# RECOMMENDED FOR FULL-TEXT PUBLICATION Pursuant to Sixth Circuit Rule 206

File Name: 05a0364p.06

## UNITED STATES COURT OF APPEALS

## FOR THE SIXTH CIRCUIT

No. 04-5211

Appeal from the United States District Court for the Western District of Tennessee at Memphis. No. 03-02576—Bernice B. Donald, District Judge.

Argued: February 2, 2005

Decided and Filed: August 23, 2005

Before: COLE and CLAY, Circuit Judges; HOOD, District Judge.

#### **COUNSEL**

**ARGUED:** Carroll C. Johnson III, LAW OFFICES OF CARROLL C. JOHNSON, Memphis, Tennessee, for Appellant. James C. Martin, REED SMITH LLP, Pittsburgh, Pennsylvania, for Appellees. **ON BRIEF:** Paul Berry Cooper III, DEAL, COOPER & HOLTON, Memphis, Tennessee, for Appellant. James C. Martin, Donna M. Doblick, REED SMITH LLP, Pittsburgh, Pennsylvania, DeWitt M. Shy, Jr., BURCH, PORTER & JOHNSON, Memphis, Tennessee, for Appellees.

## **OPINION**

HOOD, District Judge. Plaintiff-Appellant Michael Sutton appeals the November 26, 2003 order of the district court granting Defendants St. Jude Medical S.C., Inc.'s and St. Jude Medical, Inc.'s motion to dismiss for lack of standing. For the reasons set forth below, we **REVERSE** the district court's order, and **REMAND** the case to the district court for further consideration.

The Honorable Denise Page Hood, United States District Judge for the Eastern District of Michigan, sitting by designation.

#### I. INTRODUCTION

Plaintiff-Appellant Michael Sutton brought suit on behalf of a proposed class of persons who underwent cardiac bypass surgery using a medical device called the Symmetry Bypass System Connector ("device"). Heart surgeons use this device during cardiac bypass surgery to attach saphenous vein grafts to the aortic surface of the heart without sutures. Sutton was implanted with the device during treatment for his heart condition. Defendants-Appellees St. Jude Medical, S.C., Inc., and St. Jude Medical, Inc. (collectively "St. Jude") are the designers, manufacturers, and distributors of the device. Sutton alleges that St. Jude failed to use reasonable care and was negligent in designing the device, and further, that the device is defective and unreasonably dangerous, and is sold and marketed without proper warnings. In addition, Sutton specifically alleges the following facts in his complaint:

- (1) the device has "led to severe and disabling medical conditions resulting from collapse and scarring of the graft" in "numerous patients," necessitating removal of the device and/or monitoring for further harm, including death (Complaint at 6, ¶ 15; Joint Appendix at 10);
- St. Jude was informed of adverse consequences associated with the device through incident reports from cardiac surgeons, but despite these warnings, St. Jude continues to market and distribute the aortic connector (Compl. at 6, ¶¶ 16–17; J.A. at 10);
- as a result of having this allegedly defective and unreasonably dangerous device implanted in him, Plaintiff "has suffered economic losses and large medical expenses and has a device in his body which increases his risk for aortic bypass stenosis or occlusion and its resulting physical injuries" (Compl. at 6, ¶ 29; J.A. at 10).

Sutton brought a diversity suit on behalf of all persons in whom the device has been implanted.<sup>1</sup>

Sutton, on behalf of the putative class of persons implanted with the device, seeks the imposition of a medical monitoring fund providing the following: (1) notice to all persons implanted with the device of its potential harm; (2) periodic medical examinations, including necessary studies and tests, to determine the extent of graft compromise and its progression, if any; (3) education for physicians about diagnosing and treating any scarring that may result from using the device; and (4) medical treatment to remove the device from all individuals exhibiting bypass graft compromise as a result of using the device.

Pursuant to Rule 12(b) of the Federal Rules of Civil Procedure, St. Jude moved for dismissal of Sutton's complaint. St. Jude asserted Sutton lacks standing to pursue his action, and that he failed to state a claim upon which relief could be granted. Ruling that Sutton did not have standing, the district court dismissed his complaint for lack of subject matter jurisdiction. Sutton timely appealed to this Court.

