BEFORE THE DIRECTOR OF THE CONSUMER PROTECTION UNIT OF THE DELAWARE DEPARTMENT OF JUSTICE

In re:	)	
	)	
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	)	CPU Case No. _____
	)	
Respondents.	)	

CEASE AND DESIST ORDER BY AGREEMENT

This Cease and Desist Order by Agreement ("Order") is entered into by and among the State of Delaware and 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 referred to as "DePuy") and Johnson & Johnson (hereinafter, collectively referred to as "Respondents") pursuant to 29 *Del. C.* § 2525(a). The Parties have consented to the entry of this Order for the purposes of settlement only, without any admission by any party, and without trial or finding of any issue of fact or law.

PARTIES

1. The State of Delaware, acting by and through the Consumer Protection Unit of the Delaware Department of Justice, is the Petitioner in this matter. The Director of Consumer Protection, through the Consumer Protection Unit of the Delaware Department of Justice ("Director"), is charged with, among other things, the responsibility of enforcing the Delaware Consumer Fraud Act ("CFA"), 6 *Del. C.* § 2511, *et seq.*, and the Uniform Deceptive Trade Practices Act ("UDTPA"), 6 *Del. C.* § 2532, *et seq.*

2. Medical Device Business Services, Inc., f/k/a DePuy Inc., DePuy Orthopedics, Inc., and DePuy Orthopaedics, Inc., is a Respondent in this matter and is an Indiana company, with executive offices located at 700 Orthopaedic Drive, Warsaw, Indiana 46582.

3. DePuy Products, Inc. is a Respondent in this matter and is an Indiana company, with executive offices located at 700 Orthopaedic Drive, Warsaw, Indiana 46582.

4. DePuy Synthes, Inc. is a Respondent in this matter and is a Delaware company, with executive offices located at 700 Orthopaedic Drive, Warsaw, Indiana 46582.

5. DePuy Synthes Sales, Inc. is a Respondent in this matter and is a Massachusetts company, with executive offices located at 325 Paramount Drive, Raynham, Massachusetts 02767.

6. DePuy does business in the State of Delaware.

7. Johnson & Johnson is a Respondent in this matter and is a New Jersey company, with executive offices located at One Johnson & Johnson Plaza New Brunswick, New Jersey 08933.

8. Johnson & Johnson consents to the jurisdiction of the Director solely for purposes of this Order.

NOW THEREFORE, THE DIRECTOR HEREBY ORDERS AS FOLLOWS:

I. FINDINGS

A. The Director has jurisdiction over the subject matter of this Order and over the Parties.

B. The terms of this Order shall be governed by the laws of the State of Delaware.

C. Entry of this Order is in the public interest and reflects a negotiated settlement among the Parties.

D. The Parties have agreed to resolve and settle the issues resulting from the Covered Conduct (defined below) by entering into this Order.[1]

E. Respondents are willing to enter into this Order regarding the Covered Conduct in order to resolve the Signatory Attorney Generals' concerns under the State Consumer Protection Laws as to the matters addressed in this Order and thereby avoid significant expense, inconvenience, and uncertainty.

F. Respondents are entering into this Order solely for the purpose of settlement, and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law, rule, or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Respondents expressly deny. Respondents do not admit any violation of the State Consumer Protection Laws set forth in footnote 2[2], and do not admit any wrongdoing

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[1] This agreement is entered into pursuant to and subject to the State Consumer Protection Law(s) cited in footnote 2.

