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JAMES BONINI
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In the
United States District Court
for the
Southern District of Ohio

2005 JUL 19 P 4:40

U.S. DISTRICT COURT
SOUTHERN DIST. OHIO
EAST PYL. COLUMBUS

Beverly and Earl Douglas
50130 West Rustic Drive
Apartment 2
St. Clairsville, Ohio 43950

Plaintiffs,

vs.

Guidant Corporation
111 Monument Circle, #2900
Indianapolis, Indiana 46204

and

Guidant Sales Corporation.
CT Corporation System
1300 East 9th Street
Cleveland, Ohio 44114

Defendants.

Case No. **C 2 05 703**

Judge: **JUDGE SARGUS**

MAGISTRATE JUDGE KING

Complaint

I. Parties

1. Defendant Guidant Corporation is a publicly traded corporation and has its principal place of business in Indianapolis, Indiana. Guidant Corporation designs, manufactures, and markets the products that are at issue in this Complaint.
2. Defendant Guidant Sales Corporation is a wholly owned subsidiary of Defendant Guidant Corporation and has its principal place of business in Indianapolis, Indiana. Guidant Sales Corporation markets, distributes, and sells products that are at issue in this Complaint.
3. Plaintiff Beverly Douglas lives in St. Clairsville, Ohio, and has a Guidant Ventak Prizm 2DR, Model 1861, which was implanted in December, 2001. Earl Douglas is her husband.

II. Jurisdiction and Venue

4. Defendant does business in the state of Ohio and committed a tort in Ohio and hence is subject to the jurisdiction of this Court.
5. This Court has jurisdiction by virtue of complete diversity pursuant to 28 U.S.C. § 1332, and by virtue of the fact that the amount in controversy exceeds \$75,000.
6. Venue is appropriate in this federal district because plaintiff resides here.

III. General Allegations

7. Defendant designed, tested, manufactured, and provided labeling for implantable cardioverter defibrillators (ICD), including the PRIZM 2DR, Model 1861.
8. These devices are surgically implanted in persons who have a type of heart disease that creates the risk of a life-threatening heart arrhythmia (abnormal rhythm).
9. Plaintiff had one of these devices placed in her chest, and had it removed because the device was defective.
10. The ICD devices were sold to hospitals and physicians for implantation in patients to shock or pace the heart into normal rhythm if the user suffers a rapid, life-threatening heart rhythm disturbance. The CRT-D device provides electrical pulses to the heart in the event of heart failure.
11. The VENTAK PRIZM 2DR, Model 1861, manufactured on or before April 16, 2002, was recalled on June 17, 2005, by defendant. These devices can develop an internal short circuit when attempting to deliver an electrical shock to the heart, preventing the treatment of abnormal heart rhythms. The problem is caused by deterioration of electrical insulation in the device and is only detected after the device has already malfunctioned.
12. The device does not give any sign of impending failure. There is no test that could have predicted whether plaintiff Beverly Douglas' device would fail.
13. On information and belief, Guidant's decision to notify doctors and patients of the reported problems and failure of certain Guidant devices was the direct result of the imminent publication of news of such failures in a medical journal and in an article in the May 24, 2005, edition of the *New York Times*, of which the company had advance knowledge.
14. On information and belief, at no time prior to May 23, 2005, did Guidant notify any doctors or patients about the reported problems and failures of various Guidant devices, its findings regarding the Ventak Prizm ICDs, or its alteration in the

manufacturing process for the Ventak Prizm ICDs. Plaintiff had no knowledge or reason to acquire such knowledge prior to May 23, 2005.

15. Plaintiffs did not and could not have discovered the defects until on or after May 23, 2005.
16. Defendant's concealment of known defects from the FDA and from the Plaintiff constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

IV. Causes of Action

A. Negligence

17. Plaintiffs restate the preceding paragraphs as if fully restated herein.
18. Defendant carelessly designed, tested, manufactured, marketed, distributed and sold the VENTAK PRIZM 2DR, Model 1861.
19. Defendant was negligent in manufacturing Ventak Prizm defibrillators because:
 - a. the manufacturing processes for the defibrillators and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices;
 - b. the failure of the manufacturing processes for the defibrillators and certain of their components to satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects, and
 - c. the defendant failed to warn of the unreasonable risks created by these manufacturing defects.
20. Although the Food and Drug Administration's Pre-Marketing Approval process imposed requirements on the defendants in connection with the manufacture and marketing of Ventak Prizm defibrillators, it did not impose specific health or safety requirements on the device itself.
21. Defendant concealed the defects from the FDA, from physicians, and from the patients who were to receive the devices.
22. Replacement of the defective devices required surgery on the plaintiff.
23. As a direct and proximate result of the aforementioned negligence of defendant, Plaintiffs suffered personal injuries and harm, including medical expenses, lost wages, loss of consortium and needless pain and suffering.

24. Defendant's conduct was willful, wanton, malicious, reckless, and lacked all regard for the health and welfare of the plaintiffs.

B. Strict Liability

25. Plaintiffs restate the preceding paragraphs as if fully restated herein.
26. Defendant designed, tested, manufactured, marketed, distributed and sold the listed devices in a condition which rendered them unreasonably dangerous due to their propensity to fail without warning.
27. Ventak Prizm defibrillators manufactured by Guidant prior to November 2002 were unreasonably dangerous, because:
 - a. the manufacturing processes for the defibrillators and certain of their components did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices;
 - b. the failure of the manufacturing processes for the defibrillators and certain of their components to satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices resulted in unreasonably dangerous manufacturing defects, and
 - c. the defendant failed to warn of the unreasonable risks created by these manufacturing defects.
28. Although the Food and Drug Administration's Pre-Marketing Approval process imposed requirements on the defendants in connection with the manufacture and marketing of Ventak Prizm defibrillators, it did not impose specific health or safety requirements on the device itself.
29. The defects existed when defendant placed these devices into the stream of commerce.
30. Plaintiffs injuries were a proximate result of one of more of the defects.
31. As a direct and proximate result of the aforementioned liability of defendant, Plaintiffs suffered personal injuries and harm, including medical expenses, lost wages, loss of consortium and needless pain and suffering.

C. Breach of Express and Implied Warranties

32. Plaintiffs restate the preceding paragraphs as if fully restated herein.

33. Defendants' public statements about the implantable defibrillators contained express claims amounting to a warranty that the devices were safe and effective.
34. Defendants impliedly warranted that its implantable defibrillators were merchantable, fit and safe for ordinary use and for a particular purpose.
35. Defendants breached all warranties by selling their implantable defibrillators which were defective and unsafe.
36. As a direct and proximate result of defendants' breach of express and implied warranties, plaintiffs suffered personal injuries and harm, including medical expenses, lost wages, loss of consortium and needless pain and suffering.

Relief Requested

37. judgment that defendant is liable to plaintiffs;
38. payment and/or reimbursement of all costs related to diagnostic testing, monitoring and treatment incurred as a result of a patient's receipt of the defective implantable defibrillator;
39. payment for derivative claimants for loss of consortium, loss of companionship, economic loss and other harm;
40. payment and/or reimbursement of all costs related to plaintiff's removal surgery and replacement of the defective defibrillators;
41. punitive damages;
42. refund to plaintiffs for the cost of the initial defective defibrillator;



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JURY DEMAND

Plaintiffs request a jury as to all issues triable to a jury.



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