UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

IN RE: ST. JUDE MEDICAL, INC. SILZONE HEART VALVES PRODUCTS LIABILITY LITIGATION

MDL No. 01-1396 (JRT/FLN)

MEMORANDUM OPINION AND ORDER ON MOTION FOR CLASS CERTIFICATION

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On April 18, 2001, the cases comprising this multidistrict litigation were transferred to this Court by the Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings under 28 U.S.C. § 1407. This matter is now before the Court on plaintiffs' motion for class certification pursuant to Rule 23 of the Federal Rules of Civil Procedure. For the reasons discussed below, plaintiffs' motion is granted in part and denied in part.

BACKGROUND

I. Factual Background[1]

Defendant St. Jude Medical, Inc. ("St. Jude"), a company with headquarters and manufacturing facilities in Minnesota, manufactures a variety of medical devices including prosthetic heart valves. Such valves are surgically implanted into patients whose natural valves have been damaged by disease. Among St. Jude's products is the "Silzone" heart valve, which has a coating of silver on the sewing cuff, the part of the valve that is sewn to the patient's body. Aside from the silver coating, the Silzone valve is essentially the same as other St. Jude heart valves that have been approved by the U.S. Food and Drug Administration ("FDA") since 1995. Because silver has been known to have anti-microbial properties, St. Jude introduced the silver-coated valves to combat endocarditis, a potentially life-threatening infection of the cardiac tissue that is a well-known possible consequence of prosthetic heart valve implantation.

The FDA approved the Silzone valve for commercial distribution on March 24, 1998. As part of this approval, however, the FDA prohibited St. Jude from claiming that the Silzone coating would reduce the risk of endocarditis, as no clinical tests had been performed to study this claim.[2] After the FDA approved the Silzone valve, St. Jude sponsored the Artificial Valve Endocarditis Reduction Trial ("AVERT") study, a multi-national clinical trial designed to study whether the Silzone-coated heart valve reduced

[1] The facts recited in this section are based upon the submissions of the parties and should not be construed as findings of the Court.

[2] The FDA also required that all labels bearing the name "Silzone" must carry the following statement: "No clinical studies have been performed to evaluate the effect of the Silzone coating in reducing the incidence of endocarditis." (Pl. Ex. 10.)

the incidence of endocarditis in humans. Approximately 36,000 Silzone valves have been implanted in patients worldwide, with approximately 10,535 of these in the United States. AVERT was originally intended to involve 4,400 heart valve patients. However, the study enrolled only 792 patients, with approximately half of those receiving Silzone-coated valves and another half, the control group, receiving conventional (non-Silzone) valves. The results of AVERT are reviewed by an independent monitoring board.

In January 2000, the AVERT monitoring board reported that recipients of the Silzone valve were more likely to experience a complication called paravalvular leak,[3] requiring the prosthetic valve to be removed and replaced with another valve, compared to recipients of conventional valves. The data showed that 2 percent of AVERT participants with Silzone valves required such an "explant," while only .25 percent of participants with conventional valves required the procedure. On January 21, 2000, the monitoring board decided to suspend enrollment in the AVERT trial because of this increase in paravalvular leak.[4] On the same day, St. Jude voluntarily recalled all un-implanted Silzone products. As part of the recall, St. Jude immediately notified hospitals and physicians, instructing them not to use Silzone products. St. Jude also sent letters regarding the care and management of patients with implanted Silzone valves, and established a reimbursement program to pay for uninsured medical costs associated with the detection, diagnosis and treatment of paravalvular leak.

[3] Paravalvular leak involves leakage at the point where a heart valve is sutured to a patient's tissue.

[4] Although enrollment in AVERT was suspended, the participants continue to be monitored, and data are still collected and studied.

II. Procedural History and Class Structure

The MDL plaintiffs filed a Consolidated Amended Class Action Complaint in this Court on October 22, 2001. The complaint alleges five causes of action, including counts of strict liability, breach of implied and express warranties, negligence, medical monitoring, and violation of Minnesota's consumer fraud and deceptive trade practices statutes.

Plaintiffs seek certification of two classes. Class I (the "monitoring class") is comprised of every patient in the United States who still has a Silzone valve implanted. Because explantation surgery is not advised for all patients, many Silzone valve recipients still have the Silzone valve. Class I seeks equitable relief in the form of a medical monitoring program that would watch for side effects associated with defective heart valves. This would include an epidemiological program to collect data and study the effects of the Silzone valves. This monitoring program would be paid for by a trust account funded by St. Jude.

Class II (the "injury class") consists of all people in the United States who received a Silzone valve and who have sustained physical injuries due to the valve, including but not limited to injuries requiring explantation surgery and injuries resulting in death. Class II seeks money damages.[5]

[5] It is possible that a person will be a member of both classes. For example, some plaintiffs may have suffered injuries due to the Silzone valve but still have the valve implanted.

ANALYSIS

To qualify for class treatment, an action must first satisfy the threshold requirements of Federal Rule of Civil Procedure 23(a), and must then satisfy one of the three subsections of Rule 23(b). Plaintiffs seek certification of all claims by both classes pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure. Plaintiffs also seek certification of Class I pursuant to Rules 23(b)(1)(A) and 23(b)(2). District courts have broad discretion to decide whether or not to certify a class under Rule 23. *Lockwood Motors, Inc. v. General Motors Corp.*, 162 F.R.D. 569, 573 (D. Minn. 1995).

Part I of this Order analyzes the threshold requirements of Rule 23(a). Part II analyzes whether the proposed classes merit certification under any of the three provisions of Rule 23(b) that are at issue in this case.

I. Requirements of Rule 23(a)

A. Numerosity

St. Jude does not dispute that both proposed classes meet the numerosity requirements of Rule 23(a)(1). Class I consists of approximately 10,535 individuals, and plaintiffs estimate that Class II consists of more than 1,000 individuals. The Court determines that joinder of all members of either proposed class would be impracticable, and therefore concludes that plaintiffs satisfy the numerosity requirement.

B. Commonality

Rule 23(a)(2) requires that there be "questions of law or fact common to the class." This requirement is satisfied when the legal question linking the class members is substantially related to the resolution of the litigation even though the individuals may

not be identically situated. *DeBoer v. Mellon Mortgage Co.*, 64 F.3d 1171, 1174 (8th Cir. 1995). Commonality may be satisfied where one issue pervades all the class members' claims. *Paxton v. Union Nat'l Bank*, 688 F.2d 552, 561 (8th Cir. 1982). St. Jude contends that any claim of commonality in this case is "blurred by a host of individual queries." (Def. Br. at 35.) Plaintiffs respond that there is at least one significant question that links all the class members' claims – whether a defect caused by adding the Silzone coating to the St. Jude heart valves caused or risks certain injuries. While St. Jude is correct that there may be individual variations in the factual circumstances of some class members, that is not enough to defeat commonality. The Court finds that the question of the Silzone valve's alleged defect is common to all members of both classes, and that Rule 23(a)(2) is therefore satisfied.

C. Typicality

The Rule 23(a)(3) typicality requirement requires a "demonstration that there are other members of the class who have the same or similar grievances as the plaintiff." *Donaldson v. Pillsbury Co.*, 554 F.2d 825, 830 (8th Cir. 1977); *In re Lutheran Brotherhood Variable Ins. Prod. Co. Sales Practices Lit.*, 201 F.R.D. 456, 459 (D. Minn. 2001). The burden is "fairly easily met so long as other class members have claims similar to the named plaintiff." *DeBoer*, 64 F.3d at 1174. Moreover, "[f]actual variations in the individual claims will not normally preclude class certification if the claim arises from the same event or course of conduct as the class claims, and gives rise to the same legal or remedial theory." *Alpern v. UtiliCorp United, Inc.*, 84 F.3d 1525, 1540 (8th Cir. 1996).

The named plaintiffs contend that their claims are typical because each representative has at least one Silzone valve implanted, and therefore makes the same allegations regarding risk of injury stemming from the valve. Likewise, named Class II plaintiffs allege that they have all sustained some injury due to the Silzone valves that were formerly implanted in them. St. Jude argues that because each plaintiff's case has different factual circumstances, such as varying types of care, treatment, and magnitude of alleged injuries, no plaintiff is typical of all class members.