<sup>&</sup>lt;sup>1</sup>Sutton estimates the number of claimants to be approximately 50,000 people.

<sup>&</sup>lt;sup>2</sup>The district court did not reach St. Jude's failure to state a claim argument.

#### II. DISCUSSION

#### A. Jurisdiction and Standard of Review

This Court has appellate jurisdiction over the district court's final judgment under 28 U.S.C. § 1291. We review an order dismissing a case for lack of subject matter jurisdiction *de novo*. *Joelson v. United States*, 86 F.3d 1413, 1416 (6th Cir. 1996). Any factual findings made by the district court while deciding a motion to dismiss are reviewed for clear error only. *Jones v. City of Lakeland*, 175 F.3d 410, 413 (6th Cir. 1999) (overruled on other grounds) (quoting *Gafford v. Gen Elec. Co.*, 997 F.2d 150, 161 (6th Cir. 1993)).

## **B.** Standing under Article III

Sutton brings suit on behalf of a class of as-of-yet uninjured device implantees. In order to satisfy the standing requirements of Article III of the Constitution, Sutton must meet three requirements. Failure to establish any one of them deprives a federal court of jurisdiction to hear the suit. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S.Ct. 2130, 119 L.Ed. 2d 351 (1992). First, Sutton must demonstrate he has suffered "an 'injury in fact' that is both concrete and particularized and actual or imminent." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81, 120 S.Ct. 693, 145 L.Ed. 2d 610 (2000) (citing *Lujan*, 504 U.S. at 560-61). Second, the injury must be fairly traceable to the challenged action of St. Jude. *Id.* Finally, Sutton must show that "it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Id.* 

The Article III standing requirements apply equally to class actions. The class representative must allege an individual, personal injury in order to seek relief on behalf of himself or any other member of the class. *O'Shea v. Littleton*, 414 U.S. 488, 494, 94 S.Ct. 669, 38 L.Ed. 2d 674 (1974). Sutton's general factual allegations may be sufficient to show standing when assessing the issue on a motion to dismiss. *Lujan*, 504 U.S. at 561. The court must accept as true all such allegations contained in the complaint and must construe the complaint in favor of Sutton. *See Warth v. Seldin*, 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed. 2d 343 (1975); *Greater Cincinnati Coalition for the Homeless v. City of Cincinnati*, 56 F.3d 710, 716 (6th Cir. 1995) (citing *Gladstone*, *Realtors v. Vill. of Bellwood*, 441 U.S. 91, 109, 99 S.Ct. 1601, 60 L.Ed. 2d 66 (1979)).

## C. Standing Based Upon Increased Risk of Future Harm

Sutton makes three main factual allegations in his complaint: (1) the device is defective and unreasonably dangerous; (2) implantation of the device puts Sutton and class members at a substantially greater risk for developing restenosis and occlusion of the bypass graft; and (3) this increased risk necessitates both current and future medical testing and monitoring. The district court found Sutton's alleged injury "purely hypothetical" because he did "not provide[] the Court with any information from which to assess his allegedly increased risk of harm from implantation of the aortic connector." Sutton v. St. Jude Med., Inc., 292 F. Supp.2d 1005, 1008–09 (W.D. Tenn. 2003). The thrust of the district court's decision was that Sutton failed to establish a sufficient risk of harm associated with the device to survive dismissal for lack of standing. We find the district court incorrectly attempted to evaluate the merits of Sutton's contention that he is entitled to medical monitoring costs. During the threshold standing inquiry, the district court should have accepted Sutton's allegations as true and construed the complaint in Sutton's favor. See Greater Cincinnati Coalition for the Homeless, 56 F.3d at 716.

Sutton argues that exposure to an increased risk of disease has been recognized by federal courts as an injury in fact sufficient to confer Article III standing. He likens exposure to the device to exposure to toxins such as nuclear emissions and asbestos. *See Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 73-74, 98 S.Ct. 2620, 57 L.Ed. 2d 595 (1978) (finding

standing where plaintiffs had not yet manifested any physical injury as a result of exposure to nuclear emission); *Carlough v. Amchem Prod., Inc.* 834 F. Supp. 1437, 1454 (E.D. Pa. 1993) (conferring standing from mere exposure to asbestos). The district court correctly stated that the device presently at issue differs from toxic substances in that the device provides a medical benefit to individuals "exposed" to it. The district court also properly noted that medical devices can be beneficial for some users while causing complications in others. For purposes of standing however, we hold the differences between exposure to toxic substances and allegedly defective products are immaterial.

