United States Court of AppealsFOR THE EIGHTH CIRCUIT

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No.	06-3860

In re: St. Jude Medical, Inc., Silzone Heart Valve Products Liability		
Litigation,	*	
	*	
	*	
Lester Grovatt; Beatrice Bailey; Levy	*	
D. Redden; Bonnie L. Sliger; Joe W.		
Sanchez, on behalf of themselves and		
all others similarly situated,		
	*	
Plaintiffs/Appellees,		
		Appeal from the United States
V.		District Court for the
	*	District of Minnesota.
St. Jude Medical, Inc.,		
	*	
Defendant/Appellant,		
	*	
	*	
Product Liability Advisory Council;		
Minnesota Chamber of Commerce,		
	*	
not parties/	*	
Amici on Behalf of Appellant,	*	
•	*	
State of Minnesota; AARP,		
,	*	
Amici on Behalf of Appellee.	*	

Submitted: October 18, 2007

Filed: April 9, 2008 (Corrected April 10, 2008)

Before RILEY, MELLOY, and COLLOTON, Circuit Judges.

COLLOTON, Circuit Judge.

This products liability litigation is before us for a second time. The present appeal concerns the district court's certification of a class of plaintiffs, pursuant to Federal Rule of Civil Procedure 23(b)(3), to litigate claims against St. Jude Medical, Inc. ("St. Jude"), arising from alleged violations of two Minnesota consumer protection statutes. We conclude that the class was not properly certified under the standards of Rule 23(b)(3), and we therefore reverse the order of the district court.

I.

St. Jude Medical, Inc., produced the Silzone prosthetic heart valve, a product with a unique silver coating. After a clinical study showed that patients implanted with the valve experienced an increased risk of paravalvular leakage, St. Jude recalled all Silzone valves that had not yet been implanted. The plaintiffs in this action are patients who were implanted with the valve. They brought suit across the country under various theories, and the cases were consolidated in Minnesota for pretrial proceedings. The district court concluded in 2004 that a class action was the superior method to adjudicate claims under three Minnesota statutes, the False Advertising Act (MFAA), Minn. Stat. § 325F.67, the Consumer Fraud Act (MCFA), Minn. Stat. § 325F.69, and the Deceptive Trade Practices Act, Minn. Stat. § 325D.44.

In our prior opinion, we considered three orders of the district court that certified two subclasses of plaintiffs seeking damages and injunctive relief, respectively. *In re St. Jude Med., Inc.*, 425 F.3d 1116 (8th Cir. 2005). We reversed the district court's certification of a subclass of plaintiffs seeking injunctive relief, which was described as a "medical monitoring class," because the class presented "a myriad of individual issues making class certification improper." *Id.* at 1122. This holding disposed of the claims under the Deceptive Trade Practices Act, which were construed by the district court to seek only medical monitoring. With respect to the subclass seeking damages under the other two statutes, described as a "consumer protection class," we held that the district court should have conducted a more thorough choice-of-law analysis before it determined to apply Minnesota law to the claim of every plaintiff. *Id.* at 1121. We remanded the case to the district court for further consideration.

On remand, the district court determined that Minnesota law should apply to all claims in the nationwide class, and recertified the consumer protection class pursuant to Federal Rule of Civil Procedure 23(b)(3). *In re St. Jude Medical, Inc.*, No. 01-1396, 2006 WL 2943154 (D. Minn. 2006). St. Jude argues on appeal that the certification of the class was an abuse of discretion under Rule 23, that the district court erred in its conflicts-of-law analysis, and that application of Minnesota law to the claims of all plaintiffs would violate the Due Process Clause.

II.

