

VT SUPERIOR COURT
WASHINGTON UNIT

STATE OF VERMONT
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WASHINGTON UNIT

2010 JAN 22 P 3:14

STATE OF VERMONT

Plaintiff,

v.

MEDICAL DEVICE BUSINESS SERVICES,
INC. f/k/a DEPUY INC., DEPUY
ORTHOPEDECS, INC., and
DEPUY ORTHOPAEDICS, INC.;
DEPUY PRODUCTS, INC.; DEPUY
SYNTHESES, INC.; DEPUY SYNTHESES
SALES, INC., and JOHNSON & JOHNSON,

Defendants.

CIVIL DIVISION

Docket No. _____

COMPLAINT

The Vermont Attorney General brings this action against Medical Device Business Services, Inc. f/k/a Depuy Inc., Depuy Orthopedics, Inc., and Depuy Orthopaedics, Inc.; Depuy Products, Inc.; Depuy Synthes, Inc. Depuy Synthes Sales, Inc.; (hereinafter collectively referred to as "DePuy") and Johnson & Johnson for violating the Vermont Consumer Protection Act as follows:

Jurisdiction and Venue

1. This Court has jurisdiction over the Defendants because Defendants have transacted business within the State of Vermont at all times relevant hereto.
2. Venue in this Court is proper pursuant to 9 V.S.A. § 2458(a) because Defendants transact business in Washington County or some of the transactions upon which this action is based occurred in Washington County.

Parties

3. The Attorney General is authorized to represent the State in all civil matters at common law and as allowed by statute. 9 V.S.A. § 152. The Attorney General is charged with the responsibility of enforcing the Consumer Protection Act (“CPA”) and all regulations promulgated thereunder, 9 V.S.A. § 2458.

4. 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.

5. 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.

6. 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.

7. 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.

8. Defendant DePuy Synthes Sales, Inc. is a Massachusetts company, and its principal place of business and executive offices are located at 325 Paramount Drive, Raynham, Massachusetts 02767.

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

DePuy's Conduct

10. 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.

11. 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.

12. 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.

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

14. 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.

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

Violation of the CPA

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

17. DePuy, in the course of marketing, promoting, selling, and distributing its metal-on-metal hip implants, engaged in a course of trade or commerce which constitutes false, deceptive, or misleading acts or practices, and is therefore unlawful under the CPA, because DePuy made the above-described misrepresentations regarding their metal-on-metal hip implant devices.

Prayer for Relief

WHEREFORE, Plaintiff State of Vermont respectfully requests that the Court enter an order as follows:

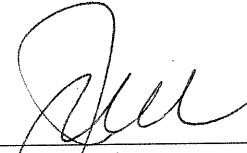
- A. A judgment in its favor and against Defendants;
- B. Permanently enjoining and restraining Defendants, their agents, employees, and all other persons and entities, corporate or otherwise, in active concert or participation with any of them, from engaging in false, misleading, or deceptive practices in the marketing, promotion, selling, and distributing of their hip implant devices;
- C. Awarding statutory civil penalties of \$10,000 for each and every violation of the CPA;
- D. Awarding costs and reasonable attorneys' fees incurred by the State of Vermont in connection with the investigation and litigation of this matter; and
- E. Such further relief as the Court deems necessary or appropriate to remedy the effects of DePuy's unlawful trade practices.

Dated:  January 22, 2019

Respectfully submitted,

THOMAS J. DONOVAN JR.
ATTORNEY GENERAL

By:



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