In recent years, tort plaintiffs have increasingly sought, and have regularly been awarded, medical monitoring costs in both toxic tort and product liability cases. *See* Arvin Maskin, *et al.*, *Medical Monitoring:* A *Viable Remedy for Deserving Plaintiffs or Tort Law's Most Expensive Consolation Prize?*, 27 Wm. Mitchell L. Rev. 521, 522 (2000) (citing *Day v. NLO*, 851 F. Supp. 869, 876 (S.D. Ohio 1994); *Bower v. Westinghouse Elec. Co.*, 522 S.E.2d 424, 427 (W. Va. 1999)). A medical monitoring award aids presently healthy plaintiffs who have been exposed to an increased risk of future harm to detect and treat any resultant harm at an early stage. *Ayers v. Jackson Township*, 525 A.2d 287, 308 (N.J. 1987).

The question of whether an increased risk of harm requiring current medical monitoring is a sufficient injury in fact to confer standing is one of first impression in this Circuit. The main basis found in the case law for allowing such claims to proceed is *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816 (D.C. Cir. 1984). *Friends for All Children* concerned a tort action on behalf of Vietnamese orphans for injuries suffered in an aviation accident in Vietnam in 1975. The court found a sufficient injury in fact for "approximately forty adopted Vietnamese children living in France fac[ing] irreparable injury unless they promptly obtained diagnostic examinations . . . ." 746 F.2d at 816. After finding the plaintiffs had standing to pursue their claim, the *Friends for All Children* court upheld the district court's decision ordering Lockheed to establish a fund to pay for medical monitoring of the children placed at risk by the incident. The court then went on to address whether the tort law of the District of Columbia encompassed a cause of action for diagnostic examinations in the absence of proof of actual injury. \*\* *Id.*\*

A distinguishing feature of *Friends for All Children*, 746 F.2d 816, is that an irreparable injury immediately confronted the plaintiffs as a result of the airplane accident. While this same immediacy cannot be imputed to Sutton's proposed class of plaintiffs, we see no reason to require it to confer standing. Nor do we see fit to deny standing to Sutton and other class members because of any differences between exposure to toxins and implantation of purportedly beneficial medical devices. A defective medical device embedded in an individual's body can pose just as serious a threat as exposure to toxic substances. Indeed, such devices may be even more dangerous given the fact that an individual with such an implant will continuously be exposed to its increased risks.

The Third Circuit considered medical monitoring in *In re Paoli Railroad Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990). *Paoli* held that a cause of action for medical monitoring is cognizable in Pennsylvania in order to cover the cost of periodic medical examinations. These examinations were needed to protect against exacerbation of latent diseases brought about by exposure to hazardous substances. The *Paoli* court delineated the difference between medical monitoring claims and damages claims involving an increased risk of harm without a present

<sup>&</sup>lt;sup>3</sup>A district court case from this Circuit has extensively discussed the issue of which states' laws allow for such actions. *See In re Telectronics Pacing Sys., Inc.*, 168 F.R.D. 203 (S.D. Ohio 1996) (noting that plaintiffs in a cause of action for medical monitoring costs do not have to prove a present, physical injury in Colorado, the District of Columbia, Kansas, Kentucky, New York, Pennsylvania, Utah, Washington, and Guam. Physical injury must be shown in Delaware, Virginia, West Virginia, and the Virgin Islands). *In re Telectronics*, and all of the cases cited therein, found a sufficient injury in fact.

physical injury. *Id.* at 849–51. *Paoli* couches the discussion by considering medical monitoring a tort in and of itself, as opposed to a remedy for the underlying tort of exposure to an increased risk of future harm. The court noted that "[m]edical monitoring is one of a growing number of nontraditional torts that have developed in the common law . . . ." *Id.* at 849. Comparing a claim for medical monitoring to a claim for damages based on the enhanced risk, the court stated, "an action for medical monitoring seeks to recover only the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm, whereas an enhanced risk claim seeks compensation for the anticipated harm itself, proportionately reduced to reflect the chance that it will not occur." *Id.* at 850.