[2] ALABAMA – *Alabama Deceptive Trade Practices Act, Ala. Code § 8-19-1 et seq.*; ALASKA – Alaska's Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 – 561; ARIZONA – *Arizona Consumer Fraud Act*, A.R.S. § 44-1521 *et seq.*; ARKANSAS – *Arkansas Deceptive Trade Practices Act, Ark. Code Ann.* § 4-88-101, *et seq.*; CALIFORNIA – Bus. & Prof Code §§ 17200 *et seq.* and 17500 *et seq.*; COLORADO – *Colorado Consumer Protection Act*, Colo. Rev. Stat. § 6-1-101 *et seq.*; CONNECTICUT – *Connecticut Unfair Trade Practices Act,* Conn. Gen. Stat. §§ 42-110a *et seq.;* DELAWARE – *Delaware Consumer Fraud Act and Uniform Deceptive Trade Practices Act*, Del. CODE ANN. tit. 6, §§ 2511 to 2536; DISTRICT OF COLUMBIA – *District of Columbia Consumer Protection Procedures Act*, D.C. Code §§ 28-3901 *et seq.*; FLORIDA – *Florida Deceptive and Unfair Trade Practices Act, Chapter 501, Part II*, Florida Statutes, 501.201 *et seq.*; GEORGIA – Fair Business Practices Act, O.C.G.A. § 10-1-390 *et seq.*; HAWAII – *Uniform Deceptive Trade Practice Act,* Haw. Rev. Stat. Chpt. 481A and *Monopolies; Restraint of Trade*, Haw. Rev. Stat. Chpt. 480; IDAHO – *Consumer Protection Act*, Idaho Code Section 48-601 *et seq.*; ILLINOIS – *Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 et seq.* and *Uniform Deceptive Trade Practices Act, 815 ILCS 510/1 et seq.*; INDIANA – *Deceptive Consumer Sales Act*, I.C. § 24-5-0.5 *et seq.*; IOWA – *Iowa Consumer Fraud Act,* Iowa Code Section 714.16, *et seq.*; KANSAS – *Kansas Consumer Protection Act*, K.S.A. 50-623 *et seq.*; KENTUCKY – KRS 367.110 *et seq.*; LOUISIANA – *Unfair Trade-Practices and Consumer Protection Law*, LSA-R.S. 51:1401, *et seq.*; MAINE – *Unfair Trade Practices Act*, 5 M.R.S. §§ 205-A through 214; MARYLAND – *Maryland Consumer Protection Act*, Md. Code Ann., Com. Law §§ 13-101 to 13-501; MASSACHUSETTS – *Mass. Gen. Laws* c. 93A, §§ 2 and 4; MICHIGAN – *Michigan Consumer Protection Act*, MCL § 445.901 *et seq.*; MINNESOTA – *Minnesota Deceptive Trade Practices Act*, Minn. Stat. §§ 325D.43-48; *Minnesota False Advertising Act*, Minn. Stat. § 325F.67; *Minnesota Consumer Fraud Act*, Minn. Stat. §§ 325F.68-694; *Minnesota Deceptive Trade Practices Against Senior Citizens or Disabled Persons Act*, Minn. Stat. § 325F.71.; MISSOURI – Merchandising Practices Act, Chapter 407, RSMo. MONTANA – *Mont. Code Ann. § 30-14-101 et seq.*; NEBRASKA – *Consumer Protection Act*, Neb. Rev. Stat. § 59-1601 *et seq.* and *Uniform Deceptive Trade Practices Act*, Neb. Rev. Stat. §§ 87-301 *et seq.*; NEVADA – *Deceptive Trade Practices Act*, Nevada Revised Statutes 598.0903 *et seq.*; NEW HAMPSHIRE – *New Hampshire Consumer Protection Act*, RSA 358-A; NEW MEXICO – *New Mexico Unfair Practices Act*, NMSA 1978, §§ 57-12-1 to -26 (1967, as amended through 2009); NEW YORK – General Business Law Art. 22-A, §§ 349-50, and Executive Law § 63(12);

that was or could have been alleged by any Signatory Attorney General. No part of this Order, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Respondents. This document and its contents are not intended for use by any third party for any purpose, including submission to any court for any purpose. The Parties acknowledge that the payment described herein is not a fine, penalty, or payment in lieu thereof.

G. This Order shall not be construed or used as a waiver or limitation of any legal right, remedy, or defense otherwise available to Respondents in any action, or of Respondents' right to defend themselves from, or make any arguments in, any private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this Order. Moreover, the Parties do not intend the terms of this Order to limit lawful non-promotional statements made by DePuy and Johnson & Johnson regarding products which are the subject of the Covered Conduct. This Order is made without trial or adjudication of any issue of fact or law, or finding of liability of any kind. Notwithstanding the foregoing, the Petitioner may file an action to enforce the terms of this Order.

