before courts in the First Circuit,\textsuperscript{10} the Second Circuit,\textsuperscript{11} the Third Circuit,\textsuperscript{12} the Fourth Circuit,\textsuperscript{13} the Fifth Circuit,\textsuperscript{14} the Sixth Circuit,\textsuperscript{15} the Seventh

\textsuperscript{10} \textit{Payton v. Abbott Labs.}, 100 F.R.D. 336 (D. Mass. 1983) (rejecting a “theory of a class-wide imposition of enterprise liability for those plaintiffs who cannot identify the source of the DBS [diethylstilbestrol] which allegedly affected them,” with the result that questions of law and fact common to the class no longer predominated over questions affecting only individual class members).

\textsuperscript{11} \textit{In re Repetitive Stress Injury Litig.}, 11 F.3d 368 (2d Cir. 1993) (individual health conditions and diverse state law); \textit{In re Agent Orange Prod. Liab. Litig.}, 818 F.2d 145 (2d Cir. 1987) (individual causation and diverse state law); \textit{In re Rezulin Prods. Liab. Litig.}, 210 F.R.D. 61 (S.D.N.Y. 2002) (diverse state law and diverse issues of causation and damages).

\textsuperscript{12} \textit{Georgine}, 83 F.3d 610 (individual causation, comparative fault, and damages issues).

\textsuperscript{13} \textit{In re Stucco Litigation}, 175 F.R.D. 210 (E.D.N.C. 1997) (class comprising stucco purchasers not certified because individual issues including negligence of third parties such as architects and contractors, variations in state law, and possible conflicts of interest between plaintiffs who had already experienced physical damage and those who had not, swamped common issues and made class action unmanageable).

\textsuperscript{14} \textit{Castano v. Am. Tobacco Co.}, 84 F.3d 734 (5th Cir. 1996) (individual issues and diverse state law); \textit{In re Fibreboard Corp.}, 893 F.2d 706 (5th Cir. 1990) (individual issues); \textit{In re Propulsid Prods. Liab. Litig.}, 208 F.R.D. 133 (E.D. La. 2002) (denying nationwide medical monitoring class because of diverse state law and issues of causation).

\textsuperscript{15} \textit{In re Am. Med. Sys.}, 75 F.3d 1069 (6th Cir. 1996) (individual issues on defect, strict liability, negligence, failure to warn, and warranties).
Circuit, the Eighth Circuit, the Ninth Circuit, the Tenth Circuit, the Eleventh Circuit, and the District of Columbia Circuit.

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16 In re Bridgestone/Firestone Inc., 288 F.3d 1012 (7th Cir. 2002) (individualized issues and diverse state law); In re Rhone-Poulenc Rorer, Inc., 51 F.3d 1293 (7th Cir. 1995) (diverse state law).

17 In re Baycol Prods. Litig., 218 F.R.D. 197, 212 (D. Minn. 2003) (denying certification of class of cholesterol drug patients because individual issues, including issues of medical causation predominated over common issues); Thompson v. American Tobacco Co., 189 F.R.D. 544 (D. Minn. 1999) (denying certification of class of cigarette smokers because named plaintiffs did not adequately protect interests of class due to their desire to reserve individual personal injury claims, and also because request for medical monitoring presented too many individual issues).

18 Zinser v. Accufix Research Inst., 253 F.3d 1180 (9th Cir.), amended, 273 F.3d 1266 (9th Cir. 2001) (individual issues and diverse state law); Valentino v. Carter-Wallace, Inc., 97 F.3d 1227 (9th Cir. 1996) (same).

19 Harding v. Tambrands, 165 F.R.D. 623 (D. Kan. 1996) (class certification denied for certain women who allegedly suffered damages from Toxic Shock Syndrome (TSS) caused by using tampon products because the “advantages of a class action do not outweigh the problems of case manageability and jury confusion” inasmuch as “each individual...class member would still have to have her own trial on the individual issues applicable specifically to her, including individual causation and damages”).


Plaintiffs’ nationwide consumer protection class action, no matter what label they attach to it, is an effort to litigate product-related personal injury claims—the very claims that the federal courts hold do not pass muster under Rule 23. Plaintiffs admit that they are pursuing personal injury claims in their proposed trial plan, where they expressly list medical expenses and lost wages among their claimed damages. It is hornbook law that medical expenses and loss of wages are personal injury damages arising out of products liability. 2 Dan B. Dobbs, The Law of Torts Damages § 377, at 1047-48 (2001).

There is, moreover, no basis for treating claims based on Silzone® heart valves any differently than any other collection of cases alleging a product defect. Product-related claims raising personal injuries, by their very nature, present individual issues on liability, causation, defenses, and damages that defy classwide resolution. The class representatives and the class members all are individuals with different backgrounds, different medical histories, different physicians, and different experiences with Silzone® heart valves.

