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ENDORSED FILED
SAN MATEO COUNTY

JAN 22 2019

Clerk of the Superior Court
By UNA FINAU
DEPUTY CLERK

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF SAN MATEO

THE PEOPLE OF THE STATE OF
CALIFORNIA,

Plaintiff,

v.

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.;
JOHNSON & JOHNSON,

Defendants,

Case No. **19C1V00422**

**COMPLAINT FOR INJUNCTION, CIVIL
PENALTIES AND OTHER RELIEF**

Plaintiff, the People of the State of California ("Plaintiff" or the "People"), acting by and through Xavier Becerra, Attorney General of the State of California, is informed and believes and thereupon alleges as follows:

JURISDICTION AND VENUE

1. The People bring this action, by Xavier Becerra, Attorney General of the State of California, pursuant to the provisions of California Business and Professions Code Sections 17200 et seq. and 17500 et seq.

2. Defendants Medical Device Business Services, Inc. f/k/a DePuy, Inc., DePuy Orthopedics, Inc., and DePuy Orthopaedics, Inc., DePuy Products, Inc., DePuy Synthes, Inc., and DePuy Synthes Sales, Inc. (collectively, "DePuy"); and Defendant Johnson & Johnson; at all relevant times, transacted business in the County of San Mateo and elsewhere in the State of California. DePuy transacts business in California and nationwide by manufacturing, marketing, promoting, advertising, offering for sale, and selling prosthetic hip implant devices.

3. The violations of law alleged in this complaint have been and are being carried out within the County of San Mateo and elsewhere in the State of California. This Court has jurisdiction over the Defendants and venue for this action properly lies in San Mateo County, California, because Defendants transact business in San Mateo County, California, or some of the transactions upon which this action is based occurred in San Mateo County, California.

PARTIES

4. Plaintiff is the People of the State of California.

5. 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, New Jersey, 08933.

6. 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.

7. 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.

8. 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.

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

4 **DEFENDANTS' COURSE OF CONDUCT**

5 10. Metal-on-metal hip implants, medical devices containing all metal components,
6 were introduced into the European market in 1997 and into the U.S. market in 2000. Surgeons
7 sought a longer-lasting hip replacement that would last more than 15 years and could be used in
8 younger, more active patients.

9 11. Defendants began to market one of these medical devices, the ASR XL, in 2005.
10 In August 2010, Defendants voluntarily recalled the ASR XL because of the high number of
11 patient failures requiring replacement surgery.

12 12. Defendants also developed and marketed another type of metal-on-metal hip
13 implant, the Pinnacle Ultamet liner, in 2000. Defendants stopped selling the Pinnacle Ultamet in
14 2013.

15 13. Defendants engaged in misrepresentations regarding the stability and fixation,
16 survivorship, and rate of wear of the ASR XL. As early as 2007, Defendants were aware that it
17 was necessary to implant the device at a precise acute angle that was difficult to achieve
18 consistently, but a design change was not adopted. Instead of deciding to redesign the device,
19 Defendants continued to market the device's stability and advanced fixation, citing implant
20 survivorship of 99.2% at three years in its "Never Stop Moving" campaign.

21 14. In 2009, Defendants learned that the National Joint Registry of England and
22 Wales found a 7% revision (failure and replacement) rate at three years for the ASR XL, but
23 Defendants continued to market the ASR platform using their "Advanced High Stability and Low
24 Wear" message. As the ASR XL failed, consumers required new implantations and experienced
25 persistent groin pain, allergy, and tissue necrosis. On revision, surgeons found metal debris in the
26 surrounding tissue. In addition, some patients experienced increased levels of metal ions in their
27 blood following the ASR XL implantation.

1 15. With respect to the Pinnacle Ultamet, Defendants engaged in misrepresentations
2 regarding the survivorship of the device. Although the National Joint Registry of England and
3 Wales reported a 4.28% revision rate, Defendants advertised that their Pinnacle brand (including
4 all liners) had a 99.8% and 99.5% survivorship at 5 years based on a 2007 study with
5 questionable data collection practices. Additionally, although Defendants initiated the underlying
6 2007 study, advertisements indicated independent researchers initiated the study.

7
8 **FIRST CAUSE OF ACTION**
9 **Violations of Business and Professions Code**
 Section 17500 (Untrue or Misleading Representations)

10 16. The People reallege and incorporate by reference each and every allegation
11 contained in the preceding paragraphs 1 through 15 as though fully set forth herein.

12 17. Defendants, in the course of engaging in the marketing, promotion, selling, and
13 distributing of their metal-on-metal hip implant devices, in violation of Business and Professions
14 Code section 17500, with the intent to induce members of the public to purchase Defendants'
15 products, have made omissions and misrepresentations about their metal-on-metal hip implant
16 devices by misrepresenting the failure rate of ASR XL and Pinnacle Ultamet metal-on-metal hip
17 implant devices, and misrepresenting the sponsorship, approval, characteristics, ingredients, uses,
18 benefits, quantities, or qualities of their metal-on-metal hip implant devices, when Defendant
19 knew, or by the exercise of reasonable care should have known, the omissions and
20 misrepresentations were untrue or misleading.

21 **SECOND CAUSE OF ACTION**
22 **Violations of Business and Professions Code**
 Section 17200 (Acts of Unfair Competition)

23 18. The People reallege and incorporate by reference each and every allegation
24 contained in the preceding paragraphs 1 through 17 as though fully set forth herein.

25 19. Defendants, in the course of marketing, promoting, selling, and distributing metal-
26 on-metal hip implants, have engaged in unfair competition as defined in Business and Professions
27 Code section 17200, by:
28

1 a. Violating Business and Professions Code section 17500 as alleged in paragraph
2 17 of the above First Cause of Action and which is incorporated by reference as though fully set
3 forth here; and,

4 b. Representing that their metal-on-metal hip implant devices have sponsorship,
5 approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they do not have.

6 **PRAYER FOR RELIEF**

7 **WHEREFORE**, Plaintiff prays that:

8 1. An injunction be issued pursuant to Business and Professions Code sections 17203
9 and 17535 restraining and enjoining Defendants and their agents, employees, and all other
10 persons or entities, corporate or otherwise, in active concert or participation with any of them,
11 from violating Business and Professions Code sections 17200 et seq. or 17500 et seq.

12 2. Pursuant to Business and Professions Code sections 17206 and 17536, Defendants be
13 assessed a civil penalty of two thousand five hundred (\$2,500) for each violation of Business and
14 Professions Code sections 17200 et seq. and 17500 et seq., as proved at trial.

15 3. The Court Order Defendants to pay Plaintiff's costs.

16 4. Plaintiff is given such other and further relief as the nature of this case may require
17 and that this Court deems equitable and proper to fully and successfully dissipate the effects of
18 the alleged violations of Business and Professions Code sections 17200 et seq. and 17500 et seq.

1 Dated: January 19, 2019

Respectfully Submitted,

2 XAVIER BECERRA
3 Attorney General of California
4 NICKLAS A. AKERS
5 Senior Assistant Attorney General
6 JUDITH FIORENTINI
7 Supervising Deputy Attorney General

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9 JINSOOK OHTA
10 LAUREL M. CARNES
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13 *California*