St. Jude is certainly correct that none of the plaintiffs' cases are factually identical. These arguments, however, are more relevant to the Court's Rule 23(b)(3) analysis. *See Lutheran Brotherhood*, 201 F.R.D. at 459-60 (noting that factual variations are less relevant to typicality analysis than to questions of predominance and superiority). Even if the named plaintiffs' cases do exhibit different factual circumstances, each of them clearly arises "from the same event or practice or course of conduct that gives rise to the claims of the other class members and [is] based on the same legal theor[ies]." *Hurd v. Monsanto Co.*, 164 F.R.D. 234, 239 (S.D. Ind. 1995). Specifically, all of the plaintiffs' contentions arise from St. Jude's design, manufacture, marketing, and sales of the Silzone valve. These contentions address the ultimate question in the lawsuit, and the Court finds that they satisfy the typicality requirement.

D. Adequacy of Representation

The final requirement of Rule 23(a) is that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). This rule has two requirements. First, the representatives' attorneys must be able and willing to

prosecute the action competently and vigorously. Second, each representative's interest must be "sufficiently similar to those of the class that it is unlikely that their goals and viewpoints will diverge." *Parkhill v. Minnesota Mutual Life Ins. Co.*, 188 F.R.D. 332, 339 (D. Minn. 1999).

St. Jude does not challenge the adequacy of plaintiffs' counsel. It does, however, contend that a conflict of interest could arise between plaintiffs, and that this potential conflict makes the representative plaintiffs inadequate. St. Jude points to *Thompson v. American Tobacco Co., Inc.*, 189 F.R.D. 544 (D. Minn. 1999), in support. In that case, the court found the representatives of a proposed class of cigarette smokers to be inadequate because a conflict of interest could arise between plaintiffs. *Id.* at 551. *Thompson*, however, is inapposite because the class in that case was structured far differently than the proposed classes here. The proposed class in *Thompson* encompassed people who had smoked a cigarette manufactured by the defendant and wished to participate in a smoking cessation and/or medical monitoring program. *Id.* at 548. Thus, the proposed class included people who had smoked only one cigarette up to current smokers who suffered from smoking-related illnesses. *Id.* However, even though the proposed class encompassed people with smoking-related illnesses, the plaintiffs sought to expressly reserve from the class any claims for personal injury. *Id.* The Court found that this effort to tailor the class to achieve certification could jeopardize class members' future claims for personal injuries, if a subsequent court found that any class action decision was *res judicata*. *Id.* at 550-551.

In this case, the proposed classes are not nearly so wide-ranging as the single omnibus class in *Thompson*. Here, plaintiffs have divided the classes between those who

have suffered some injury traceable to a Silzone valve and those for whom injury is a mere possibility. The class makes no explicit reservation of the kind used in *Thompson*. Plaintiffs contend that there is no conflict of interest between them because they all seek to "prov[e] St. Jude's wrongful conduct and establish[] St. Jude's liability" for monitoring for Class I and damages for Class II. (Pl. Br. at 35.) The Court agrees, and finds that plaintiffs all have the same incentive to pursue claims against St. Jude. The Court finds no conflict of interest that would render plaintiffs inadequate representatives of their classes. Therefore, the adequacy component of Rule 23 is satisfied.

The Court finds that plaintiffs have satisfied all the threshold requirements of Rule 23(a). The Court must now determine whether plaintiffs have satisfied any component of Rule 23(b).

II. Requirements of Rule 23(b)

Plaintiffs seek certification under three provisions of Rule 23(b). They first seek to certify both classes under Rule 23(b)(3), which permits certification where plaintiffs can show that common questions predominate and that a class action is the superior method to adjudicate the controversy. Plaintiffs also seek to certify Class I, the monitoring class, under Rule 23(b)(2), which permits injunctive relief if plaintiffs can show that St. Jude acted or refused to act on grounds generally applicable to the class. Finally, plaintiffs seek certification of Class I under Rule 23(b)(1)(A), which provides for class certification when separate actions would create a risk of inconsistent or varying

adjudications that would establish incompatible standards of conduct for the party opposing the class.[6]

A. Common Law Claims

1. Rule 23(b)(3) – Both Classes

Plaintiffs seek certification of both classes pursuant to Rule 23(b)(3). This rule has two primary requirements: (1) that common questions of law or fact predominate over any questions affecting only individual class members; and (2) that a class action is superior to other available methods of adjudicating the controversy. Fed. R. Civ. P. 23(b)(3). St. Jude argues that certification under Rule 23(b)(3) is not appropriate because there are too many factual and legal differences among the class members, thus destroying predominance. St. Jude also contends that a class action would not be a superior method of adjudicating either class's allegations because of the inherent difficulties in dealing with the laws of many states.

a. Predominance

The Court has already determined that common questions of law and fact exist in this case. Now it must determine whether these common issues predominate over those unique to individual class members. "There are no bright line rules to determine whether common questions predominate." *In re Select Comfort Corp. Securities Lit.*, 202 F.R.D. 598, 610 (D. Minn. 2001). Rather, "the fundamental question is whether the group

[6] The master complaint in this case also alleges that class certification is appropriate under Rule 23(b)(1)(B). However, plaintiffs have stated that they are not moving for certification under Rule 23(b)(1)(B), so the Court will not analyze that rule.

aspiring to class status is seeking to remedy a common legal grievance." *Lockwood Motors*, 162 F.R.D. at 580 (quoting 3B *Moore's Federal Practice* ¶ 23.45 (2d ed. 1995)).

St. Jude argues that no set of facts is so "generic" that it would be relevant to prove issues of liability, causation, and damages for either Class I or Class II. This argument is similar to that made by the defendant in another medical device class action, *Haley v. Medtronic, Inc.*, 169 F.R.D. 643 (C.D. Cal. 1996). Like the defendant in that case, St. Jude focuses on the fact that individual questions for each plaintiff will be critical because each patient has unique medical circumstances causing him or her to react differently to the Silzone valve. *See id*. at 650. Like the court in *Haley*, this Court rejects St. Jude's argument because it "ignores the fact that plaintiffs' claims actually focus on [St. Jude's] liability and [St. Jude's] conduct with regard to the [Silzone valves] – not on their effect on the plaintiffs." *Id.* Plaintiffs' allegations do not relate to any course of conduct between St. Jude and the plaintiffs; they relate only to St. Jude's liability for its course of conduct in designing, manufacturing, marketing, and selling the Silzone valves. The predominance inquiry therefore focuses on questions relating to that conduct. *Cf. Hum v. Dericks*, 162 F.R.D. 628, 639-40 (D. Hawaii 1995) (holding that individual patient issues predominate where crux of plaintiffs' complaint did not involve manufacturer's liability or defective nature of device, but on physicians' implantation of the device). "When determining whether common questions predominate, courts focus on the liability issue . . . and if the liability issue is common to the class, common questions are held to predominate over individual questions." *Select Comfort Corp.*, 202 F.R.D. at 610 (citation and internal quotation marks omitted). *See also In re Telectronics Pacing Systems, Inc.*, 172 F.R.D. 271, 288 (S.D. Ohio 1997) ("Numerous courts have

found that common issues predominate when a large number of lawsuits arise from a single disaster or single course of conduct.") Because St. Jude's course of conduct was uniform across all plaintiffs of both classes, the Court agrees with plaintiffs that common questions of fact and law predominate for each class.

St. Jude argues that plaintiffs do not satisfy the predominance requirement, noting that medical product liability actions are rarely certified as class actions. Although this is generally true, the cases that St. Jude cites are markedly different from the present case, as will be shown below. Instead, the Court finds this case to be more similar to the *Telectronics* litigation, in which a 23(b)(3) class was certified despite "the general rule that medical products liability actions require extensive proof of individualized issues." *Id.* In *Telectronics*, the court found that the "general rule" did not apply because the action involved only two products, one manufacturer, one alleged defect, and did not raise overarching questions of causation. *Id.* at 288-89. The Court finds that this case, like *Telectronics*, "does not involve many of the factual and legal complications [that] prevented certification in other medical products liability actions." *Id.* at 288.