As the district court recognized in connection with plaintiffs’ tort and warranty claims, these distinctions make a difference, and the court correctly decertified the personal injury class insofar as it asserted tort and warranty claims. Its failure to do the same with the personal injury class under Minnesota’s consumer fraud statutes is therefore all the more indefensible. It also again indisputably places the law of this Circuit outside the mainstream, reason alone for this Court to grant this appeal, examine the district court’s orders, and put the law back on its proper course.
THE MEDICAL MONITORING CLASS VIOLATES CONTROLLING PRINCIPLES OF FEDERAL LAW AND COMPELS CLASSWIDE RESOLUTION OF CLAIMS NOT AMENABLE TO CLASS TREATMENT.

A. The Medical Monitoring Class Contradicts The Consumer Fraud Class And Rests On Flawed Premises, Including The Finding That Medical Monitoring Is "Injunctive Relief" And That The 17 States Included In The Class Actually Allow Medical Monitoring Claims

Plaintiffs' separate tort-based medical monitoring class is equally flawed, if not more flawed, than their consumer fraud class. For one thing, the district court erroneously certified the medical monitoring class as "injunctive relief" under rule 23(b)(2). A St. Jude Medical-paid-for medical monitoring "fund" does not constitute injunctive relief, but rather amounts to damages, which Rule 23(b)(2) does not allow. See In re Paxil Litig., 218 F.R.D. 242, 247-48 (C.D. Cal. 2003) (denying certification of equitable remedy class under Rule 23(b)(2) in product liability pharmaceutical case because the plaintiffs claimed predominately money); Zinser, 253 F.3d at 1180 (denying certification of medical monitoring class under Rule 23(b)(2) in product liability medical device action because a medical monitoring fund is damages; not injunctive relief).  

22 See also Broughton v. Cotter Corp., 65 F.3d 823, 827 (10th Cir. 1995) (denying certification of medical monitoring class under Rule 23(b)(2) because plaintiffs sought funding for medical monitoring, which constituted a demand for money damages); Cook v. Rockwell Int'l Corp., 181 F.R.D. 473, 489-80 (D. Colo. 1998) (decertifying class because action seeking diagnostic testing and medical monitoring to aid detection and treatment was primarily a suit for damages).
In addition, neither the plaintiffs nor the district court have explained how a circumscribed medical monitoring class based on the tort law of 17 states can coexist with a nationwide medical monitoring class under a single state’s consumer protection laws. On the one hand, the district court has expressly ruled that 34 jurisdictions do not allow medical monitoring claims. Yet on the other hand, the district court has created that very remedy for patients from all of those jurisdictions under the purported authority of Minnesota’s consumer protection statutes.

It is impossible to reconcile the district court’s apparent caution when applying state medical monitoring tort law with its simultaneously unconstrained (and unconstitutional) approach to applying Minnesota’s consumer statutes. By creating a nationwide medical monitoring class under Minnesota’s statutes, the district court is essentially invoking Rule 23 to overrule, or at least render moot, the public policy choices of each of those 33 jurisdictions on the topic of medical monitoring. The Erie Doctrine and the Rules Enabling Act prohibit altering or expanding state substantive law in that fashion. This Court so mandated in Trimble v. Asarco, 232 F.3d 946, 963 (8th Cir. 2000), where it refused to sanction medical monitoring under Nebraska law, observing that Erie counsels against “blazing new state-law trails,” accepting “innovative theories of state law,” or adopting a “more expansive interpretation which creates substantially more liability.” Id.

Finally, the district court failed to heed Erie’s mandate in selecting the 17 jurisdictions that make up the medical monitoring class. Although the district court acknowledged its obligation to follow state law, it nevertheless
included in the class numerous states that do not meet the court’s own class
definition, i.e., states that do not allow a stand-alone claim for medical
monitoring absent proof of physical injury. Thus, in forming the class, the
district court essentially created a stand-alone medical monitoring claim in
numerous states with no state appellate authority supporting such a claim,
again in direct violation of *Erie*.

