

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

MICHAEL SUTTON,)	
)	
Plaintiff,)	
)	
v.)	No. 03-2576 DV
)	
ST. JUDE MEDICAL, INC., and,)	
ST. JUDE MEDICAL S.C., INC.,)	
)	
Defendants.)	

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Before the Court is the motion of St. Jude Medical, Inc. and St. Jude Medical S.C., Inc. (collectively "Defendants") to dismiss the class action complaint of Michael Sutton ("Plaintiff")¹ pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). For the following reasons, the Court grants Defendants' motion to dismiss.

I. Background Facts²

Mr. McGuinn is a citizen of Tennessee, and Defendants are Minnesota corporations. Plaintiff represents a class of thousands of individuals who have had an aortic connector implanted in their bodies.

¹The named plaintiff in this case was originally Skipper P. McGuinn. The parties substituted Michael Sutton for Skipper McGuinn on November 4, 2003, with the stipulation that such substitution would not affect any of the issues raised in Defendants' motion to dismiss. (Consent Order Substituting Pl.)

²The background facts are taken from Plaintiff's complaint. Given the parties' stipulation as to plaintiff substitution, in discussing the facts of this case, the Court will refer to Mr. McGuinn's medical history as described in the complaint, rather than to Plaintiff's own history.

This case involves use of the Symmetry Bypass Aortic Connector Device (“aortic connector”) developed, manufactured, marketed, and sold by Defendants. The aortic connector is a medical device designed for use by cardiac surgeons during cardiac bypass surgery. It is used to attach the saphenous vein graft to the aortic surface without sutures or the need for cross clamping or side biting of the aorta during cardiac bypass surgery. Over 50,000 aortic connectors have been implanted in patients.

Plaintiff alleges that implanting of the aortic connector has led to severe and disabling medical conditions resulting from collapse and scarring of the graft. These conditions have necessitated removal of the aortic connector in numerous patients, have caused severe harm to other patients, and necessitate periodic medical monitoring of other patients for signs and symptoms. Mr. McGuinn has not alleged that he personally suffered any physical injury as a result of the aortic connector’s implantation. Rather, Mr. McGuinn alleges that, as a result of having the aortic connector in his body, he suffers an increased risk of medical complications, including aortic bypass stenosis or occlusion and its resulting physical injuries.

Defendants have been informed of the adverse consequences resulting from use of the aortic connector through incident reports from cardiac surgeons who were confronted with such consequences after using the device. Defendants still market the aortic connector.

On August 5, 2003, Mr. McGuinn filed a class action complaint with this Court. Plaintiff asserts that Defendants have failed to promulgate proper warnings to physicians and the public of the potential complications caused by the device, and therefore that the aortic connector is defective or unreasonably dangerous. Plaintiff requests relief in the form of a fund paid for by Defendants to provide for a medical monitoring program, including: (1) notifying people who have had an aortic

connector implanted of the potential harm from the device; (2) providing periodic medical examinations, including all necessary studies and tests, to determine the extent of graft compromise and its progression, if any; (3) gathering and forwarding to treating physicians information related to the diagnosis and treatment of scarring that may result from use of the aortic connector; and (4) providing medical treatment to remove the aortic connectors in those individuals who exhibit bypass graft compromise as a result of implantation of the device.

On August 27, 2003, Defendants filed this motion to dismiss, arguing that (1) because Mr. McGuinn himself suffered no physical injury from Defendants' alleged conduct, Plaintiff lacked standing to litigate in federal court under Article III of the United States Constitution; (2) Plaintiff failed to state a claim for relief under Tennessee law, because a tort claim requires the plaintiff to have suffered an injury; and (3) Tennessee does not recognize the medical monitoring relief that Plaintiff requested.

II. Standing

Standing is a requirement of Article III. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). Standing must be determined at the outset of litigation, as failure of a plaintiff to show standing deprives the federal courts of jurisdiction to hear the case. See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 102 (1998). The plaintiff has the burden of proving standing. See Defenders of Wildlife, 504 U.S. at 561.

Standing consists of three elements: (1) the plaintiff must have suffered an injury in fact; (2) there must be a causal connection between the injury and the defendant's conduct of which the plaintiff complains; and (3) it must be likely that the injury will be redressed by a favorable decision. Id. at 560. The injury in fact must be actual or imminent, not conjectural or hypothetical. Id.; see

also City of Los Angeles v. Lyons, 461 U.S. 95, 101-02 (1983) (“The plaintiff must show that he ‘has sustained or is immediately in danger of sustaining some direct injury’ as the result of the challenged official conduct and the injury or threat of injury must be both ‘real and immediate,’ not ‘conjectural’ or ‘hypothetical.’”). In a class action, the named plaintiff must allege an individual, personal injury in order to seek relief on behalf of himself, or herself, or any other member of a class. See O’Shea v. Littleton, 414 U.S. 488, 494 (1974) (“If none of the named plaintiffs purporting to represent a class establishes a requisite of a case or controversy with the defendant, none may seek relief on behalf of herself or any other members of the class.”).

On a motion to dismiss, the plaintiff’s general factual allegations of injury resulting from the defendant’s conduct may suffice to show standing. See Defenders of Wildlife, 504 U.S. at 561.

Plaintiff does not allege that Mr. McGuinn suffered any physical injury or medical consequences from implantation of the aortic connector. Rather, Plaintiff alleges that Mr. McGuinn suffered an increased risk of physical complications from the device, which he alleges is defective because of insufficient warnings, while other patients actually incurred physical injuries. The Court must decide whether Mr. McGuinn’s increased risk of complications constitutes an “injury in fact” sufficient to confer standing.

