

**Health Law—Actual Injury From Medical Device Not Required To Confer Standing In Claim For Medical Monitoring—*Sutton v. St. Jude Medical, S.C., Inc.*, 419 F.3d 568 (6th Cir. 2005).**

Under the Supreme Court's interpretation of Article III of the United States Constitution, a plaintiff must suffer an injury-in-fact in order to obtain standing in federal court.<sup>1</sup> Recently, courts have relaxed this requirement and have awarded medical monitoring damages to plaintiffs who had not yet manifested any physical injury.<sup>2</sup> In *Sutton v. St. Jude Medical S.C., Inc.*,<sup>3</sup> the United States Court of Appeals for the Sixth Circuit considered whether the plaintiff had standing to bring a claim for medical monitoring against the manufacturer of an implanted medical device, where the plaintiff suffered no physical injury.<sup>4</sup> The court of appeals reversed the district court's decision and concluded that the potential for future injury constituted an injury-in-fact.<sup>5</sup>

St. Jude Medical, S.C., Inc., (St. Jude) produces a medical device called the Symmetry Bypass Aortic Connector (Aortic Connector).<sup>6</sup> Surgeons use this device in coronary artery bypass procedures to attach a vein graft to the aortic wall without the use of sutures.<sup>7</sup> Since doctors began using the device, over 50,000 Aortic Connectors have been implanted in patients.<sup>8</sup>

Michael Sutton initiated a class action suit against St. Jude, alleging that the Aortic Connector caused severe and disabling medical conditions in persons

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1. See U.S. CONST. art. III, § 2, cl. 1 (defining jurisdictional authority of federal courts). Article III requires a plaintiff to have standing or the federal court lacks jurisdiction to hear the case. See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (requiring injury-in-fact to establish standing under Article III); see also WILLIAM L. PROSSER, HANDBOOK ON THE LAW OF TORTS 330-33 (4th ed. 1971) (noting actual injury fundamental principle of tort law).

2. See *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir. 1990) (allowing action for medical monitoring by demonstrating increased risk of injury); *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 825-26 (D.C. Cir. 1984) (upholding medical monitoring claim without present physical injury).

3. 419 F.3d 568 (6th Cir. 2005).

4. *Id.* at 570-71 (examining whether Sutton's increased risk of injury provided standing).

5. *Id.* at 574-75 (concluding increased risk of injury meets injury-in-fact requirement).

6. *Id.* at 569 (connecting St. Jude to Aortic Connector). See also *Sutton v. St. Jude Med., Inc.*, 292 F. Supp. 2d 1005, 1006 (W.D. Tenn. 2003), *rev'd sub nom.*, 419 F.3d 568 (6th Cir. 2005) (establishing St. Jude produces Aortic Connector).

7. 419 F.3d at 569 (noting purpose and use of Aortic Connector).

8. *Sutton v. St. Jude Med., Inc.*, 292 F. Supp. 2d 1005, 1006 (W.D. Tenn. 2003), *rev'd sub nom.*, 419 F.3d 568 (6th Cir. 2005)(discussing use of Aortic Connector).

who had been implanted with the device.<sup>9</sup> Although Sutton did not suffer from any present injury, he argued that the implant increased his risk for a medical complication.<sup>10</sup> Sutton requested that the court establish a medical monitoring fund to provide notice of potential harm to all implant recipients, as well as periodic testing for recipients, education for physicians about diagnosing and treating medical problems resulting from the device, and medical treatment to remove the device from any recipients where necessary.<sup>11</sup>