An example is Minnesota. The district court included Minnesota in the
medical monitoring class, even though there is no authority in Minnesota for a
stand-alone medical monitoring claim absent physical injury. The court cited
a Minnesota appellate court ruled that the plaintiff had raised a triable issue of
fact on whether she suffered a “present injury” with evidence that pesticide
exposure caused rashes that covered her body and “chromosomal breakage.”
But the plaintiffs in that case *suffered demonstrable injuries*, including skin
rashes. *More importantly, neither Bryson nor any other Minnesota case has
recognized medical monitoring as anything other than a remedy that relies on
proof of an underlying cause of action.*

Another example is Delaware, which the district court included in the
medical monitoring class even though the Delaware Supreme Court has
*rejected* medical monitoring relief absent a physical injury. *See Mergenthaler
v. Asbestos Corp.*, 480 A.2d 647, 651 (Del. 1984) (rejecting medical
monitoring in asbestos exposure case because claimants had no current injury).
By including Minnesota and Delaware and any number of other states in the
medical monitoring class, the district court has expanded state law beyond its
current contours. Because it is not the role of a federal judge under Erie to expand state law in this manner, the district court’s willingness to take that role, under the guise of providing “injunctive relief” under Rule 23(b)(2), raises compelling questions that this Court can and should address.

B. Certifying A Medical Monitoring Subclass Where The Underlying Issues Cannot Be Managed In An Efficient And Economical Classwide Trial Violates Rule 23

The district court’s medical monitoring subclass raises additional issues under Rule 23, any one of which calls for appellate review.

First, the subclass definition is impossibly vague and is directly at odds with the definition of the consumer fraud class. Although the class definition refers to uninjured Silzone® valve recipients, the presence or absence of injury “can be determined only by a physician.” In re Rezulin Prods. Liab. Litig., 210 F.R.D. at 74. “And ‘[a] class definition that calls for a “medical conclusion” based on “plaintiff-specific information” is “an improper basis for maintaining a class action.’”’ Id. (quoting Newton, 163 F.R.D. at 632). But perhaps most confounding is the direct contradiction between the medical monitoring class and the consumer fraud class. The

See also, e.g., Connecticut (included in the medical monitoring class even though no Connecticut court has ever recognize medical monitoring in a personal injury action and trial court decisions have rejected it); Colorado (included in the medical monitoring class even though no state court authority has ever allowed it; relying on a federal district court opinion that recognized the issue was one of “first impression.”); Kansas (included in the medical monitoring class even though Kansas courts recognize medical surveillance as merely a component of damages recoverable on proof of an underlying claim).
former recognizes that a significant majority of states do not recognize medical monitoring, while the latter grants medical monitoring relief to Silzone® recipients nationwide. As mentioned above, it is impossible to reconcile these two classes.

Second, there is no medical consensus that additional medical monitoring is warranted for recipients of Silzone® heart valves. In the United States, no professional medical association, such as the American College of Cardiologists, no public agency, including the FDA, and no public health organization, such as the American Heart Association, has recommended any sort of medical monitoring for Silzone® valve recipients alone. The sole voice crying for medical monitoring is—unsurprisingly—that of plaintiffs’ experts. But Rule 23 should not be co-opted to meet plaintiffs’ private agenda. “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.’” In re Propulsid Prods. Liab. Litig., 208 F.R.D. at 147 (quoting Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996)).

24 See also In re Baycol Prods. Litig., 218 F.R.D. at 212 (denying certification of medical monitoring class for individuals who ingested Baycol, a prescription cholesterol-lowering drug, and noting “there is a lack of medical or scientific evidence, with the exception of Plaintiffs’ expert, which suggests or recommends that individuals who took Baycol, and have remained asymptomatic, should have their creatinine levels and blood pressure tested”); In re Rezulin Prods. Liab. Litig., 210 F.R.D. at 73 (denying certification of medical monitoring class for individuals who ingested Rezulin, a prescription diabetes-treatment drug, and noting “[n]either the American Diabetes Association nor the American Association of Clinical Endocrinologists, which (continued...)

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Third, the diverse legal issues and individual issues of proof of entitlement to medical monitoring make the certified medical monitoring class unmanageable. Although the district court professes to have limited the medical monitoring class in order to meet Rule 23, it has created in the end a 17-state class consisting of thousands of Silzone® patients with unique needs for medical follow up. This tortured and unprecedented multistate class raises fundamental issues of fairness and manageability.

Issues arise first because of diversity in state law on medical monitoring. The district court has included in the medical monitoring class numerous jurisdictions—Minnesota, Kansas, Texas, Delaware, Ohio, Texas, District of Columbia—that treat medical monitoring as a mere remedy, reliant on proof of an underlying cause of action such as negligence or strict products liability. That introduces into this class action the tort law of those states and all the diversity that exists among them. As noted above, such diversity in state tort and warranty law was a principal factor leading to the decertification of plaintiffs’ personal injury class.