First, this case involves only one product, the Silzone heart valve, manufactured by one company, St. Jude. *Cf. In re Ford Motor Co. Vehicle Paint Lit.*, 182 F.R.D. 214, 219-20 (E.D. La. 1998) (finding that common issues did not predominate in paint defect action because case did "not involve a single failure event or a simple, fungible product," but a course of conduct over seven years, different vehicles, materials, paints, and manufacturing facilities); *In re American Medical Sys., Inc.*, 75 F.3d 1069, 1085-85 (6th Cir. 1996) (holding that common questions did not predominate where plaintiffs' complaints involved multiple products); *Harding v. Tambrands Inc.*, 165 F.R.D. 623,

629-31 (D. Kan. 1996) (holding that common questions did not predominate in toxic shock syndrome case where defendants manufactured a number of different styles of tampons); *Yandle v. PPG Indus., Inc.*, 65 F.R.D. 566, 570-71 (E.D. Tex. 1974) (holding that common questions did not predominate in asbestos exposure case because plaintiffs were employed over 10-year period, worked in different positions, used varying forms of protection, and were exposed to different concentrations of toxin). Second, as in *Telectronics*, plaintiffs allege only one defect – the inclusion of the Silzone coating on the sewing cuff of St. Jude's heart valves. *See Telectronics*, 172 F.R.D. at 288. *Cf. American Medical Sys.*, 75 F.3d at 1080-81, 1085-85 (holding that common questions did not predominate where plaintiffs did not identify a defect common to all plaintiffs).

Finally, as in *Telectronics*, causation is not "the overarching issue that requires extensive individual proof." *Telectronics*, 172 F.R.D. at 288. The court in that case found that a single course of conduct – the manufacture or design of the device at issue – was probably the reason for the defect and resultant injuries to plaintiffs. *Id.* at 289. In that case, the defendant-manufacturer recalled all of the unimplanted devices. *Id.* Soon after, the FDA found that the device presented an unreasonable danger to the public health. *Id.* The facts in this case are very similar. Here, following information from the AVERT study indicating a higher rate of explantation due to paravalvular leak, St. Jude recalled all of its unimplanted Silzone valves.[7] Although the FDA made no proclamation regarding safety of the Silzone valve, several months before the recall, the British

[7] St. Jude correctly notes that its voluntary recall is no indication of fault or liability. However, it can serve as evidence linking the Silzone valves to problems experienced by valve recipients.

equivalent of the FDA, the Medical Devices Agency ("MDA"), issued a warning of possible complications involving the Silzone valve. (*See* Pl. Ex. 21.) Furthermore, both prior to and following the recall, scientific articles and studies were published noting that patients with Silzone valves experienced greater likelihood of complications. (*See, e.g.*, Pl. Ex. 37, 49-50.) Although the facts of this case may not be as conclusive as in *Telectronics*, the circumstances and the evidence produced by plaintiffs convince the Court that the question of causation here is far closer to *Telectronics* than to the cases that St. Jude cites.

For example, in *Fisher v. Bristol-Myers Squibb Co.*, 181 F.R.D. 365 (N.D. Ill. 1998), cited by St. Jude, the court found that individual questions of causation predominated in a case involving drug addiction. *Id.* at 370-71. The court noted that addiction is "not a simple concept" and that demonstrating addiction would "require each plaintiff to provide a substantial amount about his or her medical history, emotional condition, and lifestyle . . . ." *Id.* at 370. Furthermore, the court found that plaintiffs would have to address a huge "variety of potential harms plaintiffs might claim they suffered as a result of using [the drug]," ranging from cardiovascular problems to clinical depression. *Id.*

In *Harding v. Tambrands*, which involved allegations that defendants' tampons caused toxic shock syndrome, the court found that causation would be an overwhelming issue because each defendant marketed a number of different styles of tampons. *Harding*, 165 F.R.D. at 630. Thus, each plaintiff would have to provide evidence of which particular tampon type caused her damages. *Id.*

St. Jude also relies upon *Hurd v. Monsanto Co.*, in which plaintiffs alleged damages from exposure to PCBs over as many as twenty years. *Hurd*, 164 F.R.D. at 237. The court noted that "[u]ndeniably, some class members have been exposed to PCBs for only a few months and at low levels, while others, for decades and at high levels." *Id.* at 240. The court therefore found that individual questions of causation would predominate because the case would require "an individual inquiry into the circumstances involving each class member's exposure and susceptibility." *Id.*

Finally, in *Reilly v. Gould, Inc.*, 965 F. Supp. 588 (M.D. Pa. 1997), plaintiffs who lived near a battery crushing and lead processing plant sued the battery company for injuries caused by lead exposure. *Id.* at 593. The court held that "the presence of . . . individualized factors affecting individual plaintiffs . . . wreaks havoc on the notion that all plaintiffs' injuries have been caused solely by the defendant's actions." *Id.* at 602. The court specifically found that individual questions of causation predominated because there were many other possible sources of plaintiffs' lead exposure besides the defendant's facility. *Id.* at 603-04.

In each of these cases, the individualized questions barring certification all involved the core of issue of the case – plaintiffs' very exposure to the allegedly harmful substances – be it addictive levels of drugs, toxic tampon material, PCBs, or lead. In this case, as in *Telectronics*, there is no question about plaintiffs' exposure to the allegedly harmful device. Every plaintiff received a Silzone valve, and every plaintiff alleges that he or she was harmed, or faces a risk of harm, from that valve. To be sure, individual issues exist in this case, but questions about plaintiff's medical history are not as crucial to this case as is, for example, the level of PCB exposure in a PCB exposure case. The

causation question here is far simpler and unitary than in any of the cases that St. Jude cites, and as in *Telectronics*, is not an overarching issue requiring individual proof. Therefore, the Court finds that common questions predominate in plaintiffs' common law claims.

St. Jude also contends that predominance is not satisfied because individual questions of damages overwhelm common issues. This argument applies primarily to Class II, since all Class I plaintiffs seek the same relief.[8] Still, this argument is unavailing. It is well-established that "[n]o matter how individualized the issue of damages may be, these issues may be reserved for individual treatment with the question of liability tried as a class action." *Sterling v. Velsicol Chemical Corp.*, 855 F.2d 1188, 1197 (6th Cir. 1988). Thus, the fact that each member of Class II might request separate damages "is not necessarily fatal to class action treatment as long as common questions of law or fact running through each claim predominate." *Haley*, 169 F.R.D. at 651 (citation and internal quotation marks omitted). Because the Court has already determined that common questions of law and fact predominate in plaintiffs' common law claims, variations in damages will not prevent a finding of predominance. *See id.* *See also Alpern*, 84 F.3d at 1540 (holding that the fact that damage calculations might differ "is a minor matter" when the claims share "fundamental similarities"); *Select Comfort Corp.*, 202 F.R.D. at 610 (noting that "courts frequently grant class certification despite individual differences in class members' damages"); *Telectronics*, 172 F.R.D. at

[8] The fact that individual Class I plaintiffs would have monitoring programs tailored to their needs is a question of the program's administration, not one of the character or degree of relief.

290 ("The damage issue, although requiring individualized proof, does not preclude class certification."); *Minnesota v. U.S. Steel Corp.*, 44 F.R.D. 559, 571-72 (D. Minn. 1968) (holding that individual damage questions will not prevent a finding of predominance).

b. Superiority

In analyzing superiority, the Court primarily considers "the difficulties likely to be encountered in the management of a class action." Fed. R. Civ. P. 23(b)(3). Here, the main factor affecting superiority involves application of state law to plaintiffs' claims. Even if common questions of law exist, the application of multiple state laws may render the case unmanageable as a class action. Indeed, a number of courts in recent years have held that nationwide state law class actions are unmanageable and cannot be certified. *See, e.g., Andrews v. American Telephone & Telegraph Co.*, 95 F.3d 1014, 1024-25 (11th Cir. 1996); *Castano v. American Tobacco Co.*, 84 F.3d 734, 741-44 (5th Cir. 1996); *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293 (7th Cir. 1995).