The United States District Court for the Western District of Tennessee held that Sutton lacked standing and the court did not have jurisdiction because he had not suffered a present injury.<sup>12</sup> In reaching its conclusion, the court considered, but ultimately rejected, the idea that an unquantified increase in risk of future harm from a medical device constituted an injury-in-fact.<sup>13</sup> The court distinguished cases characterizing exposure to toxic substances as an injury-in-fact by noting that the risk from exposure to a toxic substance differs fundamentally from the risk of exposure to a medical device.<sup>14</sup> The court noted that while exposure to a toxic substance is inherently harmful, exposure to a medical device is not.<sup>15</sup> Ultimately, the court concluded that where Sutton had “merely a hypothetical injury” he could not demonstrate an injury-in-fact sufficient to confer standing.<sup>16</sup> The United States Court of Appeals for the Sixth Circuit reversed the lower court’s decision and held that the potential for future injury constitutes an injury-in-fact sufficient to confer standing.<sup>17</sup>

Article III of the United States Constitution requires that a plaintiff have

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9. 419 F.3d at 569 (detailing Sutton’s claims). The original plaintiff in this case was Skipper P. McGuinn, but he was substituted by Mr. Sutton before the case was decided with the stipulation that the substitution would not affect any of the issues in the case. Sutton v. St. Jude Med., Inc., 292 F. Supp. 2d at 1006 n.1 (W.D. Tenn. 2003), rev’d sub nom., 419 F.3d 568 (6th Cir. 2005). For clarity, this Comment refers to Sutton as the plaintiff throughout.

10. Sutton v. St. Jude Med., Inc., 292 F. Supp. 2d 1005, 1006 (W.D. Tenn. 2003), rev’d sub nom., 419 F.3d 568 (6th Cir. 2005) (noting plaintiff’s claim that Aortic Connector increases his risk for aortic bypass stenosis).

11. Sutton v. St. Jude Med., Inc., 292 F. Supp. 2d 1005, 1006 (W.D. Tenn. 2003), rev’d sub nom., 419 F.3d 568 (6th Cir. 2005) (discussing relief for class).

12. Sutton v. St. Jude Med., Inc., 292 F. Supp. 2d 1005, 1009 (W.D. Tenn. 2003), rev’d sub nom., 419 F.3d 568 (6th Cir. 2005) (concluding Sutton could not have standing without demonstrating injury-in-fact).

13. Sutton v. St. Jude Med., Inc., 292 F. Supp. 2d 1005, 1008-09 (W.D. Tenn. 2003), rev’d sub nom., 419 F.3d 568 (6th Cir. 2005) (rejecting unspecified increase in risk of harm as injury-in-fact sufficient to confer standing).

14. Sutton v. St. Jude Med., Inc., 292 F. Supp. 2d 1005, 1008 n.3 (W.D. Tenn. 2003), rev’d sub nom., 419 F.3d 568 (6th Cir. 2005) (basing distinction on lack of medical benefit from exposure to toxic materials).

15. Sutton v. St. Jude Med., Inc., 292 F. Supp. 2d 1005, 1008 n.3 (W.D. Tenn. 2003), rev’d sub nom., 419 F.3d 568 (6th Cir. 2005) (noting exposure to medical device not inherently harmful).

16. Sutton v. St. Jude Med., Inc., 292 F. Supp. 2d 1005, 1008 (W.D. Tenn. 2003), rev’d sub nom., 419 F.3d 568 (6th Cir. 2005) (observing past courts relied on documentation to establish increased risk as injury-in-fact).

17. 419 F.3d at 575 (holding plaintiff has standing to bring medical monitoring claim because risk of harm increased).

standing to bring a case in federal court.<sup>18</sup> Pursuant to the Supreme Court's interpretation of Article III, in order for a plaintiff to have standing, the plaintiff must have suffered an injury-in-fact, demonstrate a causal connection between the injury and the defendant's conduct, and show the likelihood that the injury will be redressed by a favorable decision.<sup>19</sup> The Supreme Court has stated that an injury-in-fact must be actual or imminent, and not merely "conjectural" or "hypothetical."<sup>20</sup>

In recent years, courts have relaxed the injury-in-fact requirement in situations where a plaintiff has suffered negligent exposure to a known toxic substance but has not yet manifested a present physical injury.<sup>21</sup> Courts have characterized the exposure to a known toxic substance as an injury-in-fact to allow for such claims.<sup>22</sup> Defining the exposure to a known toxic substance as an injury-in-fact permits a claim for medical monitoring where a plaintiff may benefit from early detection of a health risk resulting from the negligent exposure.<sup>23</sup> The Supreme Court, however, has noted in dicta that it does not

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18. U.S. CONST. art. III, § 2, cl. 1 (defining jurisdictional authority of federal courts).

