S. Constitution, the Civil Rights Act, and other federal statutes. *Id.* at 472-92. In contrast to the present case, those (b)(2) classes proceeded under a uniform rule of law, very often a federal law. However, in this case numerous and potentially conflicting state laws are applicable to the putative class.

Plaintiff suggests that the difficulty of manageability may be dealt with through the creation of subclasses and the use of simple jury instructions and questionnaires. Plaintiff points out that the court in *In re Diet Drugs Products Liability Litigation*, 1999 WL 673066 (E.D. Pa.) resolved a similar difficulty through the establishment of subclasses according to variations in state law. Plaintiff in that case sought certification of a nationwide class under Rule 23(b)(2) for medical monitoring relief. Following a choice-of-law analysis, the district court concluded that the substantive law applicable to the putative class was the law of the jurisdiction in which each class member was prescribed and ingested the diet drugs. Defendants argued that the state law applicable to each class member varied to such a degree as to render class treatment inappropriate. Nevertheless, the district court concluded that the application of numerous and potentially varying state laws to the class did not render class treatment unmanageable nor did it

destroy cohesion of the class claims. *Id.* at *16. In an effort to deal with varying state laws, the court declared that it would conditionally certify the class and establish subclasses dependent on whether the elements of medical monitoring and/or the underlying legal action differ significantly. *Id.* It should be noted that at the time of the *Diet Drugs* certification order, the plaintiffs had not briefed the issue of varying state law because they were proceeding under the assumption that Pennsylvania law would apply to the entire class. The district court, therefore, ordered briefing on the issue of varying state law with the understanding that the court's certification order would be modified as required so as to create a number of subclasses based upon the variance of both medical monitoring law and differences in the underlying claims of strict liability, negligence and breach of warranty.

Conditional certification of a class action involving multiple state laws without analyzing the effect of this variation on the manageability of the trial is not permitted in the Fifth Circuit. The Fifth Circuit Court of Appeals has rejected the notion that a district court may defer considering variations in state law in order to conditionally certify a class. Rather, what is required is that the district court consider the significance and impact of variations in state law on the manageability of the class in a unitary trial before certifying the class. *See Castano*, 84 F.3d at 741. In order to make this determination, the district court must ascertain to what extent the numerous state laws vary and to what extent this will effect the manageability of the class at trial.

As in the *Diet Drugs* case, plaintiff in the present case, as of the date of the closing of the record in the motion for class certification, has not briefed the variations in the numerous state laws which apply to the putative class having operated under the assumption that the law of only one state—New Jersey—would be applicable. Thus, the record in this case does not presently

contain any review or summary of the various applicable or relevant state laws. In fact, it is unclear exactly how many different state laws are applicable or for that matter whether these laws may be grouped into a smaller number of more manageable categories. *See, e.g., In re School Asbestos Litigation*, 789 F.2d 996 (3d Cir. 1986); *see also Castano*, 84 F.3d at 742. Furthermore, variations involving proof of causation, the effect of warnings, the significance of the defendants' direct marketing to consumers, and other similar issues may swamp any common issues and defeat cohesiveness. In any event, whether variations in state law will defeat manageability is at best uncertain. Thus the plaintiff has failed to carry her burden of establishing the prerequisites for class certification.

In addition to the problems of manageability, the issue of the timeliness of the requested remedy presents a significant obstacle for the plaintiff. Neither the FDA, nor any medical organization or institution, nor anyone else for that matter, except the plaintiff's expert, has recommended or suggested that a program of medical monitoring or a group study of all former Propulsid users be undertaken. This raises the issue of the role of the courts in such an instance. Stated succinctly, the question is whether the courts should lead the scientific community in an area of medical science.

In the *Diet Drugs Products Liability Litigation*, the court certified a class for medical monitoring to determine if an injury existed in former users of the diet drug combination. But in *Diet Drugs*, various forms of medical monitoring were first recommended by the United States Department of Health and Human Services. These recommendations were developed through cooperation among the United States Food and Drug Administration, the National Institutes of Health in consultation with the American Heart Association, the American College of Cardiology

and the American Dental Association. The American College of Cardiology and American Heart Association also issued parallel recommendations in view of the potentially serious public health implications of Fen/Phen exposure. All of these institutions recognized the potential harm of the diet drug combination. However, in the present case there is an absence of recommendations from the medical community regarding the need for a medical monitoring program or a clinical study of the effects of Propulsid on former users. In such a situation the courts should not attempt to fill the void. "The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science, it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996).

III. *CONCLUSION*

For the foregoing reasons,

IT IS ORDERED that the plaintiff's Motion for Class Certification be and hereby is DENIED.

New Orleans, Louisiana, this 4th day of June, 2002

UNITED STATES DISTRICT COURT JUDGE