While we consider the distinction set forth in *Paoli* helpful, we note that medical monitoring is more properly considered one of a number of possible remedies to an underlying tort, rather than a separatately actionable tort. *See* Andrew R. Klein, *Rethinking Medical Monitoring*, 64 Brook. L. Rev. 1, 10–11 (1998) (challenging the propriety of construing the cases as creating a unique cause of action and arguing in favor of the notion that medical monitoring "simply describes a potential remedy in established tort actions."). Instead of "[t]he injury in an enhanced risk claim [being] the anticipated harm itself" and "[t]he injury in a medical monitoring claim [being] the cost of the medical care that will, one hopes, detect that injury", *Paoli*, 916 F.2d at 850, we think it more accurate to find the increased risk of future harm is the injury in both types of cases. The difference lies in the remedy sought by the plaintiff. Based on the particular remedy a plaintiff chooses to seek, her burden of proof will vary. *See id.* (noting that proving monetary damages "is inherently speculative because courts are forced to anticipate the probability of future injury" while proving the need for medical monitoring "is much less speculative because the issue for the jury is the less conjectural question of whether the plaintiff needs medical surveillance.").

In *Metro-North Commuter Railroad v. Buckley*, the Supreme Court considered a medical monitoring claim in the context of exposure to asbestos. 521 U.S. 424, 117 S. Ct. 2113, 138 L. Ed.2d 560 (1997). The Court held that the plaintiff could not recover medical monitoring costs in a Federal Employers' Liability Act case, finding a lack of "sufficient support in the common law." *Id.* at 444. Importantly, *Metro-North* does not address standing, which by implication strongly suggests that the plaintiff, in fact, had standing to pursue medical monitoring costs.

Two district courts in other Circuits have considered the issue of standing in increased risk of future harm cases, and have answered the inquiry in the affirmative. See In re St. Jude Med., Inc., No. MDL 01-1396 JRT FLN, 2003 WL 1589527 (D. Minn. Mar. 27, 2003) ("In re St. Jude"); In re Propulsid Prod. Liab. Litig., 208 F.R.D. 133, 139 (E.D. La. 2002) ("In re Propulsid"). In re St. Jude Medical, Inc. presented a plaintiff requesting medical monitoring for side effects from implanted heart valves manufactured by St. Jude. St. Jude recalled all of the un-implanted heart valves at issue. Scientific findings revealed that these valves caused a two percent occurrence of paravalvular leak, as compared to a 0.25 percent occurrence in conventional heart valves. 2003 WL 1589527 at \*1. In addition to the voluntary recall, St. Jude "immediately notified hospitals and physicians, instructing them not to use [the] products. [Defendant] also sent letters regarding the care and management of patients with implanted . . . valves, and established a reimbursement program to pay for uninsured medical costs associated with the detection, diagnosis and treatment of paravalvular leak." Id. The plaintiff sought certification of a class of individuals who had received the valve implants, but who had not suffered any injurious side effects. Id. at \*2. The relief requested was the establishment of a medical monitoring program that would watch for side effects associated with defective heart valves. *Id.* In support of the requested relief, the plaintiff provided ample medical

<sup>\*</sup>Metro-North also supports our framing of medical monitoring as a remedy rather than a separate tort. 521 U.S. at 443 ("we are . . . troubled . . . by the potential systemic effects of creating a new, full-blown, tort law cause of action . . . .").

evidence documenting the potential complications caused by the valve and its possible long-term consequences. *Id.* at \*11. Though the court in *In re St. Jude* did not specifically address whether the plaintiff had standing, by reaching the merits of the plaintiff's claims it clearly found a sufficient injury in fact to confer Article III standing.