Whether increased risk of harm from an implanted medical device is sufficient injury in fact to confer standing is a question of first impression here. There is a split among the federal courts on this issue. In In re St. Jude Medical Heart Valves, No. MDL 01-1396 JRTFLN, 2003 WL 1589527 (D. Minn. Mar. 27, 2003), the plaintiff requested medical monitoring for side effects from implanted heart valves manufactured by the defendant. The defendant had recalled all heart valves of the model at issue that had not yet been implanted, based on findings that these new valves caused

a 2% occurrence of paravalvular leak, in comparison to a 0.25% occurrence with conventional valves. See id. at *1. The defendant also contacted all patients who had previously implanted valves of this model and established a medical program to pay for all their uninsured medical costs associated with detection, diagnosis, and treatment of any paravalvular leak. See id. The plaintiff sought certification of a class of individuals who had had the valve implants, but who had not suffered any injurious side-effect as a result. See id. at *2. The plaintiff provided medical evidence documenting the potential complications caused by the heart valve and its possible long-term health consequences. See id. at *11. The court found that the plaintiff had sufficiently alleged and provided evidence of the increased risk of harm and that that increased risk constituted an injury in fact. See id.; see also In re Propulsid Prod. Liability Litig., 208 F.R.D. 133, 139 (E.D. La. 2002) (finding that plaintiff, who had previously used heartburn drug that caused heartbeat irregularities in certain individuals, but who had not herself developed any injury, had alleged injury in fact based on increased risk of harm).

Conversely, in Martin v. American Medical Systems, Inc., No. IP 94-2067-C-H/G, 1995 WL 680630 (S.D. Ind. Oct. 25, 1995), in denying class certification, the district court expressed skepticism that plaintiffs who had received penile implants, which allegedly malfunctioned in some recipients although not in plaintiffs, could show injury in fact. See id. at *6. It was unclear to the court that plaintiffs, who themselves were satisfied with their medical devices and received some benefit therefrom, had suffered an injury in fact. See id.; cf. Taylor v. Medtronic, Inc., 861 F.2d 980 (6th Cir. 1988) (affirming judgment as a matter of law for defendant on products liability claim,

when evidence showed that particular pacemaker implanted in plaintiff was not defective, even though there was a high incidence of defects in that model of pacemaker).³

The Court holds that Plaintiff did not demonstrate that he personally suffered an injury in fact. Plaintiff has not provided the Court with any information from which to assess his allegedly increased risk of harm from implantation of the aortic connector. While some courts have held that an increased risk of harm is an injury in fact, a plaintiff must meet the constitutional requirement that an injury be neither “conjectural” nor “hypothetical.” In those cases in which a mere increased risk was held sufficient, the courts have reviewed medical evidence and expert testimony documenting the actual increased risk posed to the plaintiffs. See In re St. Jude Med., 2003 WL 1589527 at *11; In re Propulsid, 208 F.R.D. at 138-39. No such documentation was provided here either as to patients in general or Mr. McGuinn in particular. Indeed, Plaintiff does not even cite any rate of increased risks or complications among aortic connector recipients, nor does he point to any specific incidents of harm. Plaintiff merely alleges that use of the aortic connector “has led to severe and disabling medical conditions,” that “numerous patients” required their implanted devices to be removed, and that a “high rate of adverse event reports” were associated with use of the device.⁴

³Plaintiff cites to several cases where exposure to a toxic substance created an increased risk of harm held sufficient to confer standing, even when the plaintiffs in those cases had not yet manifested any physical injury as a result of their exposure. See Duke Power Co. v. Carolina Envtl. Study Group, Inc., 438 U.S. 59, 73-74 (1978) (nuclear radiation); Carlough v. Amchem Prod., Inc., 834 F. Supp. 1437, 1454 (E.D. Pa. 1993) (asbestos). Those cases are distinguishable, however. Exposure to a toxic substance rarely provides any medical benefits to an individual, therefore the exposure itself causes an injury to the exposed individual. Medical devices, on the other hand, can be entirely helpful to some patients while causing serious medical complications in some fraction of other patients. Therefore, mere “exposure” to the device is not equivalent to exposure to a toxin.

⁴Although the Federal Rules require only a “short and plain statement” of the grounds for jurisdiction, see Fed. R. Civ. P. 8, that statement must still sufficiently allege injury in fact.

(Compl. ¶¶ 15, 18.) As far as is documented in the complaint, Plaintiff himself has suffered no negative side-effects from the device and is instead enjoying the benefits conferred by an aortic connector. On the basis of these allegations, any injury in regard to Mr. McGuinn himself is purely hypothetical.

With merely a hypothetical injury, Plaintiff is unable to demonstrate standing. Absent standing in the named Plaintiff, there is also no standing in the proposed class and no subject matter jurisdiction in this Court. Having found that it is without jurisdiction to hear this case, the Court need not address Defendants' alternative arguments for dismissal.

III. Conclusion

Plaintiff's lack of standing deprives this Court of subject matter jurisdiction to hear this case. Accordingly, the Court **GRANTS** Defendants' motion to dismiss on the basis of Rule 12(b)(1).

IT IS SO ORDERED this ____ day of _____, 2003.

BERNICE BOUIE DONALD
UNITED STATE DISTRICT JUDGE