19. See *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (defining requirements for standing narrowly). The Court first requires that the injury must be "concrete and particularized." *Id.* The Court also requires "a causal connection between the injury and the [defendant's actions]." *Id.* Finally, the Court requires a "favorable decision" that the remedy sought by the plaintiff would likely redress the plaintiff's injury. *Id.* Thus, a plaintiff lacks standing when it is only speculative that the remedy sought will redress the plaintiff's claimed injury. See *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 38 (1976) (requiring plaintiff to show favorable decision likely to redress injury). The Court in *Simon* stated that exercise of a federal court's power is "gratuitous" and "inconsistent" with the limitations of Art. III absent a clear showing that a remedy will effectively redress the plaintiff's injury. *Id.* The Court further noted that "unadorned speculation will not suffice to invoke the federal judicial power." *Id.* at 44.

20. *City of Los Angeles v. Lyons*, 461 U.S. 95, 101-02 (1983) (stating "[a]bstract injury" not sufficient to confer standing). In *Lyons*, the Supreme Court stated that a "plaintiff must show that he 'has sustained or is immediately in danger of sustaining some direct injury' . . . and the injury or threat of injury must be both 'real and immediate', not 'conjectural' or 'hypothetical'." *City of L.A. v. Lyons*, 461 U.S. 95, 101-102 (U.S. 1983) (quoting *Golden v. Zwickler*, 394 U.S. 103, 109-110 (1969); *Public Workers v. Mitchell*, 330 U.S. 75, 89-91 (1947)).

21. See *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 851-52 (3d Cir. 1990) (allowing medical monitoring claim where plaintiffs exposed to toxins but not presently ill); *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 819 (D.C. Cir. 1984) (upholding injunction for medical monitoring despite lack of physical injury). See generally Kathleen A. O'Nan, Note, *The Challenge of Latent Physical Effects of Toxic Substances: The Next Step in the Evolution of Toxic Torts*, 7 J. MIN. L. & POL'Y 227 (1991-92) (discussing courts evolution towards allowing toxic tort claims where plaintiff not presently injured). But see *Ball v. Joy Techs., Inc.*, 958 F.2d 36, 39 (4th Cir. 1991) (upholding requirement for present physical injury despite plaintiff's exposure to toxic substance); *Purjet v. Hess Oil V.I. Islands Corp.*, No. 1985/284, 1986 U.S. Dist. LEXIS 15677, at \*11-\*12 (D.V.I. Jan. 8, 1986) (rejecting medical monitoring, upholding requirement for evidence of present physical injury in asbestos exposure claim).

22. See *Ayers v. Township of Jackson*, 525 A.2d 287, 307 (N.J. 1987) (recognizing right of recovery from conduct causing "significantly enhanced risk of injury"). The *Ayers* court noted that allowing pre-symptom claims for medical monitoring serves the "public interest in early detection and treatment of disease." *Id.* at 311.

