

COMMONWEALTH OF MASSACHUSETTS

BRISTOL, ss.

SUPERIOR COURT

NO. 06-208

DAVID BROWN

Plaintiff,

v.

DePUY SPINE, INC., a Massachusetts
Corporation,

Defendant.

**AMENDED COMPLAINT AND
JURY DEMAND**

I. INTRODUCTION

1. Plaintiff David Brown (“Plaintiff”) bring this action against DePuy Spine, Inc. (“Defendant” or “DePuy”) seeking damages and other relief by reason of DePuy’s wrongful activities concerning a CHARITÉ artificial disc implanted into Plaintiff David Brown. The devastating consequences of DePuy’s unlawful activities regarding the safety and use of the Charité disc resulted in serious personal injury to and substantial and unnecessary economic burdens placed upon Plaintiff. This action seeks to address the physical and economic harm suffered by Plaintiff and alleges Defendant’s product is defective and that Defendant thereby was negligent and in breach of express and implied warranties.

II. PARTIES

2. Plaintiff David Brown is a resident of the State of Colorado. On or about June 16, 2005, Dr. James Bee implanted a Charité disc in Plaintiff at the Penrose Community Hospital in Colorado Springs, Colorado.

3. Defendant DePuy Spine, Inc. (“DePuy”) is a Massachusetts corporation with its principal place of business located in Raynham, Bristol County, Massachusetts. DePuy is an operating company of DePuy, Inc., a Johnson & Johnson Company, and bills itself as “one of the world’s leading designers, manufacturers and suppliers of orthopaedic devices and supplies.... known throughout the medical world for the development, manufacture, and marketing of

innovative solutions for a wide range of spinal pathologies.” DePuy manufacturers and markets CHARITÉ artificial discs.

III. FACTS

4. This case involves an artificial spinal disc researched, developed, manufactured, marketed, promoted, advertised and sold by Defendant and implanted into Plaintiff David Brown. The defective Charité disc was deployed for surgical implantation in certain patients, like Plaintiff David Brown, with lumbar degenerative disc disease.

5. The spinal column consists of 33 vertebrae that protect the spinal cord and provide stability to the torso. Between each vertebrae is a fibrous bundle of tissue called an intervertebral disc that acts as a cushion to the spinal column by absorbing shock and pressure associated with movement. Over time, the inner, spongier portion of the intervertebral disc may degenerate, reducing its ability to properly absorb the impact associated with spinal movements, leading to back pain. Similarly, excessive pressure, strain, or injury to the rigid portion of the intervertebral disc can cause the disc to tear or bulge, bringing the adjacent vertebrae closer to one another and possibly causing impingement and compression of a spinal nerve root, along with accompanying pain or numbness. Both forms of degeneration – deterioration of the inner portion and tearing or bulging of the rigid portion of the disc – are referred to as degenerative disc disease or DDD.

6. The Charité disc implanted into Plaintiff David Brown is an artificial intervertebral disc composed of metal and plastic and was designed to be implanted in certain patients to replace a diseased or damaged intervertebral disc during a surgical procedure called spinal arthroplasty.

7. The Charité disc was originally developed in Berlin, Germany by professors at the Charité University Hospital in the 1980s.

8. In 2003, DePuy acquired the Link Spine Group, Inc. and the exclusive worldwide rights to Charité discs.

9. Charité discs are classified as medical devices. In order to market and sell Charité discs in the United States, Defendant required the approval of the Food and Drug Administration (“FDA”) pursuant to the Medical Device Amendments, 21 U.S.C. §§360c *et seq.*, to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301 *et seq.*

10. In its efforts to gain approval of the device, Defendant submitted to the FDA an application for Premarket Approval (“PMA”). PMA applications and post-approval requirements are governed by mandatory federal regulations, directing, for example, what information must be submitted to the FDA for review during and following the approval process. 21 CFR 814 *et seq.*; 21 CFR 803 *et seq.*

11. In February 2004, Defendant filed its PMA application for Charité discs.

12. The FDA approved the sale of Charité discs in October 2004, based upon information supplied by Defendant and subject to certain post-approval reporting requirements

13. These requirements include, for example, compliance with performance specifications and criteria established by Defendant and approved by the FDA.

14. The FDA’s October 26, 2004 notice of approval to Defendant states “Failure to comply with the conditions of approval invalidates this approval order.”

15. In late 2004, Defendant began selling Charité discs in the United States for use in patients with DDD at one level in the lumbar spine (L4-S1) and who have had no relief from low back pain after at least six months of non-surgical treatment.

16. On or about June 16, 2005, the device was implanted in the Plaintiff by Dr. James Bee at the Penrose Community Hospital in Colorado Springs, Colorado.

17. Following the implantation, Plaintiff continued suffering severe and debilitating back and leg pain, problems walking, and numbness in the legs. Plaintiff’s problems have not abated since the implantation and instead have affected Mr. Brown’s ability both to work and to take care of his young child. Plaintiff currently utilizes time release in an attempt to manage his pain.

18. Plaintiff has incurred substantial pain and suffering, disability, and medical expenses, lost wages and earnings and has been unable to lead a normal life since the implantation.

19. At all times relevant to this action, Defendant knew, and/or had reason to know, that the Charité disc implanted into Plaintiff David Brown was neither safe nor effective.

20. As a result of its defective design and manufacture, the Charité disc implanted into Plaintiff David Brown caused serious physical trauma. Defendant knew, and/or had reason to know, of this tendency and the resulting risk of injury and, by failing to disclose the information, prevented Plaintiff and his physician from making an informed decision about the implantation of the device.