With respect to Rule 23(b)(3), the district court concluded that questions of law and fact common to the class would predominate over individual issues, and that a class action was the superior method of adjudicating claims under the MCFA and the MFAA. *See In Re St. Jude Med., Inc.*, No. 01-1396, 2003 WL 1589527 at *18 (D. Minn. 2003) (incorporated by reference into 2006 order). St. Jude argues that this ruling was an abuse of discretion, because adjudicating claims of liability for violating

the statutes would require an inquiry into the causal relationship between any representation made by St. Jude and each plaintiff's injury. It further contends that two forms of relief sought by the plaintiffs – damages and medical monitoring – also present numerous individual issues that make the case unsuitable for class certification. We agree that the class was not properly certified under Rule 23(b)(3).

In a typical common-law fraud case, a plaintiff must show that he or she received the defendant's alleged misrepresentation and relied on it. *E.g.*, *Breezy Point Airport, Inc. v. First Fed. Sav. and Loan Ass'n of Brainerd*, 179 N.W.2d 612, 615 (Minn. 1970). Because proof often varies among individuals concerning what representations were received, and the degree to which individual persons relied on the representations, fraud cases often are unsuitable for class treatment. *See* Fed. R. Civ. P. 23 advisory committee's note (discussing the 1966 Amendment to subdivision (b)(3): "[A]lthough having some common core, a fraud case may be unsuited for treatment as a class action if there was material variation in the representations made or in the kinds or degrees of reliance by the persons to whom they were addressed."); *Darms v. McCulloch Oil Corp.*, 720 F.2d 490, 493 (8th Cir. 1983) (district court did not abuse discretion in refusing class certification where transactions were separate, and involved different representations and degrees of reliance); *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 745 (5th Cir. 1996) ("[A] fraud class action cannot be certified when individual reliance will be an issue.").

This case exemplifies the difficulty with class treatment of cases alleging fraud or misrepresentation. St. Jude has presented evidence that a number of implant patients did not receive *any* material representation about the heart valve. Two of the five named plaintiffs, Levy Redden and Lester Grovatt, testified that they did not remember hearing anything about the unique qualities of the Silzone valve. (App. 3431-32, 3479-80). On the other hand, one named plaintiff, Bonnie Sliger, testified that her doctor told her that the Silzone valve would be better because it would reduce the risk of infection. (App. 3475). Whether each plaintiff even received a

representation from St. Jude about the efficacy of the heart valve is likely to be a significant issue in each case of alleged liability.

Evidence of representations made to the treating physicians also illustrates the predominance of individual issues concerning representations and reliance. Physicians learned about St. Jude's heart valve in different ways. One doctor heard about the valve from a senior partner, another discovered it at a cardiology conference, and a third learned about the valve from a St. Jude sales representative and a St. Jude advertisement. (Sheely Depo. 69, App. 3456; Reardon Aff. ¶4, App. 3464; Blakeman Declaration ¶¶ 4-6, App. 3461). Whether the information on which physicians based their actions ultimately can be traced to a representation by St. Jude undoubtedly will vary by individual physician. Even where the present record does contain evidence that a physician eventually talked to a St. Jude representative or read Silzone promotional materials, those physicians assert that they did not rely on the representations by St. Jude in deciding to recommend the Silzone valve to their patients. (Blakeman Declaration ¶¶ 5, 7-8, App 3461; Reardon Aff. ¶ 4, App. 3465; Damus Declaration ¶ 6, App. 3469). Any trial thus would require physician-byphysician inquiries into each doctor's sources of information about the valve, and the credibility of any physician's denial that he relied on St. Jude's statements.

Despite these individual issues, plaintiffs argue that class certification is still appropriate because the Minnesota consumer protection statutes, unlike a commonlaw fraud cause of action, do not require proof of individual reliance. The district court apparently agreed, resting its certification decision in part on the view that "proof of reliance is unnecessary" under Minnesota consumer protection law. *In re St. Jude Med., Inc.*, 2003 WL 1589527, at *18 (D. Minn. 2003). The court based this conclusion largely on *Group Health Plan, Inc. v. Philip Morris Inc.*, 621 N.W.2d 2 (Minn. 2001), which stated that the Minnesota "legislature has eliminated the requirement of pleading and proving traditional common law reliance as an element of a statutory misrepresentation in sales action." *Id.* at 13.