H. It is the intent of the Parties that this Order not be admissible in other cases or binding on Respondents in any respect other than in connection with the enforcement of this Order.

NORTH CAROLINA – *North Carolina Unfair and Deceptive Trade Practices Act*, N.C.G.S. §§ 75-1.1, *et seq.*; NORTH DAKOTA – *Unlawful Sales or Advertising Practices*, N.D. Cent. Code § 51-15-02 *et seq.*; OHIO – *Ohio Consumer Sales Practices Act*, R.C. 1345.01, *et seq.*; OKLAHOMA – *Oklahoma Consumer Protection Act* 15 O.S. §§ *751 et seq.*; PENNSYLVANIA – *Pennsylvania Unfair Trade Practices and Consumer Protection Law*, 73 P.S. 201-1 *et seq.*; RHODE ISLAND – *Rhode Island Deceptive Trade Practices Act*, Rhode Island General Laws § 6-13.1-1, *et seq.*; SOUTH CAROLINA – South Carolina Unfair Trade Practices Act, S.C. Code §§ 39-5-10 *et seq.*; SOUTH DAKOTA – *South Dakota Deceptive Trade Practices and Consumer Protection*, SDCL ch. 37-24; TENNESSEE – *Tennessee Consumer Protection Act*, Tenn. Code Ann. § 47-18-101 *et seq.*; TEXAS – Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. And Com. Code 17.41, *et seq.*; UTAH – Utah Consumer Sales Practices Act, Utah Code § 13-11-1, *et seq.*; VERMONT – *Consumer Protection Act*, 9 V.S.A. §§ 2451 *et seq.*; VIRGINIA – *Virginia Consumer Protection Act*, Va. Code Ann. §§ 59.1-196 through 59.1-207; WASHINGTON – *Unfair Business Practices/Consumer Protection Act*, RCW §§ 19.86 *et seq.*; WISCONSIN – Wis. Stat. § 100.18(1) (Fraudulent Representations).

I. No part of this Order shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that the Petitioner may file an action to enforce the terms of this Order.

J. This Order (or any portion thereof) shall in no way be construed to prohibit Respondents from making representations with respect to any DePuy Product that are permitted under Federal law or regulations or in Food and Drug Administration ("FDA") approved Labeling for the device under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidance for Industry, so long as the representation, taken in its entirety, is not false, misleading, or deceptive. Nothing in this Order shall prohibit Respondents from revising their procedures and policies to be consistent with then current Federal law under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), FDCA regulations, FDA Guidance, other FDA interpretations or amendments thereto, as it relates to medical devices.

K. Nothing in this Order shall:

1. require Respondents to take any action that is prohibited by the FDCA or any regulation promulgated thereunder, or by the FDA; or

2. require Respondents to fail to take any action that is required by the FDCA or any regulation promulgated thereunder, or by the FDA, unless facts are or become known to Respondents that cause the claim to be false, misleading, or deceptive; or

3. preclude Respondents from providing health care economic information to a formulary committee or similar entity or its members in the course of the committee or entity carrying out its responsibilities for the selection of medical

devices for managed care or other similar organizations pursuant to the applicable standards of Section 114 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA"), as FDAMA may be amended or revised.

II. DEFINITIONS

The following definitions shall be used in construing this Order:

A. "Clearly and Conspicuously" shall mean a disclosure in size, color, contrast, font, and location that is readily noticeable, readable and understandable and is presented in proximity to all information necessary to prevent it from being misleading or deceptive. A statement may not contradict or be inconsistent with any other information with which it is presented. If a statement modifies, explains, or clarifies other information or is necessary to prevent other information from being misleading or deceptive, that the statement must be presented in close proximity to that information, in a manner that is readily noticeable, readable, and understandable, and it must not be obscured in any manner.

B. "Covered Conduct" shall mean Promotional practices and dissemination of information regarding the ASR XL Acetabular, ASR Hip Resurfacing, and Pinnacle Ultamet metal-on-metal hip replacement systems, or any parts thereof.

C. "Respondents' Scientifically Trained Personnel" shall mean Respondents' personnel who are highly trained experts with specialized scientific or medical knowledge whose roles involve the provision of specialized, medical or scientific information, scientific analysis and/or scientific information but excludes Respondents' personnel who perform sales, marketing, or other primarily commercial roles.