St. Jude contends that such is the case here. It argues that because plaintiffs reside in all 50 states, the law of each state must be at least analyzed, and likely applied to the individual cases. St. Jude further contends that because each state has different laws and elements governing negligence, strict liability, breach of warranty, and medical monitoring, common questions of law will not predominate in any nationwide case attempting to apply the law of all 50 states. Plaintiffs contend that it is not necessary to apply the laws of all 50 states, and that the Court should instead apply Minnesota law to

the entire case. Given this dispute over which law to apply, the Court must conduct a conflict of laws analysis.[9]

Federal courts sitting in diversity apply the forum state's choice-of-law rules. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941); *Nesladek v. Ford Motor Co.*, 46 F.3d 734, 736 (8th Cir. 1996). Before proceeding with the choice-of-law analysis, the court must determine that a conflict exists between the laws of the forums under consideration. *Nodak Mutual Ins. Co. v. American Family Ins. Co.*, 604 N.W.2d 91, 93-94 (Minn. 2000). Given that the common laws of negligence, strict liability, warranties, and monitoring of all 50 states are potentially implicated, the Court presumes that a true conflict of laws exists. Minnesota has adopted the "significant contacts test" for choice of law analyses. *Id.* at 94; *Nesladek*, 46 F.3d at 738. This test consists of the following choice-influencing factors: (1) predictability of results; (2) maintenance of interstate and international order; (3) simplification of the judicial task; (4) advancement of the forum's governmental interest; and (5) application of the better rule of law. *Nodak*, 604 N.W.2d at 94.

The first factor applies primarily to contractual and other "consensual transactions where the parties desire advance notice of which state law will govern in future disputes." *Id.* Minnesota courts have held that the "unplanned nature" of accidents and, by

[9] The Court notes that the minimal constitutional requirements to apply Minnesota law to this action are satisfied. *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985). In *Shutts*, the Court held that "for a State's substantive law to be selected in a constitutionally permissible manner, that State must have a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." *Id.* at 818. This Court agrees with plaintiffs that Minnesota has significant contacts by virtue of St. Jude having its headquarters and manufacturing facilities in Minnesota, and because many of the decisions regarding the Silzone valve were made by St. Jude in Minnesota.

extension, torts, "lessens the importance of predictability of results" in such cases. *Id.* (quoting *Hime v. State Farm Fire & Casualty Co.*, 284 N.W.2d 829, 833 (1979)). Thus, the Court finds that the first factor is not applicable in this tort case.

The second factor, maintenance of interstate order, is primarily concerned with whether application of one state's law "would manifest disrespect" for the sovereignty of the state with conflicting law, or would "impede the interstate movement of people and goods." *Jepson v. General Casualty Co. of Wis.*, 513 N.W.2d 467, 471 (Minn. 1994). In tort cases, this factor is satisfied "as long as the state whose laws are purportedly in conflict has sufficient contacts with and interest in the facts and issues being litigated."[10] *Nesladek*, 46 F.3d at 739. Given that St. Jude is located in Minnesota and that many decisions regarding the Silzone valves were made in this state, the Court finds that Minnesota has sufficient contacts to the litigation. Thus, this factor favors applying Minnesota law. The third factor, simplification of the judicial task, would also seem to favor application of Minnesota law, because it would be easier to apply the law of one state rather than those of all fifty states.

The fourth factor, advancement of the forum's governmental interests, is probably the most important. *See id.* at 738 (noting that some Minnesota courts skip the first three factors). Plaintiffs contend that Minnesota's governmental interests favor application of Minnesota law, but plaintiffs' analysis is flawed. Although plaintiffs analyze Minnesota's interests under the choice-influencing factors, they do not compare

[10] This standard is more exacting than the constitutional test of *Shutts*. *See Nesladek v. Ford Motor Co.*, 46 F.3d 734, 739 (8th Cir. 1995) (holding that a state can have sufficient contacts to satisfy *Shutts* but not enough to satisfy the second choice-influencing factor).

Minnesota's interests with those of any other state. Minnesota law, however, requires such a side-by-side comparison. *Nesladek*, 46 F.3d at 739 (noting that the governmental interests factor would always favor choice of forum law unless the court considers the relative policy interests of the two states) (quoting *Lommen v. City of East Grand Forks*, 522 N.W.2d 148, 152 (Minn. Ct. App. 1994)); *Gate City Fed. Sav. & Loan Ass'n v. O'Connor*, 410 N.W.2d 448, 451 (Minn. 1987); *Myers v. Government Employees Ins. Co.*, 225 N.W.2d 238, 242 (Minn. 1974). Here, plaintiffs' analysis reveals that they gave serious consideration only to Minnesota's governmental interests, arriving at the conclusory determination that Minnesota law should apply.[11]

Although Minnesota clearly has significant interests in applying its law to this case, the Court cannot ignore the interests of states in which class members were implanted with Silzone valves. These states' interests go beyond ensuring that their citizens are compensated for alleged damages; the states also have strong interests in applying their relevant laws to the marketing, sale, and implantation of medical devices within their borders. *See In re Diet Drugs Prod. Liability Lit.*, Civ. No. A-98-20626, 1999 WL 673066 at *15 (E.D. Pa. Aug. 26, 1999). Given the potential diversity of state laws that apply to both classes, the Court cannot find – and plaintiffs have not demonstrated – that Minnesota's governmental interests are more important than those of

[11] The three cases that plaintiffs cite in support of applying Minnesota law provide no help. Choice of law considerations are irrelevant in *In re Lutheran Brotherhood Variable Ins. Prod. Co. Sales Practices Lit.*, 201 F.R.D. 456 (D. Minn. 2001), because that case was an action under Minnesota statutes. The other two cases, *Peterson v. BASF Corp.*, 618 N.W.2d 821 (Minn. Ct. App. 2000) and *Heller v. Schwan's Sales Enterprises, Inc.*, 548 N.W.2d 287 (Minn. Ct. App. 1996) do not help plaintiffs because they contain no analysis of relevant choice-of-law considerations.

other states. *See Nesladek*, 46 F.3d at 749. The Court finds that this crucial factor militates against applying Minnesota law here. Therefore, based upon this analysis of relevant factors, and recognizing the importance of the compared governmental interests, the Court determines that it will apply the law of the state in which each class member's claim arose to the members of the class .[12]

St. Jude contends that applying the laws of fifty states to these classes would be so complicated as to render the class unmanageable. Although many courts have so held, no case has held that certification of such classes is *per se* impossible. *See, e.g., In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1016-18 (7th Cir. 2002) (holding that application of laws of all 50 states renders class unmanageable); *Andrews*, 95 F.3d at 1024-25 (same); *Castano*, 84 F.3d at 741-44 (same); *Rhone-Poulenc*, 51 F.3d at 1293 (same).

At least one court has addressed such variations in state law by the creation of subclasses that group similar state laws together. *See Telectronics*, 172 F.R.D. at 290-94 (certifying nationwide negligence, strict liability, and medical monitoring classes). This method would eliminate the problem of instructing one jury on the laws of all fifty states, while still retaining the efficiencies of the class action procedure and fulfilling the collective-action purpose of Rule 23. *See generally*, Comment, Ryan Patrick Phair, *Resolving the "Choice-of-Law Problem" in Rule 23(b)(3) Nationwide Class Actions*, 67 U. Chi. L. Rev. 835, 851 (Summer 2000). To create appropriate subclasses, the Court

[12] The Minnesota Supreme Court recently held that it has not placed any emphasis on the fifth factor, the better rule of law, for nearly 20 years. *Nodak Mutual Ins. Co. v. American Family Mutual Ins. Co.*, 604 N.W.2d 91, 96 (Minn. 2000). This court therefore finds it unnecessary to address this factor.

will have to evaluate which variations in state law are "important or substantial enough to preclude class certification or require subclasses." *Telectronics*, 172 F.R.D. at 292. For "while it is certainly true that state tort law varies, the question under the superiority prong of Rule 23(b)(3) is can the relevant variations be dealt with in a simple and efficient manner." *Id.* The Court finds that the superiority requirement can be met, and certification granted under Rule 23(b)(3) to various subclasses of the relevant causes of action. "[I]f the elements of the cause of action are the same and the legal standards on 'important/meaningful/significant/pivotal' issues are substantially similar, the state laws can be grouped for purposes of class certification." *Id.* The Court envisions a minimal number of subclasses, and will find that only significant variations in state law will be sufficient to require different subclasses.

