

IN THE DISTRICT COURT IN AND FOR POLK COUNTY

STATE OF IOWA, ex. rel.)	
THOMAS J. MILLER, Attorney General,)	
)	
Plaintiff,)	
v.)	<u>PETITION</u>
)	
Medical Device Business Services, Inc. f/k/a)	
DePuy Inc., DePuy Orthopedics, Inc., and)	
DePuy Orthopaedics, Inc.;)	CASE NO. _____
DePuy Products, Inc.; DePuy Synthes, Inc.;)	
DePuy Synthes Sales, Inc. &)	
Johnson & Johnson)	
)	
)	
Defendants.)	

Introduction

1. Plaintiff, State of Iowa in its sovereign capacity, by Attorney General Thomas J. Miller and through Assistant Attorney General Amy Licht (“Attorney General” or “State”), 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 SYNTHES, INC.; DEPUY SYNTHES SALES, INC. (hereinafter collectively referred to as “DePuy”) and JOHNSON & JOHNSON for violating the Iowa Consumer Fraud Act, Iowa Code section 714.16, as follows:

Jurisdiction and Venue

2. This action is brought for and on behalf of the State pursuant to the provisions of the Iowa Consumer Fraud Act, Iowa Code section 714.16.

3. This Court has jurisdiction over the Defendants pursuant to Iowa Code section 714.16 because the Defendants have transacted business within Iowa at all times relevant to this petition.

4. Venue for this action properly lies in Polk County pursuant to Iowa Code section 714.16(10) because Defendants transact business in Polk County or some of the transactions upon which this action is based occurred in Polk County.

Parties

5. Plaintiff the State of Iowa, ex. rel. Attorney General of Iowa, is charged with enforcing the Iowa Consumer Fraud Act, Iowa Code section 714.16, which prohibits unfair or deceptive acts or practices in connection with the lease, sale, or advertisement of any merchandise. Pursuant to Iowa Code section 714.16(7), the Attorney General may initiate civil law enforcement proceedings in the name of the State to enjoin violations of the Iowa Consumer Fraud Act and to secure such equitable and other relief as may be appropriate in each case.

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, New Jersey 08933.

7. 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.

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. At all relevant times, DePuy transacted business in Iowa 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, 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.

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, polyethelene, 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.

Violation of the Iowa Consumer Fraud Act

Count One

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

20. 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 the Iowa Consumer Fraud Act, Iowa Code section 714.16(2), including but not limited to representing that goods or services had sponsorship, approval, characteristics, benefits, or qualities that they did not have. DePuy violated Iowa Code section 714.16(2) when they misrepresented the sponsorship, approval, characteristics, benefits or qualities of their metal-on-metal hip implant devices.

Count Two

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

22. 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 Iowa Code section 714.16(2), including but not limited to misrepresenting the failure rate of ASR XL and Pinnacle Ultamet metal-on-metal hip implant devices

Prayer for Relief

23. WHEREFORE, the State of Iowa respectfully requests that:

A. Pursuant to Iowa Code section 714.16(7), 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 Iowa Code section 714.16(7), the Defendants be ordered to pay civil penalties in the amount of \$40,000.00 for each and every violation of the Iowa Consumer Fraud Act;

C. Pursuant to Iowa Code section 714.16(11), the Defendants be ordered to pay costs and reasonable attorneys' fees incurred by the Iowa Attorney General's office 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.

Respectfully submitted,

THOMAS J. MILLER
Attorney General of Iowa

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