Even the jurisdictions that allow a stand-alone medical monitoring claim are by no means the same. Some states impose a negligence standard, while others allow medical monitoring on proof of “tortious” conduct, which could include conduct calling for strict liability. Compare, e.g., Florida (requires promulgate guidelines for the care and treatment of diabetics, nor any public health agency or professional medical society or institution, has recommended special monitoring for patients who formerly took Rezulin®).
proof of defendant’s negligence, *Petito v. A.H. Robins*, 750 So. 2d 103, 107-08 (Fla. Ct. App. 2000), with *West Virginia* (requires proof of tortious conduct, *Bower v. Westinghouse*, 522 S.E.2d 424, 432-33 (W. Va. 1999)). Some states call for proof of an increased risk of future injury caused by exposure to a known toxin, while others expressly require proof of a *significantly* increased risk of future injury, begging the question of how much these two standards differ and how to instruct a jury on both at the same trial. *Compare*, e.g., *New Jersey* (requires proof of a relative increase in risk of injury, *Ayers v. Township of Jackson*, 525 A.2d 287, 312 (N.J. 1987), with *Pennsylvania* (requires proof of *significantly* increased risk, *Redland Soccer Club, Inc. v. Department of the Army*, 696 A.2d 137, 143-46 (Penn. 1997)). Utah is unique in requiring proof that a beneficial treatment exists to treat whatever disease medical monitoring might detect for each individual patient. *Hansen v. Mountain Fuel Supply*, 858 P.2d 970 (Utah 1993). Plaintiffs have *not* explained how they intend to handle their varying burdens, nor has the trial court ordered them to submit a trial plan.

Equally troubling are the factual issues that these cases present. The right to medical monitoring, and the nature and extent of any medical monitoring that might be required, is a patient-by-patient inquiry that cannot be handled on a class basis. For each class member, plaintiffs must prove “that the monitoring program he requires is ‘different from that normally recommended in the absence of exposure’” to the Silzone® coating, *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 146 (3d Cir. 1998) (quoting *Redland Soccer Club*, 696 A.2d at 146). To do so, each class member would need to “prove the monitoring program that is prescribed for the general public and the
monitoring program that would be prescribed for him. Although the general public's monitoring program can be proved on a classwide basis, an individual's monitoring program by definition cannot.” Id. (emphasis added).

Other elements of medical monitoring likewise will require individual proof, such as whether the Silzone® heart valve (an FDA-approved medical device) is “dangerous” or “toxic” to an individual who had diseased native heart valves to begin with and bears multiple risk factors for heart valve complications. See Perez v. Metabolife, 218 F.R.D. at 270-71 (rejecting class certification partly because of individualized inquiry into whether a dietary supplement was “dangerous or hazardous” to class members with different medical histories). Individual issues will also predominate on issues of causation—whether an increased risk of future injury is actually attributable to the Silzone® valve and not to the numerous possible alternate causes that each of these heart valve patients presents. Id. In states that require a showing of negligence, the inquiry will diverge based on when the patient received his or her valve and what St. Jude Medical knew about the valve’s risks at the time. Id.

Individual issues like those presented by these heart valve cases have recently and correctly led courts to reject certification of medical monitoring classes. In Perez v. Metabolife, 218 F.R.D. at 271-72, a federal district court denied certification of a medical monitoring class because of individual issues and “vast differences in individual class members” on every element of Florida’s seven-element medical monitoring claim. State courts in California and New Jersey similarly denied certification of medical monitoring classes in
toxic exposure cases because of predominating individual issues on causation and the appropriate level of medical monitoring, needed for each class member, if any. See *Lockheed Martin Corp. v. Superior Court*, 63 P.3d 913, 920-22 (Cal. 2003); *Goasdone v. American Cyanamid Corp.*, 808 A.2d 159, 170 (N.J. Super. Law. Div. 2002).

The district court simply ignored these differences, finding instead that plaintiffs had presented “one overarching ‘causation’ issue” with regard to medical monitoring. Because of that, the court found that there would be no significant conflict-of-law questions nor lengthy individual analyses. But as the discussion above shows, these heart valve cases—as a matter of indisputable fact—present hotly contested issues that could hardly be more diverse. The record below conclusively shows that the Silzone® valve claims are individual personal injury claims brought by different patients with different histories, different risk factors, and different needs for follow-up care. The district court cannot override these demonstrable and manifest differences by the crafting of a single sentence in an order. For this reason

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too, this action presents a marked departure from reasoned precedent that calls for immediate appellate scrutiny.

VI. CONCLUSION

In certifying these multistate claims as a nationwide class action seeking personal injury and medical monitoring damages for thousands of diverse individuals, the district court has taken procedural and substantive law well beyond its current boundaries. The court has made an unprecedented use of Rule 23 that challenges the Constitution, precedent in every Circuit, and, ultimately, the parties' right to just and fair claim resolution. This Court therefore should grant St. Jude Medical's petition and declare whether the law in this Circuit in fact supports the district court's novel and risky course.


Respectfully Submitted,

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By

[Signature]

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