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IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

State of Arizona, *ex rel.* Mark Brnovich, Attorney General,

Plaintiff,

Medical Device Business Services, Inc. f/k/a DePuy Inc. and DePuy Orthopaedics, Inc.; DePuy Products, Inc.; DePuy Synthes, Inc.; DePuy Synthes Sales, Inc. and Johnson & Johnson

Defendants.

Case No: CV 2019-000270

CIVIL COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

(Non-Classified: Consumer Fraud)

1. Plaintiff, State of Arizona, *ex rel.* Mark Brnovich, Attorney General, brings this action complaining of Defendants MEDICAL DEVICE BUSINESS SERVICES, INC. F/K/A DEPUY 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 Arizona Consumer Fraud Act, Ariz. Rev. Stat. ("A.R.S.") §§ 44-1521 to 44-1534 (the "ACFA") as follows:

Jurisdiction and Venue

2. This action is brought on behalf of the State of Arizona, by Mark Brnovich, the Arizona Attorney General, pursuant to the provisions of the ACFA.

3. The Arizona Superior Court has jurisdiction to enter appropriate orders, both prior to and following a determination of liability pursuant to A.R.S. § 44-1528, because the Defendants have transacted business within Arizona at all times relevant to this complaint.

4. Venue is proper in Maricopa County pursuant to A.R.S. § 12-401.

Parties

5. Plaintiff is the State of Arizona (the "State").

6. 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.

7. Defendant Medical Device Business Services Inc., formerly known as DePuy 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.

8. 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.

9. 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.

10. 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.

11. DePuy was at all times relevant hereto, engaged in the sale and advertisement of merchandise in Arizona as defined by the ACFA.

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

DePuy's Conduct

13. 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.

14. 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.

15. 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 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.

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

17. 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.

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

Violations of the ACFA

19. Plaintiff realleges and incorporates by reference herein each and every allegation contained in the preceding paragraphs 1 through 18.

20. DePuy, in connection with the advertisement and sale of its metal-on-metal hip implants, has engaged in false, deceptive, or misleading acts or practices in violation of A.R.S. § 44-1522, including:

A. Misrepresenting the characteristics, benefits or qualities of their metal-on-metal hip implant devices; and

B. Misrepresenting the failure rates of ASR XL and Pinnacle Ultamet metal-on-metal hip implant devices.

Prayer for Relief

21. WHEREFORE, the State respectfully request that:

A. Pursuant to A.R.S. § 44-1528, the Court permanently enjoin and restrain 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. Pursuant to A.R.S. § 44-1531, the Defendants be ordered to pay civil penalties in the amount of $10,000 for each and every violation of the ACFA;

C. Pursuant to A.R.S. § 44-1534, the Defendants be ordered to pay costs and reasonable attorneys' fees incurred by the State in connection with the investigation and litigation of this matter; and

D. That the Court grant such further relief as the Court deems necessary or appropriate to remedy the effects of DePuy's unlawful trade practices.

DATED this 22nd day of January, 2019.

MARK BRNOVICH,
ATTORNEY GENERAL

BY: _____
Mitchell W. Allee
Assistant Attorney General
Attorney for State of Arizona