It is evident from the parties' briefs that they did not focus on the possibility of certifying subclasses. Therefore, the Court will request briefing from the parties on what minimum number and type of subclasses would be appropriate for plaintiffs' negligence, strict liability, breach of warranty, and monitoring claims. However, the Court now finds that common issues of fact and law predominate for both proposed classes, and conditionally finds that a class action is the superior method of adjudicating the claims of both classes. Therefore, the Court will conditionally certify plaintiffs' common law claims for both classes pursuant to Rules 23(b)(3) and (c)(4).[13]

[13] Rule 23(c)(4) gives the court authority to divide a proposed class into subclasses. *See* Fed. R. Civ. P. 23(c)(4).

2. Rule 23(b)(2) – Monitoring Class Only

St. Jude challenges certification of Class I under Rule 23(b)(2) on three grounds. First, that plaintiffs do not have constitutional standing to bring a monitoring claim. Second, that monitoring is not an injunctive remedy and is therefore unavailable under Rule 23(b)(2). Finally, St. Jude contends that diverse issues of state law undermine the cohesiveness of the class and prevent certification.

a. Article III Standing

St. Jude first argues that the monitoring plaintiffs do not satisfy the constitutional requirements for standing under Article III of the U.S. Constitution. Plaintiffs bear the burden of establishing that they have standing to bring the claim for medical monitoring. *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 very power to hear the case. *Rivera v. Wyeth-Ayers Laboratories,* 283 F.3d 315, 319 (5th Cir. 2002). To demonstrate standing under Article III, plaintiff must satisfy three elements: (1) an "injury-in-fact;" (2) a causal connection between such injury and St. Jude's conduct; and (3) a likelihood that a favorable decision will redress the injury. *Defenders of Wildlife,* 504 U.S. at 560-61.

When analyzing standing at the class certification stage, the Court assumes the truth of facts alleged by the plaintiff. *Id.*; *Eisen v. Carlisle & Jacquelin,* 417 U.S. 156, 178 (1974) (holding that preliminary inquiry into merits of the case is not proper at class certification stage). *See In re Propulsid Prod. Liability Lit.,* 208 F.R.D. 133, 139 (E.D. La. 2002) (noting that the standard is similar to that used under Fed. R. Civ. P. 12(b)(6)).

St. Jude contends that plaintiffs do not have standing because they have not suffered an injury-in-fact. Such an injury must be concrete and particularized, and it must be actual or imminent, not conjectural or hypothetical. *Defenders of Wildlife*, 504 U.S. at 560. Furthermore, the injury may not be to a mere cognizable interest, but plaintiffs must show that they were themselves among the injured. *Sierra Club v. Morton*, 405 U.S. 727, 734-35 (1972).

St. Jude specifically argues that plaintiffs alleged "subclinical" injuries stemming from the implant of Silzone valves is not a sufficient basis for injury-in-fact under Article III. Although the parties dispute whether the Silzone valves will have a permanent or long-term hazardous effect on implanted patients, at this early stage in the litigation the Court finds that Class I plaintiffs have satisfied their burden. Specifically, plaintiffs have alleged and provided evidence that the Silzone valve places them at increased risk of paravalvular leak and other complications.[14] "[C]ourts have long recognized that an increased risk of harm . . . is an injury in fact." *Propulsid*, 108 F.R.D.

[14] Plaintiffs have submitted testimony by medical experts supporting their claim for medical monitoring. (*See, e.g.*, Abramson Dec., Pl. Ex. 28; Tyers Dec., Pl. Ex. 37.) The admissibility of some of this evidence was extensively debated prior to the hearing on class certification. The Court, in denying plaintiffs' motion to exclude St. Jude's objections to their medical expert testimony, ruled that a full analysis of the medical expert evidence under *Daubert v. Merrill Dow Pharmaceuticals*, 509 U.S. 579 (1993), is not appropriate at this time. (*See* 6/25/02 Status Conference Tr. at 30.) Nevertheless, the Court has carefully scrutinized plaintiffs medical evidence to determine whether it supports class certification. *See Bacon v. Honda of America Mfg., Inc.*, 205 F.R.D. 469-71 (S.D. Ohio 2001). Keeping in mind that at this stage plaintiffs need only properly allege and support their claim, not prove it, *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 178 (1974), the Court has avoided conducting a lengthy substantive analysis of plaintiffs' experts, ensuring only that "the basis of the expert opinion[s are] not so flawed that [they] would be inadmissible as a matter of law." *In re Visa Check/Mastermoney Antitrust Lit.*, 280 F.3d 124, 135 (2d Cir. 2001).

at 139. *See Friends For All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 826 (D.C. Cir. 1984) (holding that the need for medical monitoring constitutes an injury-in-fact when the need is "supported by testimony of competent medical experts"); *In re Paoli R.R. Yard PCB Lit.*, 916 F.2d 829, 849-52 (3d Cir. 1990) (holding that medical monitoring action can be premised upon proof of exposure to hazardous substances resulting in the potential for injury). *Cf. Rivera*, 283 F.3d at 319 (holding that plaintiffs had not established injury-in-fact where they claimed mere economic injury and did not allege that drug had any future health consequences). The Court finds that plaintiffs have adequately supported their allegations of "monitoring injury," and therefore that they satisfy the injury-in-fact standard. (*See* Abramson Dec., Pl. Ex. 28; Tyers Dec., Pl. Ex. 37.) *See also Friends For All Children*, 746 F.2d at 826 (describing a person's "interest in avoiding expensive diagnostic examinations").

St. Jude does not dispute that plaintiffs have satisfied the remaining two requirements for Article III standing, and the Court finds that they have been satisfied. Causation is satisfied because plaintiffs have alleged an injury – the need for medical monitoring – that is fairly traceable to St. Jude's marketing and selling the Silzone valves that were implanted in them, which plaintiffs claim are defective. *See Propulsid*, 208 F.R.D. at 139. The Court also finds that enacting a medical monitoring and research program would likely redress plaintiffs' alleged injuries – namely, a need for monitoring

due to increased risk of complications. Therefore, the Court concludes that Class I plaintiffs have standing to pursue their medical monitoring claim.[15]

b. Monitoring – Injunctive or Legal Relief?

Plaintiffs may be eligible for relief under Rule 23(b)(2) when the party opposing certification has acted or refused to act on grounds generally applicable to the class. Fed. R. Civ. P. 23(b)(2); *DeBoer*, 64 F.3d at 1175. St. Jude contends that Class I may not be certified under this rule because plaintiffs do not seek equitable relief. Class certification under Rule 23(b)(2) is only appropriate where the primary relief sought is declaratory or injunctive, and certification is unavailable where the "principal relief sought is money damages." *Haley*, 169 F.R.D. at 647.[16] St. Jude claims that because the proposed medical monitoring trust fund would be paid for by St. Jude, the medical monitoring claim is equivalent to one for money damages.

In this case, plaintiffs do not ask St. Jude to pay a sum of money, nor do they request an order directing St. Jude to pay their medical expenses directly. *See Day v. NLO, Inc.*, 144 F.R.D. 330, 335 (S.D. Ohio 1992), *vacated on other grounds*, *In re NLO*, 5 F.3d 154 (6th Cir. 1993). Rather, plaintiffs ask the Court to establish a medical

[15] St. Jude also argues that there is a "lack of need" for plaintiffs' requested medical monitoring, and even suggests that the proposed monitoring may itself be dangerous. (*See* Def. Opp. Br. at 60-62.) The Court finds that this question involves the merits of plaintiffs' claim, and is therefore not appropriate to consider at the class certification stage. *See Eisen*, 417 U.S. at 178.

[16] The Advisory Committee Note to Rule 23(b)(2) explicitly states that the rule "does not extend to cases in which the appropriate final relief relates exclusively or predominately to money damages." Fed. R. Civ. P. 23(b)(2) Adv. Comm. Note.

monitoring program that is managed by the Court and in which the medical data is utilized for group studies. Just because St. Jude – if found liable – would have to pay for such relief does not eliminate the injunctive nature of this remedy. *See id.* at 336. *See also In re NLO*, 5 F.3d at 159 (holding that medical monitoring claims are generally injunctive in nature).

