


STATE OF NORTH CAROLINA IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION
WAKE COUNTY

FILED

2019 JAN 22 P 12:46 19CVS _____

STATE OF NORTH CAROLINA *ex rel.*
JOSHUA H. STEIN,
ATTORNEY GENERAL,

WAKE CO., C.S.C.
BY 

Plaintiff,

v.

MEDICAL DEVICE BUSINESS
SERVICES, INC. F/K/A DEPUY INC.,
DEPUY ORTHOPEDICS, INC., AND
DEPUY ORTHOPAEDICS, INC.;
DEPUY PRODUCTS, INC.; DEPUY
SYNTHESES, INC.; DEPUY SYNTHESES
SALES, INC. & JOHNSON & JOHNSON,

Defendants.

COMPLAINT

INTRODUCTION

Plaintiff State of North Carolina, by and through its Attorney General, brings this action against Defendants MEDICAL DEVICE BUSINESS SERVICES, INC. F/K/A DEPUY INC., DEPUY ORTHOPEDICS, INC., and DEPUY ORTHOPAEDICS, INC.; DEPUY PRODUCTS, INC.; DEPUY SYNTHESES, INC.; DEPUY SYNTHESES SALES, INC. (hereinafter collectively referred to as "DePuy"), and JOHNSON & JOHNSON, pursuant to North Carolina's Unfair and Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, *et seq.* Plaintiff seeks a permanent injunction, statutory civil penalties, costs, and other appropriate relief.

PLAINTIFF COMPLAINS OF DEFENDANTS AND ALLEGES AND SAYS AS FOLLOWS:

PARTIES

1. Plaintiff is the State of North Carolina acting on relation of its Attorney General, Joshua H. Stein, who brings this action pursuant to authority found in Chapters 75 and 114 of the North Carolina General Statutes.

2. Defendant Johnson & Johnson is a New Jersey company and its principal place of business and executive offices are located at One Johnson & Johnson Plaza, New Brunswick, NJ, 08933.

3. Defendant Medical Device Business Services Inc., formerly known as DePuy Inc., DePuy Orthopedics, Inc., and DePuy Orthopaedics, Inc., is an Indiana company and its principal place of business and executive offices are located at 700 Orthopaedic Drive, Warsaw, Indiana 46582.

4. Defendant DePuy Products, Inc. is an Indiana company and its principal place of business and executive offices are located at 700 Orthopaedic Drive, Warsaw, Indiana 46582.

5. Defendant DePuy Synthes, Inc., is a Delaware company and its principal place of business and executive offices are located at 700 Orthopaedic Drive, Warsaw, Indiana 46582.

6. Defendant DePuy Synthes Sales, Inc., is a Massachusetts company, with executive offices located at 325 Paramount Drive, Raynham, Massachusetts 02767.

7. DePuy transacts business in North Carolina and nationwide by manufacturing, marketing, promoting, advertising, offering for sale, and selling prosthetic hip implant devices.

COMMERCE

8. DePuy was at all times relative hereto, engaged in trade or commerce in the State of North Carolina as defined in North Carolina's Unfair and Deceptive Trade Practices Act, N.C.G.S. §§ 75-1.1, *et seq.*

DEPUY'S CONDUCT

9. The hip is a ball and socket joint with the head of the femur (ball) fitting into the acetabulum (hip socket) of the pelvis. DePuy marketed metal-on-metal hip devices, including the ASR XL and Pinnacle Ultamet. Beginning in 2005, DePuy marketed its ASR XL as a device that would be appropriate for relatively younger more active patients.

10. As early as 2007, DePuy was aware that it was necessary to implant the ASR XL at a precise acute angle but that it was difficult for orthopedic surgeons to implant the devices at such a precise angle consistently. Because the ASR XL had a comparatively large femoral head, it was especially important to implant the cup at an angle of less than 45 degrees to avoid excessive wear. Beginning in 2006, DePuy received complaints that the ASR cups, which were implanted into the acetabulum of the pelvis, became loose resulting in premature failure.

11. Even though DePuy was aware that its implants became loose, DePuy continued to market the device as having stability and advanced fixation, citing survivorship of 99.2% at three years in its "Never Stop Moving" marketing campaign. In 2009, DePuy learned that the National Joint Registry of England and Wales reported a 7% revision rate at three years, but the company continued to market the ASR XL using its "Advanced Stability and Low Wear" message. As the ASR XL failed, consumers

required new implantations and experienced persistent groin pain, allergy, and tissue necrosis. On revision, surgeons found metal debris in the surrounding tissue and some patients experienced increased levels of metal ions in their blood following implantation with the ASR XL.

12. In August 2010, DePuy voluntarily recalled the ASR XL because of the number of patients requiring revision surgery.

13. The Pinnacle implant system is a hip implantation system that permitted the surgeon to choose to implant a ceramic, polyethylene, or metal cup liner to interface with the metal femoral head of the metal taper implanted in the femur. Pinnacle Ultamet was the metal cup liner device that DePuy marketed to provide a metal-on-metal hip implant using the Pinnacle platform. Beginning in 2007, DePuy advertised that its Pinnacle Ultamet hip implant device had 99.8% survivorship at five years based on a 2007 study that DePuy designed. DePuy continued to promote its devices as having 99.8% and 99.9% survivorship at five years, even though the National Joint Registry of England and Wales reported a 2.2% 3-year-revision rate in 2009 increasing to a 4.28% 5-year-revision rate in 2012.

14. DePuy ceased marketing and selling the Pinnacle Ultamet in 2013.

VIOLATIONS OF LAW - COUNT I

15. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 14.

16. DePuy, in the course of marketing, promoting, selling, and distributing its metal-on-metal hip implants, has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful

under N.C.G.S. § 75-1.1, including but not limited to representing that goods or services had sponsorship, approval, characteristics, benefits, or qualities that they did not have. DePuy violated N.C.G.S. § 75-1.1 when they misrepresented the sponsorship, approval, characteristics, benefits or qualities of their metal-on-metal hip implant devices.

VIOLATIONS OF LAW - COUNT II

17. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 16.

18. DePuy, in the course of marketing, promoting, selling, and distributing its metal-on-metal hip implants, has engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under N.C.G.S. § 75-1.1, including but not limited to misrepresenting the failure rate of ASR XI and Pinnacle Ultamet metal-on-metal hip implant devices.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

A. That this Court issue a permanent injunction, pursuant to N.C.G.S. § 75-1.1, enjoining and restraining Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in false, misleading, or deceptive practices in the marketing, promotion, selling, and distributing of their hip implant devices;

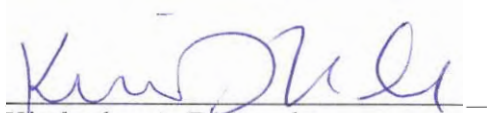
B. That this Court fashion equitable relief to cure Defendants' deceptive practices;

C. That this Court order Defendants to pay all costs for the prosecution and investigation of this actions, as provided by N.C.G.S. § 75-16.1; and

D. That this Court grant such other and further relief as the Court deems just and proper.

This the 22nd day of January, 2019.

JOSHUA H. STEIN
Attorney General



Kimberley A. D'Arruda
Special Deputy Attorney General
N.C. Department of Justice
P.O. Box 629
Raleigh, NC 27602-0629
(919) 716-6000
kdarruda@ncdoj.gov
State Bar No. 25271