The *Group Health* decision, however, did not entirely remove the element of reliance in Minnesota consumer fraud claims. Group Health held that the Minnesota legislature had relaxed the "traditional common law reliance" standard in two ways. First, under Minnesota's consumer fraud statutes "it is not necessary to plead individual consumer reliance on the defendant's wrongful conduct." Id. at 13 (emphasis added). Second, although plaintiffs must still "prove a causal nexus between the allegedly wrongful conduct of the defendants and their damages," id. (emphasis added), this proof "need not include direct evidence of reliance by individual consumers of defendants' products." Id. at 14 (emphasis added). At least in the class of cases described in *Group Health*, "the causal nexus and its reliance component may be established by other direct or circumstantial evidence that the district court determines is relevant and probative as to the relationship between the claimed damages and the alleged prohibited conduct." Id. (emphasis added). But causation is still a necessary element of a damages action under the consumer fraud statutes, and proof of a reliance component is still required: "[W]here, as here, the plaintiffs allege that their damages were caused by deceptive, misleading, or fraudulent statements or conduct in violation of the misrepresentation in sales laws, as a practical matter it is not possible that the damages could be caused by a violation without reliance on the statements or conduct alleged to violate the statutes." Id. at 13 (emphasis added). See also Tuttle v. Lorillard Tobacco Co., 377 F.3d 917, 927 (8th Cir. 2004) (holding that a plaintiff must "establish some proof that the [defendants' conduct] caused consumers to continue using smokeless tobacco and to sustain physical injury in reliance on the defendants' conduct."); Flynn v. Am. Home Prods. Corp., 627 N.W.2d 342, 351 (Minn. Ct. App. 2001) (plaintiff must still "at least present circumstantial evidence of some reliance on [the] alleged misrepresentations").

Since *Group Health*, the Minnesota Supreme Court declined to say whether the relaxed proof requirements apply when a consumer sues a defendant directly based on a one-on-one consumer transaction. *Wiegand v. Walser Automotive Groups, Inc.*,

683 N.W.2d 807, 813 (Minn. 2004). But assuming this case fits within the *Group* Health category, and thus does not require the plaintiffs to present direct proof of individual reliance, Group Health surely does not prohibit St. Jude from presenting direct evidence that an individual plaintiff (or his or her physician) did not rely on representations from St. Jude. When such evidence is available, then it is highly relevant and probative on the question whether there is a causal nexus between alleged misrepresentations and any injury. Whatever *Group Health* means about the need for these plaintiffs to present direct evidence of individual reliance, it does not eliminate the right of a defendant to present evidence negating a plaintiff's direct or circumstantial showing of causation and reliance. Given the showing by St. Jude that it will present evidence concerning the reliance or non-reliance of individual physicians and patients on representations made by St. Jude, it is clear that resolution of St. Jude's potential liability to each plaintiff under the consumer fraud statutes will be dominated by individual issues of causation and reliance. The need for such plaintiff-by-plaintiff determinations means that common issues will not predominate the inquiry into St. Jude's liability.

The record also shows that individual issues would predominate the remedial phase of the proposed class action. The plaintiffs request the highly individualized remedy of medical monitoring. Our prior decision in this case rejected a medical monitoring class certified under Rule 23(b)(2), precisely because it presented too many individual factual and legal issues:

[E]ach plaintiff's need (or lack of need) for medical monitoring is highly individualized. Every patient in the 17-state class who has ever been implanted with a mechanical heart valve already requires future medical monitoring as an ordinary part of his or her follow-up care. A patient who has been implanted with the Silzone valve may or may not require additional monitoring, and whether he or she does is an individualized inquiry depending on that patient's medical history, the condition of the patient's heart valves at the time of implantation, the patient's risk

factors for heart valve complications, the patient's general health, the patient's personal choice, and other factors.