D. "DePuy" shall mean 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 Synth Sales, Inc. including all of their predecessors, subsidiaries, successors, and assigns, and each and all of their current and former officers, directors, shareholders, employees, agents, responsible for manufacturing, selling, offering for sale, marketing, Promoting, or distributing any DePuy Product in the United States. This term shall also encompass any contractor responsible for marketing or Promoting any DePuy Product in the United States.

E. "DePuy Marketing" shall mean DePuy personnel responsible for marketing any DePuy Product (defined below) in the United States.

F. "DePuy Product" or "DePuy Products" or "Product(s)" shall mean any hip replacement system, including its individual components, manufactured and/or Promoted by DePuy or DePuy Sales (defined below).

G. "DePuy Sales" shall mean DePuy and third party personnel responsible for Promoting (defined below) DePuy Products in the United States.

H. "Effective Date" shall mean the date on which a copy of this Order, duly executed by Respondents and by Petitioner, is approved and signed by the Director, and Respondents have been notified via e-mail or regular U.S. mail that all the Parties hereto have fully executed the Order.

I. "Health Care Professional" or "HCP" shall mean any U.S.-based physician or other health care practitioner who is licensed to provide health care services or to recommend hip replacement systems.

J. "Johnson & Johnson" shall mean Johnson & Johnson including all of its predecessors, subsidiaries, successors, and assigns, and each and all of their current and former officers, directors, shareholders, employees, and agents, doing business in the United States. This term shall also encompass any contractor responsible for marketing or Promoting (defined below) any DePuy Product in the United States.

K. "Multistate Executive Committee" shall mean the Attorneys General and their staff representing Florida, Indiana, North Carolina, Ohio, Pennsylvania, South Carolina, Texas, and Washington.

L. "Multistate Working Group" shall mean the Attorneys General and their staff representing Alabama, Arkansas, Alaska, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, Wisconsin, Utah, and District of Columbia.

M. "Parties" shall mean Respondents and the Petitioner.

N. "Petitioner" shall mean the State of Delaware, or its authorized designee, which has agreed to this Order.

O. "Promotional," "Promoting," "Promote," or "Promoted" shall refer to any representation about a DePuy Product intended to influence sales of that product, including attempts to influence Health Care Professional practices for recommending and utilizing that product, which would be deemed promotional labeling or advertising under the FDCA or any

regulation promulgated thereunder, or by the FDA, under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidance for Industry.

P. "Sponsor" or "Sponsorship" or "Sponsored" shall mean to pay or have paid in whole or in part, to provide or have provided financial support or subsidization, or to provide or have provided goods or materials of value in support of more than de minimis value.

Q. "State Consumer Protection Laws" shall mean the consumer protection laws under which the Signatory Attorney Generals have conducted their investigation, as listed in Footnote 2.[3]

III. COMPLIANCE PROVISIONS

IT IS FURTHER ORDERED, ADJUDGED AND DECREED THAT:

1. General Provision:

A. In Promoting a DePuy Product, DePuy shall not violate the Delaware Consumer Fraud Act, 6 *Del. C.* § 2511 *et seq.*, or the Uniform Deceptive Trade Practices Act, 6 *Del. C.* § 2531 *et seq.*.

2. Specific Provisions:

The following subsections of Section III. shall be effective for five years from the Effective Date of this Order.

A. In Promoting a DePuy Product, any representations by DePuy about implant wear, survivorship, stability, or dislocations of any DePuy Product or component part of a DePuy Product shall be based on information approved by Scientifically Trained Personnel as relevant,

[3] The applicable Delaware laws are the Delaware Consumer Fraud Act, 6 *Del. C.* § 2511 *et seq.*, and the Uniform Deceptive Trade Practices Act, 6 *Del. C.* § 2531 *et seq.*

cite to the source of the information consistent with all guidelines for citation promulgated by the information source, and expressly disclose if DePuy Sponsored or otherwise funded the study that generated the cited information consistent with provision III.2.C below. Where such Promotions utilize registry data, DePuy shall use the most recent dataset available from the registry at the time the Promotional material is approved for distribution, and shall notate on the Promotional material the registry sources and dates utilized.