23. See *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir. 1990) (relaxing standing requirements where plaintiff exposed to known toxic substance but suffers no present injury). Where a plaintiff suffers a cognizable health risk related to exposure to a known toxic substance, equity disfavors preventing him from bringing a claim until the exposure-related illness physically manifests itself. See *Hansen v. Mountain*

support the creation of a new tort law cause of action for medical monitoring where a plaintiff has not manifested a present physical injury.<sup>24</sup>

Despite the Supreme Court's criticism of the validity of medical monitoring claims where the plaintiff suffers no present physical injury, a few courts have expanded the concept of an increased risk of harm as an injury-in-fact beyond the field of toxic torts.<sup>25</sup> These courts have applied the concept to claims for medical monitoring in product liability cases where the plaintiff is unable to demonstrate a present physical injury but has clearly shown an increased risk of harm.<sup>26</sup> Attempts to apply this new standard to medical devices have not

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Fuel Supply Co., 858 P.2d 970, 976 (Utah 1993) (noting injustice in forcing plaintiff to pay for medical costs caused by defendant's negligence). Allowing pre-symptom claims for medical monitoring enables early diagnosis and treatment of disease. *Id.* But see Christopher P. Guzelian, *A Quantitative Methodology for Determining the Need for Exposure-Prompted Medical Monitoring*, 79 IND. L.J. 57, 100 (2004) (noting medical monitoring inappropriate where risk from monitoring greater than perceived injury). Guzelian notes that a perceived risk may not justify medical monitoring. Guzelian, *supra*, at 100. Medical monitoring can result in significant harm and therefore requires careful use. *Id.* at 63. For example, employing "cardiac catheterization to monitor cardiac disease in patients who had previously suffered heart attacks has been suggested to actually lead to more deaths than in an unmonitored group with approximately equal coronary artery disease histories." *Id.* at 71-72. Guzelian suggests that to justify medical monitoring "(i) one must know the prevalence of unrecognized disease prior to testing and (ii) that prevalence must be sufficiently high to merit testing." *Id.* at 85-86. Ultimately, Guzelian argues that courts should reject medical monitoring claims where the level of increased risk from a claimed injury falls below the level of risk posed by the act of medical monitoring. *Id.* at 100; see also George W.C. McCarter, *Medical Sue-veillance: A History And Critique of the Medical Monitoring Remedy in Toxic Tort Litigation*, 45 RUTGERS L. REV. 227, 273-80 (1993) (noting inherent risks posed by medical testing).

24. See *Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 427 (1997) (denying medical monitoring claim where plaintiff suffers no present injury). Although *Metro-North* only applied to the Federal Employees Liability Act (FELA), the Supreme Court discussed its skepticism of medical monitoring claims involving plaintiffs suffering no present physical injury. *Id.* at 442. The Court further stated that it disfavors the creation of a new tort cause of action for medical monitoring. *Id.* at 443. Specifically, the Supreme Court noted that where millions of individuals may have suffered some level of exposure to a toxic substance that might justify some level of monitoring, "that fact, along with uncertainty as to the amount of liability, could threaten . . . a 'flood' of less important cases (potentially absorbing resources better left available to those more seriously harmed . . .)." *Id.* at 442; see also *Ball v. Joy Techs, Inc.*, 958 F.2d 36, 39 (4th Cir. 1991) (declaring legislature should decide whether plaintiffs with no physical injury may bring medical monitoring claims); Richard W. Bourne, *Medical Monitoring Without Physical Injury: The Least Justice Can Do for Those Industry Has Terrorized With Poisonous Products*, 58 SMU L. REV. 251, 258-61 (2005) (discussing arguments against medical monitoring claims where plaintiff suffers no present injury); Victor E. Schwartz ET AL., *Medical Monitoring-Should Tort Law Say Yes?*, 34 WAKE FOREST L. REV. 1057, 1059 (1999) (noting public policy concerns over medical monitoring suggest legislature should resolve issue). See generally, Matthew D. Hamrick, Comment, *Theories of Injury and Recovery for Post-Exposure, Pre-Symptom Plaintiffs: The Supreme Court Takes a Critical Look*, 29 CUMB. L. REV. 461 (1998-99) (discussing *Metro-North*, issues involved in allowing pre-symptom plaintiffs to seek medical monitoring damages).