In re St. Jude Med., 425 F.3d at 1122. Although the present appeal involves a class certified under Rule 23(b)(3), and the district court eliminated the diversity of legal issues by applying Minnesota law to all claims, the need for detailed and individual factual inquiries concerning the appropriate remedy for any violation still weighs strongly against class certification. Windham v. Am. Brands, Inc., 565 F.2d 59, 68 (4th Cir. 1977) (en banc); Abrams v. Interco Inc., 719 F.2d 23, 31 (2d Cir. 1983); see also Amchem Products, Inc. v. Windsor, 521 U.S. 591, 624 (1997) ("[Exposure-only plaintiffs] will also incur different medical expenses because their monitoring and treatment will depend on singular circumstances and individual medical histories." (internal quotation omitted)). The plaintiffs' effort to recover damages – alleged in the complaint to be "the cost of the medical care arising out of the use of the product together with any and all consequential damages recoverable under the law including, but not limited to, both past and future medical expenses, past wage loss, loss of future earning capacity, past and future pain, suffering, disability and emotional distress" (App. 47) – likewise would require individual determinations concerning the extent to which particular plaintiffs have suffered injuries caused by the Silzone valve.

We recognize that plaintiffs may present certain issues that are common to all of their claims, assuming it is proper under Minnesota choice of law principles and the Constitution to apply Minnesota law to every claim. Whether a certain published representation by St. Jude was materially false may be amenable to common resolution. If liability were established, then the entitlement of plaintiffs to restitution (i.e., a refund of the cost of the valve) or to a trust fund for financing medical research (assuming this is a proper remedy under the Minnesota statutes) may be decided on a class-wide basis. But given the individual issues necessarily involved in determining liability and the requested relief of medical monitoring and damages, we

think it is clear that the common issues do not predominate over individual issues that must be litigated to resolve the plaintiffs' claims.

The district court did not limit its class certification to specific *issues* that may be amenable to class-wide resolution, and there is a conflict in authority on whether such a class may properly be certified under Rule 23. Compare, e.g., Castano, 84 F.3d at 745-46 n.21, with In re Nassau County Strip Search Cases, 461 F.3d 219, 226-27 (2d Cir. 2006), and Valentino v. Carter-Wallace, Inc., 97 F.3d 1227, 1234 (9th Cir. 1996). See also Joel S. Feldman & Winston G. Collier, Attempting to Manufacture Predominance: Practical and Legal Concerns with Issue Certification Under Rule 23(c)(4), Practising L. Inst., Litig. & Admin. Practice Course Handbook Series, Class Action Litigation 2007: Prosecution and Defense Strategies, No. 761, p. 55 (2007); Jon Romberg, Half a Loaf is Predominant and Superior to None: Class Certification of Particular Issues Under Rule 23(c)(4), 2002 Utah L. Rev. 249 (2002). Even courts that have approved "issue certification" have declined to certify such classes where the predominance of individual issues is such that limited class certification would do little to increase the efficiency of the litigation. E.g., McLaughlin v. American Tobacco Co., No. 06-4666, slip op. at 39 (2d Cir. Apr. 3, 2008) (issue certification would not "materially advance the litigation because it would not dispose of larger issues such as reliance, injury, and damages"); In re Baycol Prods. Litig., 218 F.R.D. 197, 209 (D. Minn. 2003) (concluding that issue certification under Rule 23(c)(4) was not appropriate, because "individual trials will still be required to determine issues of causation, damages, and applicable defenses."). Given the individual issues discussed above, we think this is such a case.

In view of our decision that the certification order cannot be sustained consistent with Rule 23, we find it unnecessary to consider the merits of the district court's choice-of-law analysis or the constitutionality of applying Minnesota law to a nationwide class in these circumstances. *See In re St. Jude Med.*, 425 F.3d at 1120 ("We believe it prudent not to decide issues unnecessary to the disposition of the case,

especially given the numerous constitutional issues implicated in such an analysis.") (internal quotation omitted). For the foregoing reasons, we reverse the class certification order of the district court and remand for further proceedings.