In re Propulsid found that a plaintiff who had previously used a heartburn drug causing irregular heartbeats in some users, but who had not herself developed any such injury, had alleged a sufficient injury in fact based on the increased risk of harm. The court stated a broad standard for demonstrating injury in fact: "plaintiff has satisfied her burden of establishing this element [injury in fact] because the courts have long recognized that an increased risk of harm, which the plaintiff alleges, is an injury-in-fact." In re Propulsid, 208 F.R.D. at 139 (citing Friends for All Children, 746 F.2d 816; Paoli, 916 F.2d 829; In re Orthopedic Bone Screw Prods. Liab. Litig., Nos. Civ. A. 98-4643, MDL 1014, 1999 WL 455667 (E.D. Pa. July 2, 1999)). In re Propulsid sets a relatively low bar for satisfying the injury in fact doctrine in exposure to prescription drugs and, by analogy, medical device cases. Id. at 133; see also, In re Orthopedic Bone Screw Prods. Liab. Litig., Nos. Civ. A. 98-4643, MDL 1014, 1999 WL 455667 (E.D. Pa. July 2, 1999) (finding standing to challenge federal agency action when plaintiffs argued their injury was exposure to a potentially dangerous medical device whose safety has not been demonstrated in accordance with the Food, Drug and Cosmetic Act and the Medical Device Amendments).

In Taylor v. Medtronics, Inc., 861 F.2d 980 (6th Cir. 1988), this Circuit affirmed judgment as a matter of law for defendant on a products liability claim. We found the evidence showed that the plaintiff's particular pacemaker was not defective, even though there was a high incidence of defects in that model of pacemaker. *Id.* In our view, *Taylor* is distinguishable from the instant case, and the district court erroneously relied upon it to find that Sutton lacks standing. In Taylor, the plaintiff sought compensatory and punitive damages for an allegedly defective pacemaker. This Court granted summary judgment to the defendant manufacturer, because plaintiff failed to show that her actual pacemaker was defective. *Id.* at 988. *Taylor* does not suggest that the plaintiff lacked standing because her pacemaker was not defective. On the contrary, because this Court decided the case on the merits at the summary judgment stage, it necessarily follows that the plaintiff did satisfy the requirements of Article III standing; she simply did not have a meritorious claim. *Id.*; cf. Baur v. Veneman, 352 F.3d 625, 634 (2d Cir. 2003) (enhanced risk of contracting food-borne illness due to consumption of downed livestock sufficient injury in fact to confer standing); Willet v. Baxter Int'l, Inc., 929 F.2d 1094 (5th Cir. 1991) (no discussion of standing where plaintiffs sought damages for fear that allegedly defective, but currently functioning, heart valves would cause future injury); Harris v. Purdue Pharma, L.P., 218 F.R.D. 590, 595 (S.D. Ohio 2003) (presuming that plaintiffs have standing based on increased risk of drug dependency through use of prescription pain medication).

Other courts have indicated they would not find standing to pursue medical monitoring costs in increased risk of future harm situations. One such case supporting the denial of standing to uninjured plaintiffs, relied upon by the district court in the instant case, is *Martin v. American Medical Systems, Inc.*, No. IP 94-2067-C-H/G, 1995 WL 680630 (S.D. Ind. Oct. 25, 1995). There the district court denied class certification to a group of plaintiffs who had received penile implants. Some of the implants had malfunctioned, though not any of those implanted in the plaintiffs. The *Martin* court expressed doubt as to whether the plaintiffs, who were satisfied with their particular implants and had derived some benefit therefrom, could point to an injury in fact. *Id.* at \*6.

<sup>&</sup>lt;sup>5</sup>While we have included the particular factual findings of the district court in our discussion of the *In re St. Jude* decision, we again note that specific evidence of the alleged increased risk of harm is not a requirement to confer standing.

Analyzing Sutton's present action in light of the above precedent, we disagree with the result reached by the district court below. Sutton has alleged sufficient facts, when accepted as true, to suggest an increased risk of future harm resulting from being implanted with St. Jude's device. Whether Sutton is likely to prevail on the merits is not a proper consideration at this time. We decline to preclude the possibility of a plaintiff or class of plaintiffs bringing suit under an increased risk of future harm theory due to the implantation of a medical device.