25. See, e.g., *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 825-26 (D.C. Cir. 1984) (upholding injunction for medical tests on infant orphans potentially harmed in plane crash); *In re St. Jude Medical, Inc.*, MDL No. 01-1396 (JRT/FLN), 2003 U.S. Dist. LEXIS 5188, at \*37-\*39 (D. Minn. Mar. 27, 2003) (defining increase in potential harm from implanted heart valve device as injury-in-fact); *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 139 (E.D. La. 2002) (describing increased risk for heart disease as injury-in-fact).

26. See *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 825-26 (D.C. Cir. 1984) (finding increased risk of harm as injury-in-fact in exposure to decompression). In *Friends for All Children*, a

always been successful.<sup>27</sup> Whether an allegation of an increased risk of harm from an implanted medical device is sufficient to confer standing in a claim for medical monitoring damages was a question of first impression for the Sixth Circuit.<sup>28</sup>

In *Sutton v. St. Jude Medical, S.C., Inc.*, the United States Court of Appeals for the Sixth Circuit held that a claim of an increased risk of harm from an implanted medical device was sufficient to confer standing in a suit for medical monitoring.<sup>29</sup> To reach this conclusion, the court determined that although fundamental differences exist between exposure to toxic substances and exposure to medical devices, these differences are immaterial for determining standing.<sup>30</sup> The court noted that an embedded medical device might create an increased risk of future harm as severe as an exposure to a toxic substance.<sup>31</sup> The court further stated that requiring a “plaintiff to suffer physical injury before allowing any redress whatsoever is both overly harsh and economically inefficient.”<sup>32</sup> Ultimately, the court concluded that it would not prohibit a

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defective aircraft design caused cabin decompression at high altitude, resulting in oxygen deprivation to a number of newborn infants. *Id.* at 819. The plaintiffs sought damages to cover initial medical tests to discover if any of the infants had suffered neurological damage as a result of the oxygen deprivation. *Id.* at 825-26. The court awarded injunctive relief requiring Lockheed to pay for the requisite medical tests. *Id.* at 838; *see also In re St. Jude Medical, Inc.*, MDL No. 01-1396 (JRT/FLN), 2003 U.S. Dist. LEXIS 5188, at \*37-\*38 (D. Minn. Mar. 27, 2003) (finding injury-in-fact where device caused substantial increase in risk of harm). The court granted standing to a plaintiff who presented evidence that the medical device at issue created a 2% chance for a paravalvular leak as compared to a 0.25% chance with a conventional valve. *In re St. Jude Medical, Inc.*, MDL No. 01-1396 (JRT/FLN), 2003 U.S. Dist. LEXIS 5188, at \*4 (D. Minn. Mar. 27, 2003); *see also In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 139 (E.D. La. 2002) (finding injury-in-fact in exposure to pharmaceutical drugs). In *In re Propulsid Prods. Liab. Litig.*, exposure to a medication had harmful effects that extended beyond the period during which a person took the drug. *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 138 (E.D. La. 2002). The court denied class certification and in dicta expressed concern about whether the judiciary was the proper forum for determining whether medical monitoring is appropriate. *Id.* at 147 (noting FDA had not recommended medical monitoring for persons who had used Propulsid). Subsequent to *In re Propulsid*, the Louisiana Legislature amended a statute on damages to require physical injury in medical monitoring claims. *See Motorola, Inc. v. Associated Indem. Corp.*, 878 So. 2d 824, 833 (La. Ct. App. 2004) (noting 1999 statute revision adding physical injury requirement for medical monitoring damages). The statute limits liability damages and only permits damages for future medical monitoring if the costs are directly related to a manifest physical injury. *See LA. CIV. CODE ANN.* art. 2315 (West 2005).

27. *See Taylor v. Medtronic, Inc.*, 861 F.2d 980, 988 (6th Cir. 1988) (explaining no injury-in-fact where plaintiff's pace-maker device not malfunctioning); *Martin v. Am. Med. Sys. Inc.*, No. IP 94-2067-C H/G, 1995 U.S. Dist. LEXIS 22169, at \*19-\*21 (S.D. Ind. Oct. 25, 1995) (noting no injury-in fact where plaintiffs' particular penile implants functioning).