B. When submitting or publishing a study, manuscript, or abstract, DePuy shall follow its practice of following the most recent Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals developed by the International Committee of Medical Journal Editors (ICMJE) guidelines for the naming of authors.

C. In all DePuy-Sponsored manuscripts reporting the results of a DePuy-Sponsored study, DePuy shall comply with its policy of disclosing DePuy's role as a Sponsor, and any author's potential conflict of interest, consistent with the disclosure requirements of the ICMJE.

D. In any materials used to Promote any DePuy Product, including, but not limited to abstracts, posters, brochures, and direct-to-consumer marketing advertisements, whether distributed in hard copy, digital, or electronic format, in which information is derived primarily from a study that has been designed or Sponsored by DePuy, DePuy shall Clearly and Conspicuously identify itself as the Sponsor of the study. This provision shall not apply to communications or materials that are only used internally by DePuy. Any such communications or materials that are used internally by DePuy that do not Clearly and Conspicuously identify DePuy as the Sponsor of a study shall not be used to market or Promote any DePuy Product.

E. DePuy shall, when citing to any clinical study, clinical data, or preclinical data in any materials used to Promote any DePuy Product:

1. Present in accordance with applicable FDA guidance a fair balance of available scientific literature with respect to the safety, efficacy, risks, and complications of DePuy Products;

2. Present favorable information or conclusions only from studies that DePuy Scientifically Trained Personnel determine to have clinical significance or validity in terms of study design, scope, and conduct;

3. Use only data that DePuy Scientifically Trained Personnel determine to have clinical significance or validity, and use such data only in a manner approved by DePuy Scientifically Trained Personnel prior to the distribution of Promotional materials.

F. DePuy shall update as warranted, and maintain a post market surveillance program that provides for a comprehensive review and analysis of product performance and safety information, and a product complaint handling program that promotes compliance with product complaint handling and medical device reporting regulations and requirements, including, but not limited to, what is currently titled 21 CFR Part 803 and relevant FDA Guidance documents.

G. DePuy shall update as warranted, and maintain internal product complaint handling operating procedures and guidance that provide clear instruction, comply with applicable regulations, and define terms consistent with applicable FDA definitions of those terms. Any DePuy employee whose responsibilities include complaint handling shall review the operating procedures and guidance and be trained on them.

H. DePuy shall update as warranted, and maintain processes and procedures to track and analyze product complaints, including those that do not meet the definition of Medical

Device Reportable Event under applicable regulations, have more than one cause, or present more than one symptom or issue.

I. DePuy shall comply with any and all federal requirements regarding the reporting of any Medical Device Reportable Event associated with any DePuy Products, and shall report any such event from any source to the federal Food and Drug Administration as required under the Mandatory Device Reporting regulation (21 CFR 803).

J. DePuy shall maintain a quality assurance program that includes an audit procedure for tracking complaints regarding DePuy Products that do not rise to the level of a Medical Device Reportable Event but that may indicate a device-related serious-injury or malfunction.

K. DePuy shall perform at least quarterly reviews of complaints, and where any clearly identifiable and definable sub-group of the patient population has a higher incidence of adverse events or Medical Device Reportable Events than the rest of the patient population indicating a potential safety signal, DePuy shall: (1) take good faith measures to determine the cause, if any, of a higher incidence, and (2) communicate findings to DePuy Marketing and engage in good faith discussions regarding whether such findings should alter Promotional practices that may Promote the product to the portion or group of the patient population in question. In the event that DePuy determines that such findings should alter Promotional practices, DePuy shall notify Health Care Professionals accordingly, either in person or via Dear Doctor letters.

L. DePuy shall not represent or imply that the Petitioner or the Director acquiesces in or approves of DePuy's past or current business practices, efforts to reform it practices, or any future practices that DePuy may adopt or consider adopting.