Both parties claim support from *Werlein v. United States*, 746 F. Supp. 887 (D. Minn. 1990), *vacated in part on other grounds*, 793 F. Supp. 898 (D. Minn. 1992). *Werlein*, however, makes clear that the relief plaintiffs seek here is injunctive. In that case, plaintiffs sought an order forcing defendants "to pay a lump sum of cash into a fund, and . . . persons eligible for medical monitoring [would] use that pot of cash to obtain reimbursement" for their medical screenings. *Id.* at 895. The court held that this proposed fund was nothing "besides an exchange of money," and therefore could not be authorized as injunctive relief. *Id.* In this case, however, plaintiffs propose no "pot of cash" and no reimbursements. Rather, they propose a unified monitoring program administered by the Court and paid for by a trust funded by St. Jude. The program also has provisions for research, epidemiological studies, and information sharing. The *Werlein* court recognized that "where a number of persons are exposed to a toxin about which little is known, and it is necessary to gather and share information regarding diagnosis and treatment through screening, the Court would consider framing a medical monitoring and information sharing program as injunctive relief." *Id.* Such are the circumstances in this case. Plaintiffs allege that the silver coating on the Silzone valves has increased the risk of injury to the members of Class I, and their proposed monitoring program includes research and information sharing components. Thus, the Court finds

that *Werlein* supports the conclusion that plaintiffs' monitoring claim seeks equitable relief and may therefore be certified under Rule 23(b)(2). *See Craft v. Vanderbilt Univ.*, 174 F.R.D. 396, 406-07 (M.D. Tenn. 1996) (holding that an action for court-supervised medical monitoring qualifies as injunctive under Rule 23(b)(2)); *Yslava v. Hughes Aircraft Co.*, 845 F. Supp. 705, 713 (D. Ariz. 1993) (same).

Despite the equitable nature of medical monitoring, plaintiffs' monitoring claim would still be inappropriate under Rule 23(b)(2) if plaintiffs also sought such significant monetary relief that the equitable monitoring claim became merely "incidental to the larger claims for damages." *In re Copley Pharmaceutical, Inc.*, 158 F.R.D. 485, 490-91 (D. Wyo. 1994). *See Allison v. Citgo Petroleum Corp.*, 151 F.3d 402, 415 (5th Cir. 1998). In this case, however, Class I plaintiffs seek primarily injunctive relief. The only portion of Class I's complaint that seeks monetary damages is the claim for restitution under Minnesota's consumer protection laws. (*See* Complaint ¶ 78.) Although this count seeks a refund of money paid for Silzone products and certain consequential damages, it nevertheless is clear from the record and the pleadings that plaintiffs' major concern is whether the Silzone-coated valves are defective. *See In re Telectronics Pacing Systems, Inc., Accufix Atrial "J" Leads Prod. Liability Lit.*, 164 F.R.D. 222, 229 (S.D. Ohio 1995) (certifying a class under Rule 23(b)(2) where plaintiffs sought monetary and injunctive relief, but plaintiffs' "major concern" addressed whether medical device was defective). In *Haley*, the court refused to certify a monitoring class under Rule 23(b)(2) where the action "was not brought with the purpose of identifying whether the [medical devices] in question were defective or not, like the court in *Telectronics* assumed . . . but to recover from defendant for selling these defective [devices]." *Haley*, 169 F.R.D. at 657. The

present case is like *Telectronics*, in that plaintiffs seek primarily a monitoring and epidemiological program; the crux of their action is not money damages or treatment of future illness. *See Zinser v. Accufix Research Institute, Inc.*, 253 F.3d 1180, 1195-96 (9th Cir. 2001), *superceded on other grounds*, 273 F.3d 1266 (denying certification of monitoring class where plaintiffs sought a fund that would pay for future medical treatment, plus other compensatory and punitive damages). Indeed, in the majority of cases that St. Jude cites in opposing 23(b)(2) certification, the plaintiffs also sought significant monetary damages. *See Duncan v. Northwest Airlines, Inc.*, 203 F.R.D. 601, 610-11 & n.10 (W.D. Wash. 2001) (denying certification of monitoring class where the plaintiff's desired relief "always focused on damages and a fund of money," and where plaintiff sought no research or information sharing program); *Dhamer v. Bristol-Myers Squibb Co.*, 183 F.R.D. 520, 529 (N.D. Ill. 1998) (denying certification of medical monitoring claim where plaintiffs' requested damages for emotional distress, fraud, refund, punitive and exemplary damages showed that the "crux of the action [was] for money damages"); *Smith v. Brown & Williamson Tobacco Corp.*, 174 F.R.D. 90, 100 (W.D. Mo. 1997) (refusing to certify class under 23(b)(2) where plaintiff's "many other claims for monetary relief demonstrate[d] that monetary relief is the predominate relief sought"). Because Class I plaintiffs primarily seek to implement a court-supervised program requiring ongoing, elaborate medical monitoring, and do not seek money damages, the Court finds that the requested relief is predominantly injunctive.[17]

[17] Plaintiffs' briefs and oral presentations sought medical monitoring only for Class I. The master complaint, however, appears to seek monitoring for Class II, the "injury class." For the reasons discussed above, Class II cannot be certified under Rule 23(b)(2). It is clear from the entire record and plaintiffs' presentations that Class II seeks primarily compensatory money

(Footnote continued on next page.)

c. Cohesiveness of Proposed Class

St. Jude next contends that even if plaintiffs satisfy the requirements for injunctive relief, the proposed monitoring class may not be certified because it is not cohesive. Although Rule 23(b)(2) has no predominance or superiority requirements, the rule does include "an implicit 'cohesiveness' requirement, which precludes certification when individual issues abound." *Thompson*, 189 F.R.D. at 557. *See Barnes v. American Tobacco Co.*, 161 F.3d 127, 143 (3d Cir. 1998); *In re Rezulin Prod. Liability Lit.*, 210 F.R.D. 61, 75 (S.D.N.Y. 2002); *Diet Drugs*, 1999 WL 673066 at *14 (noting that Rule 23(b)(2) requires that "the class be entitled to the same relief"). This requirement recognizes that "the claims contemplated in a (b)(2) action are **class** claims, claims resting on the same grounds and applying more or less equally to all members of the class." *Holmes v. Continental Can Co.*, 706 F.2d 1144, 1155 (11th Cir. 1983) (emphasis original). This assumed cohesiveness is one basis for the less stringent requirements of Rule 23(b)(2), which does not generally require individual notice and does not permit members to opt out of the lawsuit. *Id.*; *Allison*, 151 F.3d at 413-14.

St. Jude primarily contends that there are too many individual factual and other issues among the members of the monitoring class, and that these differences destroy any common interest across the class. Although St. Jude is correct that a raft of individual issues can destroy a class's cohesiveness, St. Jude focuses here on superficial factual

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(Footnote continued.)
damages, and that these clams predominate over any medical monitoring or other injunctive relief. *See Allison v. Citgo Petroleum Corp.*, 151 F.3d 402, 415 (5th Cir. 1998). Therefore, to the extent that plaintiffs seek certification of Class II pursuant to Rule 23(b)(2), that certification will be denied.

differences between the class members, while the cases it cites emphasize the nature of the relief sought. "The underlying premise of the (b)(2) class – that its members suffer from a common injury properly addressed by class-wide relief – 'begins to break down when the class seeks to recover . . . forms of monetary relief to be allocated based on individual inquiries.'" *Allison*, 151 F.3d at 413 (quoting *Eubanks v. Billington*, 110 F.3d 87, 95 (D.C. Cir. 1997). Courts have thus suggested that individual issues destroy cohesiveness primarily when parties assert monetary claims, which require individual factual determinations and therefore mandate "enhanced procedural safeguards to protect the individual rights of class members." *Allison*, 151 F.3d at 413. *See Lemon v. International Union of Operating Engineers, Local No. 139, AFL-CIO*, 216 F.3d 577, 580 (7th Cir. 2000) ("A suit for money damages, even if the plaintiffs seek uniform, class-wide equitable relief as well, jeopardizes [the] presumption of cohesion . . . because individual claims for compensatory or punitive damages typically require judicial inquiry into the particularized merits of each individual plaintiff's claim."). In this case, as discussed above, plaintiffs' action for medical monitoring is injunctive in nature, and the Court has determined that any claim for monetary relief is merely incidental. Therefore, because individual questions of monetary relief will not arise for Class I, its cohesiveness is not impaired.