21. Defendant's device failed to perform as warranted and violated the conditions of its approval by the FDA. Plaintiff seeks to enforce the requirements of the FDA approval of the device as well as warranties provided by Defendant to Plaintiff.

IV. FIRST CLAIM FOR RELIEF: BREACH OF WARRANTY (PRODUCTS LIABILITY)

22. Plaintiff reincorporates by reference all preceding paragraphs as if fully set forth herein.

23. Defendant manufactured and sold the device that was implanted in Plaintiff David Brown.

24. Plaintiff was a person whom Defendant might reasonably have expected to use or be affected by the device in a manner that Defendant intended or reasonably could have foreseen.

25. The defective condition of the device rendered the device unreasonably dangerous at the time the device left the hands of Defendant such that the device was not reasonably suitable for the ordinary uses for which the device was sold.

26. As a direct and proximate result of the defective condition of the device which existed at the time of the sale of the device, Plaintiff was caused to incur substantial pain and

suffering, disability, loss of a normal life, loss of wages and earnings, and substantial medical expenses.

27. **WHEREFORE**, Plaintiff prays that judgment be entered in favor of the Plaintiff and against the Defendant for an amount in excess of the minimum jurisdictional amount of this Court and for such other and further relief as the Court deems just and appropriate.

V. SECOND CLAIM FOR RELIEF: NEGLIGENCE (PRODUCTS LIABILITY)

28. Plaintiff reincorporates by reference all preceding paragraphs as if fully set forth herein.

29. At all times material herein, Defendant had a duty to Plaintiff to comply with FDA standards and regulations, use reasonable care in the design, manufacture and testing of its device, provide a safe product in design and manufacture, and warn Plaintiff of a defect at the earliest possible date.

30. Defendant breached its duty of reasonable care to Plaintiff by violating FDA requirements, standards and regulations and incorporating a defect into the design of the device implanted into Plaintiff David Brown.

31. Defendant breached its duty of reasonable care by manufacturing and assembling the device in such a manner that it was prone to fail to operate as advertised and warranted, thereby exposing Plaintiff to injury.

32. Defendant breached its duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances and through the manufacture and sale of the device which was in a defective condition as alleged in the common allegations.

33. As a direct and proximate result of the Defendant's negligent acts and/or omissions in the manufacture and sale of the device, Plaintiff was caused to incur substantial pain and suffering, disability, loss of a normal life, loss of wages and earnings, and substantial medical expenses.

34. **WHEREFORE**, Plaintiff prays that judgment be entered in favor of the Plaintiff and against the Defendant for an amount in excess of the minimum jurisdictional amount of this Court and for such other and further relief as the Court deems just and appropriate.

VI. THIRD CLAIM FOR RELIEF: BREACH OF EXPRESS WARRANTY

35. Plaintiff reincorporates by reference all preceding paragraphs as if fully set forth herein.

36. Defendant expressly warranted to Plaintiff by and through Defendant or its authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, medical patients, and the general public, that the device is safe, effective, fit, and proper for its intended use.

37. Prior to surgical implantation of the device, Defendant provides, either directly or through others, certain documentation to the patient, including the Plaintiff herein, whereby DePuy expressly warrants: "The CHARITÉ™ Artificial Disc has a clinical history spanning 17 years. Its safety, efficacy, and remarkable durability have been proven through thousands of implants worldwide." DePuy also warrants that for patients utilizing a Charité disc "natural motion is back."

38. Defendant has breached its express warranty in one or more of the following respects:

- a. The safety of the device was not proven and, rather, the device was unsafe;
- b. The efficacy of the device was not proven and, rather, the device was not efficacious;
- c. The durability of the device was not proven and, rather, the device was not sufficiently durable; and
- d. The device does not restore natural motion.

39. As a direct and proximate result of the breach of express warranties as aforesaid the device was surgically implanted in the Plaintiff, and Plaintiff was caused to incur substantial pain and suffering, disability, loss of a normal life, loss of wages and earnings, and substantial medical expenses.

40. **WHEREFORE**, Plaintiff prays that judgment be entered in favor of the Plaintiff and against the Defendant for an amount in excess of the minimum jurisdictional amount of this Court and for such other and further relief as the Court deems just and appropriate.

VII. DEMAND FOR RELIEF

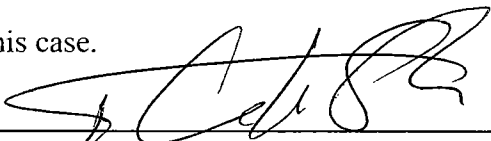
Wherefore, Plaintiff prays for judgment against Defendant as follows:

- a. On Plaintiffs' Breach of Warranty (Products Liability) Claim, judgment be entered in favor of the Plaintiff and against the Defendant for an amount in excess of the minimum jurisdictional amount of this Court and for such other and further relief as the Court deems just and appropriate;
- b. On Plaintiffs' Negligence (Products Liability) Claim, judgment be entered in favor of the Plaintiff and against the Defendant for an amount in excess of the minimum jurisdictional amount of this Court and for such other and further relief as the Court deems just and appropriate; and
- c. On Plaintiffs' Breach of Express Warranty Claim, judgment be entered in favor of the Plaintiff and against the Defendant for an amount in excess of the minimum jurisdictional amount of this Court and for such other and further relief as the Court deems just and appropriate.

VIII. DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in this case.

Dated: October 27, 2006



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