IN THE DISTRICT COURT IN AND FOR POLK COUNTY

STATE OF IOWA, ex rel. THOMAS J. MILLER, Attorney General	)	CASE NO.: EQCE 084013
Plaintiff, v.	)	CONSENT JUDGMENT
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.	)	

Plaintiff, State of Iowa ex. rel. Attorney General Thomas J. Miller, by Assistant Attorney General Amy Licht, has brought 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 referred to as "DePuy") and Johnson & Johnson (hereinafter, collectively referred to as "Defendants") pursuant to the Iowa Consumer Fraud Act, Iowa Code section 714.16 *et. seq.* ("Iowa Consumer Fraud Act"). The Parties have consented to the entry of this Consent Judgment ("Judgment") 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 Iowa, Thomas J. Miller ("Attorney General"), by and through his Consumer Protection Division is the Plaintiff in this case. The Attorney General, by and through

his Division is charged with, among other things, the responsibility of enforcing the Iowa Consumer Fraud Act.

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

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

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

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

6. DePuy does business in the State of Iowa and at all times relevant hereto engaged in trade affecting consumers through the lease, sale or advertisement of merchandise within the meaning of the Iowa Consumer Fraud Act.

7. Johnson & Johnson is a Defendant in this case 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 court solely for purposes of this judgment.

NOW THEREFORE, IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:

I. FINDINGS

A. This Court has jurisdiction over the subject matter of this lawsuit and over the Parties.

B. The terms of this Judgment shall be governed by the laws of the State of Iowa.

C. Entry of this Judgment 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 Judgment.[1]

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

F. Defendants 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 Defendants expressly deny. Defendants do not admit any violation of the State Consumer Protection Laws set forth in footnote 2[2], and do not admit any wrongdoing

[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.*

that was or could have been alleged by any Signatory Attorney General. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Defendants. 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 Judgment shall not be construed or used as a waiver or limitation of any legal right, remedy, or defense otherwise available to Defendants in any action, or of Defendants' 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 Judgment. Moreover, the Parties do not intend the terms of this Judgment to limit lawful non-promotional statements made by DePuy and Johnson & Johnson regarding products which are the subject of the Covered Conduct. This Judgment is made without trial or adjudication of any issue of fact or law, or finding of liability of any kind. Notwithstanding the foregoing, the State of Iowa may file an action to enforce the terms of this Judgment.

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); 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 Ac*t, 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).

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

I. No part of this Judgment 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 State of Iowa may file an action to enforce the terms of this Judgment.

J. This Judgment (or any portion thereof) shall in no way be construed to prohibit Defendants 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 Judgment shall prohibit Defendants 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 Judgment shall:

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

2. require Defendants 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 Defendants that cause the claim to be false, misleading, or deceptive; or

3. preclude Defendants 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 Judgment:

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. "Defendants' Scientifically Trained Personnel" shall mean Defendants' 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 Defendants' 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 Defendants and by the Signatory Attorney General, is approved by, and becomes a Judgment of the Court and Defendants have been notified via e-mail or regular U.S. mail that all the Parties hereto have fully executed the Judgment.

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 Defendants and the Signatory Attorney General

N. "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.

O. "Signatory Attorney General" shall mean the Attorney General of Iowa, or his authorized designee, who has agreed to this Order.

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 law(s) under which the Signatory Attorney General has conducted his investigation.[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 Iowa Consumer Fraud Act, listed in Footnote 2.

2. Specific Provisions:

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

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] Iowa Code section 714.16 *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 Plaintiff or the Signatory Attorney General 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 Judgment, Defendants shall pay a total amount of $ 120,000,000.00 (One Hundred Twenty Million Dollars) to be divided and paid by Defendants 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.[4] 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 Judgment, the State of Iowa releases and forever discharges Defendants (the "Released Parties") from the following: all civil claims, causes of action, damages, restitution, disgorgement, fines, costs, attorneys' fees, remedies, and/or penalties that the Signatory Attorney General has asserted or could have asserted against the Released Parties under the State Consumer Protection Laws, 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 Signatory Attorney General has the authority to release resulting from the Covered Conduct up to and including the Effective Date that is the subject of the Judgment.

[4] The payment to the Signatory Attorney General under this paragraph shall be $1,726,885.38.

B. Notwithstanding any term of this Judgment, 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 Iowa.

2. any civil or administrative liability that any person and/or entity, including Released Parties, has or may have to the State of Iowa 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 the State of Iowa arising from the purchase of a DePuy Product.

3. any claims individual consumers, including classes of consumers bringing class actions, have or may have under the State of Iowa'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 Judgment, should the Signatory Attorney General have a reasonable basis to believe that Defendants have violated, or are violating, any provision of this Judgment subsequent to the Effective Date, then the Signatory Attorney General shall notify Defendants in writing of the specific objection, identify with particularity the provisions of this Judgment that the practice appears to violate, and give Defendants 30 days to respond to the notification.

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

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

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

E. The Signatory Attorney General may assert any claim that Defendants have violated this Judgment in a separate civil action to enforce compliance with this Judgment, or may seek any other relief afforded by law for violations of the Judgment, but only after

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

VII. GENERAL PROVISIONS

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

B. This Judgment does not constitute an approval by the Signatory Attorney General of Defendants' business practices, and Defendants shall make no representation or claim to the contrary.

C. Any failure by any party to this Judgment to insist upon the strict performance by any other party of any of the provisions of this Judgment shall not be deemed a waiver of any of the provisions of this Judgment, 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 Judgment.

D. This Judgment 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 Judgment 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 Judgment and no prior versions of any of its terms that were not entered by the Court in this Judgment may be introduced for any purpose whatsoever.

E This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate

F. The Judgment may be modified by a stipulation of the Parties, once it is approved by, and becomes a Judgment of the Court, or by court proceedings 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 Iowa, and the requirements of such law or regulation create a conflict with any terms of this Judgment, Defendants shall notify the Iowa Attorney General in writing as to the extent of the conflict. If the Iowa Attorney General agrees, he shall consent to a modification of such provision of the judgment to the extent necessary to eliminate such conflict. If the Attorney General disagrees and the Parties are not able to resolve the disagreement, Defendants may seek a modification from this court of any provision of this Judgment 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 Judgment, shall not be deemed to create a conflict with a provision of this Consent Judgment unless Defendants cannot reasonably comply with both such law or regulation and the applicable provision of this Judgment.

H. This Judgment 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 Judgment shall be provided to the following via e-mail and Overnight Mail:

For Defendants:

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 Defendants to receive such notice of failure to comply.

For the State of Iowa:

Director, Consumer Protection Division
Iowa Office of the Attorney General
1305 East Walnut Street, 2nd floor
Des Moines, IA 50319

J. To the extent that any provision of this Judgment obligates Defendants to change any policy(ies) or procedure(s) and to the extent not already accomplished, Defendants 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 Judgment.

For Plaintiff State of Iowa

By: _____
Amy Licht
Assistant Attorney General

Date: 1/22/19

Defendants

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 Defendants

Counsel for Defendants

State of Iowa Courts

Type: ORDER FOR JUDGMENT

Case Number	**Case Title**
EQCE084013	STATE OF IOWA VS MEDICAL DEVICE BUSINESS SERVICES INC ET AL

So Ordered

Samantha Gronewald, District Court Judge
Fifth Judicial District of Iowa