28. *See 6th Circuit Reverses Denial of Medmon Case Involving St. Jude Heart Bypass Device*, 5-13 MEALEY'S LITIG. REP.: CLASS ACTIONS 2 (Sept. 1, 2005) (noting medical monitoring for medical device constituted issue of first impression for Sixth Circuit).

29. 419 F.3d at 575-76 (holding asymptomatic plaintiffs have standing to bring medical monitoring claims against medical device manufacturers).

30. *Id.* at 571 (stating difference between embedded medical device and toxic substances inconsequential).

31. *Id.* at 572 (noting embedded medical device can pose as serious threat as exposure to toxic substance). The court concluded that suffering continuous exposure to an embedded medical device may be more dangerous than a one-time exposure to a known toxic substance. *Id.*

32. *Id.* at 575 (discussing importance of “disease prevention, as opposed to disease treatment”). The court

plaintiff implanted with a medical device but suffering no present physical injury from bringing suit under the theory of an increased risk of future harm.<sup>33</sup>

To support its conclusion, the court noted that although the Supreme Court ultimately rejected a claim for medical monitoring where a plaintiff suffered no present physical injury, the fact that the Court heard the case suggests that at the least such a plaintiff had standing.<sup>34</sup> Having established standing, the court then determined that the plaintiff did not have to provide any specific evidence of the alleged risk of future harm in responding to a motion to dismiss, reasoning that such a requirement would constitute a premature evaluation of the merits of a plaintiff's claim.<sup>35</sup> Finally, the court concluded that the plaintiff satisfied all of the requirements necessary to obtain standing because the plaintiff's alleged increased risk of future harm was traceable to the defendant's medical device, and medical monitoring would help remedy the situation.<sup>36</sup>

In *Sutton v. St. Jude Medical, S.C., Inc.*, the United States Court of Appeals for the Sixth Circuit applied the concept of an increased risk of harm as an injury-in-fact to implanted medical devices.<sup>37</sup> The court determined that in a claim for medical monitoring against a medical device manufacturer, a plaintiff does not need to specify any level of increased harm in order to obtain standing.<sup>38</sup> In reaching this conclusion, the court failed to acknowledge that one purpose of the injury-in-fact requirement is to prevent speculative litigation over hypothetical injuries.<sup>39</sup> As a result, the court's holding unreasonably increases the liability of medical device manufacturers, because now virtually any person who has an implanted medical device has standing to bring a claim for medical monitoring, regardless of whether there is a quantifiable level of increased future harm.<sup>40</sup>

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suggested that requiring a clear showing of an increased risk of harm in order to obtain standing is economically inefficient because it may result in a later, more costly redress of any resulting harm. *Id.*

33. 419 F.3d at 574-75 (refusing to prohibit claims of increased risk of harm from medical devices).

34. *Id.* at 573 (discussing Supreme Court's handling of similar case suggests existence of standing).

35. *Id.* at 571 (holding plaintiff not required to specify increased risk in motion to dismiss). The court noted that, although in *In re St. Jude Medical* a plaintiff seeking medical monitoring damages who suffered no present physical injury demonstrated a 700% increase in risk of harm from an implanted heart valve device, this was not a requirement for standing. *Id.* at 575. The court dismissed the notion that a plaintiff must provide evidence of an increased risk of harm and maintained that a plaintiff should not have to make such a clear showing of an increased risk of harm in order to obtain standing. *Id.*

36. 419 F.3d at 575 (holding plaintiff satisfied standing requirements).

37. *Id.* (applying theory of increased risk of harm as injury-in-fact to medical devices).

38. *Id.* (holding plaintiff need not specify any level of increased risk of harm).