Though the plaintiffs in *In re St. Jude Medical, Inc.* were able to demonstrate a 700-percent increase in risk associated with using the heart valves there at issue, we hold it unnecessary for a plaintiff to make such a showing as a matter of course. Such a vast increase in the risk of injury clearly establishes an injury in fact, but to require a plaintiff to so clearly demonstrate her injury in order to confer standing is to prematurely evaluate the merits of her claims. Here Sutton alleges an increased risk of harm when comparing those individuals implanted with the device to those undergoing traditional surgery. Accepting Sutton's allegations as true, the standing requirements have been met. *See Lujan*, 504 U.S. at 561; *Greater Cincinnati Coalition for the Homeless*, 56 F.3d at 716. We also note that there is something to be said for disease *prevention*, as opposed to disease *treatment*. Waiting for a plaintiff to suffer physical injury before allowing any redress whatsoever is both overly harsh and economically inefficient.

The last two requirements for standing are easily met in this instance. The increased risk of future harm must be "fairly traceable" to St. Jude's actions. *Friends of the Earth, Inc.*, 528 U.S. at 180–81. St. Jude is the undisputed designer, manufacturer, and distributor of the device. There is no question that any increased risk of harm arising from implantation of the device is fairly traceable to St. Jude. Finally, Sutton must demonstrate his injury is redressable by a favorable decision. *Id.* Assuming Sutton is capable of proving the device puts implantees at a substantially greater risk for developing restenosis and occlusion of the bypass graft – as he asserts in his complaint – medical monitoring will undoubtedly help to remedy the situation.

The court below improperly concluded Sutton lacks standing to seek medical testing and monitoring allegedly made necessary by the implantation of a medical device that has not yet malfunctioned or caused Sutton any physical injuries, but presents an increased risk of future harm. We accordingly reverse and remand Sutton's action.

### III. TENNESSEE PRODUCT LIABILITY LAW

In the alternative, St. Jude moved for dismissal of Sutton's complaint arguing that Tennessee product liability law does not allow a claim for medical monitoring where no physical injury or property damage manifests itself. "As a general rule, appellate courts do not consider any issue not passed upon below." *Dubuc v. Mich. Bd. of Law Exam'rs*, 342 F.3d 610, 620 (6th Cir. 2003) (citing

<sup>&</sup>lt;sup>6</sup>Sutton also filed a Motion to Certify Questions of Law to Tennessee Supreme Court, which this panel has previously denied.

Singleton v. Wulff, 428 U.S. 106, 119-20, 96 S.Ct. 2868, 49 L.Ed. 826 (1976)). We therefore decline to reach this issue, as the district court did not address it below.

#### IV. CONCLUSION

For the foregoing reasons, we **REVERSE** the district court's order of dismissal and **REMAND** the case for further evaluation consistent with this opinion.

In an effort to guide the district court on remand, we note that although Tennessee law is murky on the issue of whether claims for medical monitoring are cognizable, there are reasons why such claims are most probably proper. First, we note that two Tennessee cases at least suggest that the state recognizes medical monitoring claims. See Laxton v. Orkin Exterminating Co., Inc., 639 S.W.2d 431 (Tenn. 1982) (allowing recovery for medical expenses and mental anguish in the absence of physical injury where defendant negligently contaminated plaintiffs' household water supply with toxic chemicals, and stating that "[t]here is no question as to the reasonableness of the medical expenses . . . . Even though the tests proved negative, in our opinion a jury could find sufficient 'injury' to these plaintiffs to justify a recovery for their natural concern and anxiety for the welfare of themselves and their infant children'); Newsom v. Markus, 588 S.W.2d 883, 887 (Tenn. Ct. App. 1979) (holding that "a party is entitled to recover reasonable medical expenses for examinations, etc., in an effort to determine if personal injuries were sustained as a result of defendants [sic] negligence, even though it develops that the party suffered no personal injury"). Additionally, several other state courts have recognized such claims. See, e.g., Ayers, 525 A.2d 287; Bower, 522 S.E.2d 424; Potter v. Firestone Tire & Rubber Co., 863 P.2d 795 (Cal. 1993); Hansen v. Mountain Fuel Supply Co., 858 P.2d 970 (Utah 1993); Burns v. Jaquays Mining Corp., 752 P.2d 28 (Ariz. Ct. App. 1987); see also Paoli, 916 F.2d 829.