St. Jude does note that even if the requested relief is injunctive, individual factual questions may abound that would destroy cohesiveness. St. Jude particularly relies upon two smoking-related actions, *Barnes v. American Tobacco Company* and *Thompson v. American Tobacco Company*. In both of these cases, courts held that an abundance of individual issues destroyed the cohesion of proposed (b)(2) classes. *See Barnes*, 161 F.3d

at 143; *Thompson*, 189 F.R.D. at 557. Neither of these cases is analogous here, however. Both *Barnes* and *Thompson* dealt with complicated issues of nicotine addiction and smoking-related illnesses. *See Barnes*, 161 F.3d at 143; *Thompson*, 189 F.R.D. at 553-54. In this case, the monitoring class does not present similar complex issues.

Although the factual issues do not present sufficient individual questions that would defeat cohesiveness, as with the Rule 23(b)(3) analysis, the Court must also address the issue of variance in state law. St. Jude notes that not all states have recognized medical monitoring as an independent cause of action, and that those states that have recognized such an action have varying legal elements. St. Jude contends that this variation also undermines cohesiveness, barring certification of the monitoring class under Rule 23(b)(2).

Plaintiffs argue that Minnesota would join an emerging majority of states in adopting the medical monitoring elements outlined by the Pennsylvania Supreme Court in *Redland Soccer Club v. Department of the Army*, 696 A.2d 137 (Pa. 1997). *See Barnes*, 161 F.3d at 138-39, 146 (applying the *Redland* elements). Implicit in this argument is plaintiffs' contention that Minnesota law alone should apply to the monitoring claim. As discussed in the context of Rule 23(b)(3), however, this Court cannot simply apply the law of one particular state without regard to whether a given class member's claim arises in a jurisdiction that recognizes such a legal theory, or what the elements for such a theory may be. *See Diet Drugs*, 1999 WL 673066 at *14. The Court must consider that some jurisdictions do not even recognize a cause of action for medical monitoring, while others have varying requirements for such a claim. The court in *Diet Drugs* faced a similar situation, and recognized that a real conflict exists between

laws modeled on the *Redland* elements, which plaintiffs propose for this case, and other states which, for instance, may require evidence of physical injury for a monitoring claim. *See id*. at *15 (citing Louisiana's law barring plaintiffs who cannot demonstrate a "manifest physical or mental injury or disease" from recovering for a medical monitoring claim).

Here, as in *Diet Drugs*, the Court must first undertake a Minnesota choice-of-law analysis to determine whether Minnesota law (or plaintiffs' prediction thereof) or the laws of all fifty states would apply to the medical monitoring claim. As discussed previously in the Court's Rule 23(b)(3) analysis, the "advancement of the forum's governmental interests" is the most significant choice-influencing factor. *See Nodak*, 604 N.W.2d at 94 (applying Minnesota's choice of law rules); *Nesladek*, 46 F.3d at 738-41(same). The Court is mindful, however, that other states have consciously developed different standards for medical monitoring, or have not adopted such an action at all. These states' interests in applying their laws to the medical device industry within their borders is at least as strong as Minnesota's interest in doing so. *See Diet Drugs*, 1999 WL 673066 at *15. Therefore, the Court again finds that Minnesota's governmental interests do not outweigh those of other states, and the Court will apply the law of the state in which each class member's claim arose to all members of the monitoring class.

St. Jude argues that such diversity of state law destroys the cohesiveness of the monitoring class and bars certification under Rule 23(b)(2). *See Rezulin*, 210 F.R.D. at 75 (holding that variation in state law on monitoring prevented certification). *Rezulin*, a drug case, involved many complicated facts, "as class members took [the drug] at different times, for different periods, in different amounts, and while undergoing different

levels of . . . health monitoring." *Id.* at 66. Another drug case, however, *Diet Drugs*, held that these challenges are not insurmountable. *Diet Drugs*, 1999 WL 673066 at *16. In that case, "the class members' ingestion of the Diet Drugs was discrete and ascertainable[, and the] dates, duration and amounts of ingestion and the combination of drugs ingested [could] be confirmed through the use of fact sheets and medical records." *Id.* at *15. The present case involves a discrete and ascertainable number of valve recipients. It is known exactly how long each person had the Silzone valve and the circumstances of the implant. These facts are more readily ascertainable than the drug-related information in *Diet Drugs*, and certainly more so than in *Rezulin*.[18] The *Diet Drugs* court determined that applying the laws of 50 states to a 23(b)(2) class action does not destroy cohesiveness of the class and does not necessarily render the class unmanageable. *Id.* at *16. The court instead determined that the case could be managed by creating subclasses "dependant on whether the elements of medical monitoring or the underlying legal action significantly differ." *Id.* The court in *Propulsid* recognized this approach, but could not grant conditional certification because Fifth Circuit law does not permit it. This Court is aware of no similar prohibition in the Eighth Circuit. This Court accordingly finds the approach in *Diet Drugs* both persuasive and appropriate in the

[18] As with its argument about injunctive relief, St. Jude primarily relies here upon tobacco cases, which involve issues of nicotine addiction and smoking-related illnesses. *See Barnes v. American Tobacco Co.*, 161 F.3d 127 (3d Cir. 1998); *Thompson v. American Tobacco Co.*, 189 F.R.D. 554 (D. Minn. 1999). These issues, however, are even less susceptible to class treatment and are more likely to destroy cohesiveness. *See In re Diet Drugs Prod. Liability Lit.*, Civ. No. A. 98-20626, 1999 WL 673066 (E.D. Pa. Aug. 26, 1999) (describing how extreme factual variations undermine cohesiveness in tobacco litigation). The facts of this case are far more certain, and therefore these tobacco cases do not undermine certification of the monitoring class.

present case.[19] As with the classes under Rule 23(b)(3), the Court will therefore conditionally certify the monitoring class pursuant to Rules 23(b)(2) and (c)(4).

As discussed in the Rule 23(b)(3) analysis, the Court finds that the parties have not sufficiently addressed the question of how the Court would manage a class action with subclasses grouped according to categories of varying state laws. Therefore, the Court will require such briefing according to a schedule determined after discussion with counsel. As in the *Diet Drugs* case, the court anticipates creating subclasses based upon the variance of both medical monitoring law and variances in the underlying claims of strict liability, negligence, and breach of warranties, for which monitoring serves as a remedy in some jurisdictions. *See id.* at *17.

3. Rule 23(b)(1)(A) – Monitoring Class Only

Plaintiffs also seek certification of the monitoring class pursuant to Rule 23(b)(1)(A). This rule provides for class certification when separate actions would create a risk of inconsistent or varying adjudications that would establish incompatible standards of conduct for the party opposing the class. Fed. R. Civ. P. 23(b)(1)(A). The rule is designed to avoid situations where different results in separate actions would impair the opposing party's ability to pursue a uniform continuing course of conduct. *Telectronics*, 172 F.R.D. 271, 284 (S.D. Ohio 1997) (quoting 7A Charles A. Wright,

[19] As in *Diet Drugs*, the Court envisions that Class I will be broken down into at least two sub-groups of plaintiffs: those who are asymptomatic but who may have some injury that is presently unknown, and those who have some known injury (that has not yet required explantation) but who have not filed a personal injury claim. Also as in *Diet Drugs*, a consequence of this sub-classing is that class members who are asymptomatic and whose claims arise in jurisdictions that require injury for a tort action to proceed will have to be excluded from the class entirely. *See id.* at *16.

Arthur R. Miller, & Mary Kay Kane, *Federal Practice & Procedure: Federal Rules of Civil Procedure* § 1773 (2d ed. 1986)).

The Court finds that this case is not suitable for certification under Rule 23(b)(1)(A) because plaintiffs are not suing for different or incompatible relief. *See Fogie v. Rent-A-Center*, 867 F. Supp. 1398, 1403 (D. Minn. 1993) (holding that certification under 23(b)(1)(A) is not appropriate where plaintiffs do not seek incompatible relief). Although a monitoring program may be tailored differently to various members of Class I, these are matters of program administration, and do not affect the character or the relief that Class I seeks. Furthermore, Rule 23(b)(1)(A) was designed to protect the party opposing certification – here, St. Jude – and at least one decision in this District has found that a defendant waives protection of the rule by opposing certification. *Id. See* 5 *Moore's Federal Practice* § 23.40. Here, St. Jude opposes certification under 23(b)(1)(A). For these reasons, the Court concludes that the monitoring class should not be certified under that rule.

