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Mass Torts & Product Liability Practice

Eighth Circuit Reverses Certification of Nationwide Class of Uninjured Medical Device Recipients

In an opinion with potentially far-reaching consequences for plaintiffs seeking to obtain class certification in actions alleging violations of state consumer protection statutes and in actions seeking medical monitoring, the Eighth Circuit has reversed certification of a nationwide class of uninjured medical device recipients. *In re St. Jude Med., Inc.*, _F.3d _, 2008 WL 942274 (8th Cir., Apr. 9, 2008).

In *St. Jude*, a putative nationwide class of individuals who received prosthetic heart valves made by St. Jude alleged that the company violated several Minnesota consumer protection statutes by misrepresenting and concealing information about the valves' safety. Although each plaintiff's heart valve continued to function properly, the plaintiffs alleged that the valves contained latent defects that placed them at an increased risk of future harm. Plaintiffs sought, *inter alia*, an order requiring St. Jude to pay for a medical monitoring program that would screen for side effects associated with defective heart valves. The district court certified the nationwide class under Fed. R. Civ. P. 23(b)(3). In doing so, the court avoided an obstacle that has led many courts to deny certification of nationwide consumer fraud classes—the need to apply varying state laws—by concluding that it could apply Minnesota's consumer protection statutes to the claims of all class members.

On April 9, 2008, the Eighth Circuit reversed, holding that certification was inappropriate even assuming that Minnesota law could be applied to all claims. First, the court observed that many of the plaintiffs had not received any representations about their heart valves and that their physicians had learned about the valves from a variety of sources unconnected to St. Jude's alleged fraud. Accordingly, a class trial would devolve into a series of individualized inquiries concerning whether plaintiffs and their physicians relied on St. Jude's alleged misrepresentations. The court rejected the contention that class treatment was warranted because Minnesota's consumer protection statutes do not require proof of individual reliance. Although Minnesota has "relaxed the 'traditional common law reliance' standard" under its consumer protection statutes, the court held that "causation is still a necessary element…and proof of a reliance component is still required." The court further held that, even if the plaintiffs did not need to prove reliance, St. Jude maintained the right "to present evidence negating a plaintiff's direct or circumstantial showing of causation and reliance."

Second, the court concluded that "individual issues would predominate the remedial phase." The court explained that whether a plaintiff needs medical monitoring "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 choices, and other factors." Finally, the court held that "issue certification" under Fed. R. Civ. P. 23(c)(4) was inappropriate because it "would do little to increase the efficiency of the litigation."

The Eighth Circuit's decision, if followed in other jurisdictions, will make it very difficult for plaintiffs to obtain class certification in actions brought under even the most liberal consumer protection statutes.

Under the Eighth Circuit's reasoning, certification of consumer fraud classes is inappropriate when defendants introduce evidence showing that some plaintiffs did not hear or rely upon the alleged misrepresentations. The court made it clear that plaintiffs cannot evade individualized causation inquiries either by suing under consumer protection statutes that lack a reliance requirement or by seeking certification under a single state's statute. Accordingly, *St. Jude* promises to have a broad impact not only in medical device suits but also in consumer fraud class actions generally.

The Eighth Circuit's decision is also significant for its analysis of the medical monitoring request. In a prior opinion in the same litigation, the Eighth Circuit held that individual issues concerning whether a plaintiff needs medical monitoring predominate over any common issues in suits alleging stand-alone monitoring claims. On remand, the plaintiffs and the district court attempted an end-run around the Eighth Circuit's decision through the unusual, and perhaps unprecedented, step of making medical monitoring a remedy to the plaintiffs' consumer fraud claims. The Eighth Circuit rejected this gambit and thus made it clear that medical monitoring classes are inappropriate regardless of whether plaintiffs frame monitoring as a stand-alone claim or as a remedy tied to a separate cause of action. Moreover, *St. Jude* confirms that plaintiffs may not obtain certification of statewide medical monitoring classes, as individual issues predominate even when plaintiffs limit their claims to a single state's law.

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