39. See Bourne, *supra* note 24 at 260-61 (discussing arguments against medical monitoring claims where plaintiff suffers no present injury). Bourne states that requiring a present injury prevents "speculative and wasteful litigation where injuries are uncertain to ever occur." *Id.* at 261. Bourne further states that the injury-in-fact requirement protects a defendant's resources for use by more deserving plaintiffs who seek compensation for actualized, rather than hypothesized, injuries. *Id.*

40. See *Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 442 (1997) (noting "systemic harms that can accompany unlimited and unpredictable liability"). In declining to grant medical monitoring damages to an individual who suffered no present physical injury but alleged an increased risk of harm from exposure to asbestos, the Supreme Court noted that awarding medical monitoring damages in the case might lead to a

In its conclusion, the court failed to analyze whether the remedy sought by the plaintiff is likely to redress the alleged injury-in-fact.<sup>41</sup> Medical studies have shown that where an increased risk of harm falls below a certain level, medical monitoring becomes inappropriate and actually may cause more harm than good.<sup>42</sup> By not requiring the plaintiff to specify the increased risk of harm and by not analyzing whether medical monitoring is an appropriate remedy, the court failed to establish whether medical monitoring would redress the plaintiff's injury sufficient to confer standing.<sup>43</sup>

Courts initially relaxed the injury-in-fact requirement for standing to address situations where a plaintiff suffered negligent exposure to a known toxic substance but had not yet manifested any physical illness.<sup>44</sup> An entirely different question for determining whether courts should relax requirements for standing is presented, however, where a plaintiff consents to implantation of a medical device in order to avert a health risk and enjoys the benefits of that device without suffering any present physical injury.<sup>45</sup> Allowing plaintiffs to bring medical monitoring claims against medical device manufacturers when they are unable to specify an increase in their future risk of harm unjustifiably increases the liability of medical device manufacturers.<sup>46</sup> Due to this increased liability, the legislature, not the courts, should decide whether such plaintiffs have standing to bring medical monitoring claims.<sup>47</sup>

In *Sutton v. St. Jude Medical, S.C., Inc.*, the United States Court of Appeals for the Sixth Circuit considered whether a plaintiff had standing to bring a medical monitoring claim against the manufacturer of an implanted medical device where the plaintiff suffered no present physical injury. In determining that the plaintiff had standing, the court allows plaintiffs to bring medical monitoring claims against medical device manufacturers regardless of whether they suffer any present physical injury or quantifiable increase in risk of future harm. Ultimately, the decision in *Sutton* unreasonably reduces the standing

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significant increase in litigation. *Id.* The Court further noted that expending limited resources on medical monitoring for presently healthy individuals might come at the expense of later individuals with more severe injuries. *Id.*

41. See 419 F.3d at 575 (stating all three requirements for standing satisfied). The court's analysis of the third requirement for standing concluded that "medical monitoring will undoubtedly help to remedy the situation." *Id.*

42. See Guzelian, *supra* note 23, at 74 (discussing appropriateness of medical monitoring where plaintiff suffers no present injury); see also McCarter, *supra* note 23, at 273-80 (noting inherent risks in medical testing).

43. See 419 F.3d at 575 (finding of standing without analyzing appropriateness of medical monitoring).

44. See *supra* note 23 (discussing purpose for allowing medical monitoring claims).

45. See *supra* note 23 and accompanying text (discussing reasoning for allowing medical monitoring claims in incidences of negligent exposure to toxic substances).

46. See *supra* note 24 and accompanying text (discussing risks of allowing asymptomatic plaintiffs to bring medical monitoring claims).

47. See *Ball v. Joy Techs., Inc.*, 958 F.2d 36, 39 (4th Cir. 1991) (stating legislature should decide whether plaintiffs with no present injury may bring medical monitoring claims); see also Schwartz, *supra* note 24, at 1059 (noting public policy concerns warrant resolution by legislature not courts).

requirements under Article III and threatens to flood the courts and medical device manufacturers with medical monitoring claims based primarily on a plaintiff's fear of harm rather than on an ascertainable risk of future injury.

*Jeffrey C. Clausen*