IV. PAYMENT

No later than 30 days after the Effective Date of this Order, Respondents shall pay a total amount of $ 120,000,000.00 (One Hundred Twenty Million Dollars) to be divided and paid by Respondents directly to each Attorney General of the Multistate Working Group in an amount to be designated by and in the sole discretion of the Multistate Executive Committee. The payment to the Petitioner under this paragraph shall be $ 1,343,008.57. Said payment shall be used by the States as attorneys' fees and other costs of investigation and litigation, or to be placed in, or applied to, consumer protection enforcement funds, including future consumer protection enforcement, consumer education, litigation or local consumer aid fund or revolving fund, used to defray the costs of the inquiry leading hereto, or for any lawful purpose, at the sole discretion of each Attorney General of the Multistate Working Group.

V. RELEASE

A. By its execution of this Order, the Petitioner releases and forever discharges Respondents (the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, disgorgement, fines, costs, attorneys' fees, remedies, and/or penalties that Petitioner has asserted or could have asserted against the Released Parties under the Delaware Consumer Fraud Act, 6 *Del. C.* § 2511 *et seq.*, or the Uniform Deceptive Trade Practices Act, 6 *Del. C.* § 2531 *et seq.*, or any amendments thereto, or by common law claims concerning unfair, deceptive, or fraudulent trade practices or, if applicable, state statutes equivalent to the federal Food, Drug, and Cosmetic Act that the Petitioner has the authority to release resulting from the Covered Conduct up to and including the Effective Date that is the subject of the Order.

B. Notwithstanding any term of this Order, specifically reserved and excluded from the release in Paragraph V.A. as to any entity or person, including Released Parties, are any and all of the following:

1. any criminal liability that any person and/or entity, including Released Parties, has or may have to the State of Delaware.

2. any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Delaware not expressly covered by the release in Paragraph V.A. above, including, but not limited to, any and all of the following claims:

   a. state or federal antitrust violations;

   b. claims involving "best price," "average wholesale price," "wholesale acquisition cost," or any reporting practices;

   c. Medicaid claims, including, but not limited to, federal Medicaid drug rebate statute violations, Medicaid fraud or abuse, and/or kickback violations related to any State's Medicaid program;

   d. state false claims violations; and

   e. actions of state program payors of Delaware arising from the purchase of DePuy Product.

3. any claims individual consumers, including classes of consumers bringing class actions, have or may have under the State of Delaware's above-cited consumer protection law, and any common law claims individual consumers, including classes of consumers bringing class actions, may have concerning unfair, fraudulent or deceptive trade practices against any person and/or entity, including Released Parties.

VI. DISPUTE RESOLUTION

A. For the purposes of resolving disputes with respect to compliance with this Order, should the Petitioner have a reasonable basis to believe that Respondents have violated, or are violating, any provision of this Order subsequent to the Effective Date, then the Petitioner shall notify Respondents in writing of the specific objection, identify with particularity the provisions of this Order that the practice appears to violate, and give Respondents 30 days to respond to the notification.

B. Upon receipt of written notice from the Petitioner, Respondents shall provide a good-faith written response to the Petitioner's notification, containing either a statement explaining why Respondents believe they are in compliance with the Order or a detailed explanation of how the alleged violation occurred and statement explaining how and when Respondents intend to remedy the alleged violation.

C. Except as set forth in Sections VI.D. and E. below, the Petitioner may not take any action concerning the alleged violation of this Order during the 30 day response period. Nothing shall prevent the Petitioner from agreeing in writing to provide Respondents with additional time beyond the 30 days to respond to the notice.

D. Nothing in this Order shall be interpreted to limit the State of Delaware's investigative subpoena authority, to the extent such authority exists under applicable state law, and Respondents reserve all of their rights in responding to an investigative subpoena issued pursuant to such authority.

E. The Petitioner may assert any claim that Respondents have violated this Order in a civil action to enforce compliance with this Order, or may seek any other relief afforded by law for violations of the Order, but only after providing Respondents an opportunity to respond to the

notification as described above and to remedy, to the satisfaction of the Petitioner, the alleged violation within the 30 day response period as described above, or within any other period as agreed to by Respondents and the Petitioner. However, the Petitioner may take any action, including, but not limited to legal action to enforce compliance with the Order, without delay if the Petitioner believes that, because of the specific practice, a threat to the health or safety of the public requires immediate action.

VII. GENERAL PROVISIONS

A. Respondents shall not knowingly permit, cause, or encourage third parties acting on their behalf, to engage in practices from which Respondents are prohibited by this Order.