B. Minnesota Consumer Protection & Deceptive Trade Practices Statutes

Finally, plaintiffs seek certification of both classes for violations of Minnesota statutes governing false statements in advertising, Minn. Stat. § 325F.67, unlawful consumer practices, Minn. Stat. § 325F.69, and deceptive trade practices, Minn. Stat. § 325D.44. St. Jude argues that Minnesota law should not presumptively apply to all class members, and that even if it did, plaintiffs must demonstrate individual reliance in each case. These two factors, St. Jude contends, would overwhelm any common issues and make a class action unmanageable.

First, St. Jude argues that plaintiffs cannot presume that Minnesota law applies to all class members, who are citizens of various states. As it did in the 23(b)(2) and (b)(3) contexts, St. Jude contends that plaintiffs – and this Court – must undertake a state-by-state analysis to determine which law applies. Such an exhaustive inquiry, St. Jude claims, would "swamp" any common issues and make either class impossible to certify. Although these arguments affected the Court's analysis of common law claims under Rules 23(b)(2) and (b)(3), they do not apply with equal force here. This is because in contrast with plaintiffs' common law claims of negligence, strict liability, monitoring, and breach of warranty, these claims are brought under specific provisions of Minnesota's consumer protection and deceptive trade practices statutes.

The District of Minnesota addressed this precise question in the *Lutheran Brotherhood* case. In that case, plaintiffs sought certification under Rule 23(b)(3) for alleged violations of a provision of Minnesota's consumer protection statute.[20] *See Lutheran Brotherhood*, 201 F.R.D. at 460-64. The court rejected the contention that there were any impediments to applying Minnesota's consumer protection statutes to a nationwide class, noting that these statutes explicitly permit "any person" injured by violations of the statutes to bring suit. *Id.* at 461 n.1.

This holding is foursquare with the present case. Plaintiffs' claims under provisions of Minnesota's consumer protection statute, Minn. Stat. §§ 325F.67 and 325F.69, find support in another provision of Minnesota law that permits "any person" injured by a violation of these statutes to bring suit. Minn. Stat. § 8.31, subd. 3a. As the

[20] The statute was Minn. Stat. § 325F.69, which plaintiffs also allege in this case.

Minnesota Supreme Court held in *Group Health Plan, Inc. v. Philip Morris Inc.*, 621 N.W.2d 2 (Minn. 2001), none of these statutes contain any language restricting who may sue for violation of the consumer protection laws. *Id.* at 8. Likewise, plaintiffs' claims under Minnesota's Uniform Deceptive Trade Practices Act, Minn. Stat. § 325.D44, are authorized by a provision of that law permitting "**a person** likely to be damaged" by a deceptive trade practice to seek injunctive relief. Minn. Stat. § 325D.45, subd. 1 (emphasis added).[21] In the present case, it is clear that plaintiffs meet these definitions of "any person" or "a person," and may therefore bring suit under Minnesota law. The fact that individual plaintiffs hail from other states is immaterial.[22] Plaintiffs seek relief under particular Minnesota statutes. In the absence of evidence that plaintiffs do not have standing to sue – and St. Jude provides none – the Court finds no reason to deny plaintiffs their chosen claim of action. Minnesota law may therefore apply to the classes' consumer protection and deceptive trade practices allegations.

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[21] St. Jude correctly notes that relief under the deceptive trade practices act ("DTPA"), Minn. Stat. § 325D.44, is limited to injunctive remedies. *See Tuttle v. Lorillard Tobacco Co.*, Civ. No. 99-1550, 2001 WL 821831 at *4 (D. Minn. July 5, 2001) (stating that "courts have uniformly held that the sole remedy for violations of the DTPA is injunctive relief," and citing cases). This count of plaintiffs' complaint seeks both monetary relief and injunctive relief, in the form of monitoring. The Court will therefore construe the § 325D.44 allegations as applying only to the request for monitoring.

[22] To the extent St. Jude argues that applying Minnesota law to the classes is unconstitutional, the Court disagrees. To apply Minnesota law here in a constitutional manner, the Court must find only that Minnesota has "a significant contact or significant aggregation of contacts, creating state interests, such that choice of its law is neither arbitrary nor fundamentally unfair." *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 818 (1985); *Lutheran Brotherhood*, 201 F.R.D. at 461 n.1. Here, as the Court has discussed, the parties – especially the defendant, St. Jude – have at least a significant contact with Minnesota. St. Jude is headquartered in Minnesota and according to plaintiffs, "much of the conduct relevant to the statutory consumer fraud claims occurred in or emanated from Minnesota." *See Lutheran Brotherhood*, 202 F.R.D. at 461 n.1. Therefore, the Court finds that Minnesota has a significant interest in this litigation, and that application of its law is neither arbitrary nor fundamentally unfair.

Second, St. Jude argues that even if Minnesota law does apply, common questions will not predominate because each individual plaintiff must prove reliance under Minnesota's consumer protection statute. This proposition directly contradicts Minnesota law. It is by now well established that plaintiffs need not establish reliance when seeking injunctive relief under Minnesota's consumer fraud and deceptive trade practices statutes. *Thompson*, 189 F.R.D. at 552-53 (construing the same statutes at issue in this case, Minn. Stat. §§ 325D.44, 325F.67, and 325F.69). More recently, the Minnesota Supreme Court broadened the scope of statutory claims under these statutes in *Group Health*, holding that a plaintiff need not plead individual consumer reliance on a defendant's wrongful conduct to state a claim for damages. *Group Health*, 621 N.W.2d at 12; *Lutheran Brotherhood*, 201 F.R.D. at 462-63. Rather, plaintiffs seeking damages need only establish a "causal nexus between their damages and the defendant's wrongful conduct." *Group Health*, 621 F.R.D. at 14; *Lutheran Brotherhood*, 201 F.R.D. at 463.

In this case, the Court finds that plaintiffs have pleaded and presented evidence that their damages stem at least in part from St. Jude's marketing material that, according to plaintiffs, claimed that Silzone effectively prevented endocarditis. (*See, e.g.*, Pl. Ex. 59-60.) Plaintiffs have also demonstrated that these common issues of fact predominate over individual issues, as do the common questions of law regarding St. Jude's alleged violation of Minnesota's consumer protection and deceptive trade practices statutes. The Court also finds that given the common issues and the fact that proof of reliance is unnecessary, class action treatment is a superior mechanism for resolving these claims. Accordingly, the Court finds that plaintiffs' consumer protection claims may be certified as class actions under Rule 23(b)(3) for both Class I and Class II.

CONCLUSION

The Court finds that both proposed classes meet the threshold requirements of Rule 23(a). Furthermore, the Court finds that common issues of law and fact predominate in both classes, and that a class action is likely the superior way to adjudicate the claims of both classes. Therefore, the Court conditionally certifies plaintiffs' common law claims for both Class I and Class II pursuant to Rule 23(b)(3). Likewise, the Court conditionally finds that Class I is cohesive, and conditionally certifies the monitoring class pursuant to Rule 23(b)(2). The Court further determines that separate actions would not create a risk of inconsistent or varying adjudications that would establish incompatible standards of conduct for St. Jude, and therefore refuses to certify Class I pursuant to Rule 23(b)(1)(A). Finally, the Court determines that common issues of law and fact predominate in plaintiffs' claims under Minnesota's consumer protection and deceptive trade practices acts, and that a class action is the superior method of adjudicating those claims. Therefore, the Court certifies plaintiffs' claims under those statutes pursuant to Rule 23(b)(3).

ORDER

Based on the foregoing, all the records, files, and proceedings herein, **IT IS HEREBY ORDERED** that plaintiffs' Motion for Class Certification [Docket No. 49] is **GRANTED IN PART and DENIED IN PART** as detailed in the "Conclusion" section of the Memorandum Opinion accompanying this Order.

DATED: March 27, 2003
at Minneapolis, Minnesota.

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JOHN R. TUNHEIM
United States District Judge