B. This Order does not constitute an approval by Petitioner or the Director of Respondents' business practices, and Respondents shall make no representation or claim to the contrary.

C. Any failure by any party to this Order to insist upon the strict performance by any other party of any of the provisions of this Order shall not be deemed a waiver of any of the provisions of this Order, and such party, notwithstanding such failure, shall have the right thereafter to insist upon the specific performance of any and all of the provisions of this Order.

D. This Order represents the full and complete terms of the settlement entered into by the Parties hereto. The Parties acknowledge that no other promises, representations, or agreements of any nature have been made or entered into by the Parties. The Parties further acknowledge that this Order constitutes a single and entire agreement that is not severable or divisible, except that if any provision herein is found to be legally insufficient or unenforceable, the remaining provisions shall continue in full force and effect. In any action undertaken by the

Parties, no prior versions of this Order and no prior versions of any of its terms that were not entered by the Director in this Order may be introduced for any purpose whatsoever.

E The Director retains jurisdiction of this Order and the Parties hereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary and appropriate

F. The Order may be modified by a stipulation of the Parties, once it is approved by the Director, or by proceedings in a court of competent jurisdiction resulting in modifying judgment of the court.

G. In the event any law or regulation is enacted or adopted by the federal government or by the State of Delaware, and the requirements of such law or regulation create a conflict with any terms of this Order, Respondents shall notify the Director in writing as to the extent of the conflict. If the Director agrees, he shall consent to a modification of such provision of the Order to the extent necessary to eliminate such conflict. If the Director disagrees and the Parties are not able to resolve the disagreement, Respondents may seek a modification from a court of competent jurisdiction of any provision of this Order that presents a conflict with any such federal or state law or regulation. Changes in federal or state laws or regulations, with respect to the matters governed by this Order, shall not be deemed to create a conflict with a provision of this Order unless Respondents cannot reasonably comply with both such law or regulation and the applicable provision of this Order.

H. This Order may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

I. All Notices under this Order shall be provided to the following via e-mail and Overnight Mail:

For Respondents:

William Craco

Johnson & Johnson Law Department

One Johnson & Johnson Plaza

New Brunswick, NJ 08933

wcraco@its.jnj.com

Ross Galin

O'Melveny & Myers LLP

7 Times Square, New York, NY 10036

rgalin@omm.com

Notice shall also be provided to any person subsequently designated by Respondents to receive such notice of failure to comply.

For the State of Delaware:

Christian Douglas Wright

Director of Consumer Protection

Consumer Protection Unit

Delaware Department of Justice

820 N. French Street, 5th Floor

Wilmington, DE 19801

(302) 577-8600

Christian.Wright@state.de.us

J. To the extent that any provision of this Order obligates Respondents to change any policy(ies) or procedure(s) and to the extent not already accomplished, Respondents shall implement the policy(ies) or procedure(s) as soon as reasonably practicable but no later than 120 days after the Effective Date of this Order.

APPROVED:

PETITIONER, THE STATE OF DELAWARE

By: David Weinstein Date: 1/22/19
Name: David Weinstein
Title: Deputy Attorney General

[Additional approvals on subsequent pages]

Respondents

Johnson & Johnson

Date: JAN 15 2019

By: _____
Tina French
Assistant Corporate Secretary

Medical Device Business Services, Inc. f/k/a DePuy Inc., and DePuy Orthopaedics, Inc.

Date: JAN 15 2019

By: _____
Tina French
Assistant Corporate Secretary

DePuy Products, Inc.

Date: JAN 15 2019

By: _____
Tina French
Assistant Corporate Secretary

DePuy Synthes, Inc.

Date: JAN 15 2019

By: _____
Tina French
Assistant Corporate Secretary

DePuy Synth Sales, Inc.

Date: JAN 15 2019

By: _____
Tina French
Assistant Corporate Secretary

Approved as to form:

Date: 1/16/2019

By: _____
ROSS GALIN
STEVE BRODY
O'Melveny & Myers
Counsel for Respondents

IT IS SO ORDERED, this 22ND day of January, 2019.

_____
Director of Consumer Protection