

**AMENDMENT TO THE  
CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
SYNTHESE, INC.**

**I. PREAMBLE**

The Office of Inspector General (OIG) of the Department of Health and Human Services and Synthes, Inc. (Synthes) entered into a Corporate Integrity Agreement effective December 7, 2010 (hereafter “Synthes CIA” or “CIA”). On June 14, 2012, Johnson & Johnson (J&J), through one of its indirectly-owned subsidiaries, acquired all of the shares of Synthes. Synthes will remain an indirectly-owned subsidiary of J&J and will operate within the DePuy Synthes family of companies (DePuy Synthes). Any legal entity owned, directly or indirectly, by Synthes that performs Covered Operations as defined in Section II.G of this Amendment shall be subject to Section X of the CIA.

Pursuant to Section XI.C of the Synthes CIA, the Synthes CIA may be modified only with written consent of both Synthes and OIG. OIG and Synthes hereby agree that the Synthes CIA shall be modified as described below.

**II. MODIFICATIONS**

Unless otherwise noted, the references in the CIA to Synthes shall apply only to the Covered Operations, as defined below in Section II.G of this Amendment. In this Amendment, references to legacy Synthes and legacy DePuy shall refer to those companies as they existed before June 14, 2012.

A. Section II.C.1.c of the CIA, “Covered Persons,” is revised as follows:

c. (1) except as carved out below in this Section II.C.1 of the CIA, all employees of DePuy Synthes who are based in the United States and whose job responsibilities relate to the Covered Operations, defined in Section II.C.13, or include the performance of any Covered Function for any Covered Operations; (2) all employees of DePuy Synthes who are based outside the United States and whose job responsibilities relate to the Covered Operations, as defined in Section II.C.13, or include the performance of any Covered Function<sup>1</sup> for any Covered Operations; and (3) all functional department employees of DePuy Synthes and any other J&J company who are based in the United States and who are assigned to provide support for Covered Operations, including but not limited to Legal, Health Care Compliance, Finance, Human Resources, Regulatory Affairs, Medical Affairs, Clinical Affairs, Research and Development, and Quality.

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<sup>1</sup>The Promotional and Product Services Related Functions, Clinical Investigation Related Functions, IDE-Exempted Investigation Related Functions and Reporting Related Functions shall be referred to collectively as the “Covered Functions.”

B. Section II.C.1.d of the CIA is revised to read as follows:

d. all contractors, subcontractors, agents, and other representatives of DePuy Synthes or another J&J company who perform any Covered Functions related to the Covered Operations on behalf of DePuy Synthes either in the United States or with U.S.- based health care practitioners (HCPs).

C. The first clause of the last paragraph of Section II.C.1 of the CIA is revised to read as follows:

Notwithstanding the above, this term does not include: (a) part-time or per diem employees, contractors, subcontractors, agents and other persons who are not reasonably expected to work more than 160 hours per year performing Covered Functions related to the Covered Operations, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year performing Covered Functions related to the Covered Operations;...

D. Section II.C.3 of the CIA, Government Reimbursed Products, is revised to read as follows:

3. "Government Reimbursed Products" refers to human products of Covered Operations and human products of any Covered Operations foreign subsidiary or foreign affiliate that are promoted or sold by Covered Operations in the United States, where such products are reimbursed by Federal health care programs.

E. Section II.C.4 of the CIA, Promotional and Product Services Related Functions, is revised to read as follows:

4. "Promotional and Product Services Related Functions" include the following functions performed for Covered Operations: (a) the promotion, marketing, advertising, and sale of Government Reimbursed Products; (b) the development or dissemination of materials or information about, or the provision of services, training, or consumer preference testing related to, Government Reimbursed Products; and (c) the activities of the Professional Relations Department.

F. Section II.C.12 of the CIA, Synthes Consultants, is revised to read as follows:

12. "DePuy Synthes Consultants" are employees, contractors, subcontractors, agents and other representatives of DePuy Synthes whose responsibilities include the provision of Promotional and Product Services Related Functions for Covered Operations within assigned geographic territories within the United States, as well as those individuals who serve as Biomaterials Technical Specialists.

G. A new Section II.C.13, "Covered Operations," is added to Section II.C of the CIA and reads as follows:

13. "Covered Operations" shall include the following DePuy Synthes operating companies: Spine; Trauma; CranioMaxillo Facial (CMF); Biomaterials; and Power Tools.

Covered Operations shall not include business operations related to other operating companies, even if housed in the same legal entity as operations related to a Covered Operation. For example, DePuy Synthes may decide to conduct all sales activities through a single legal entity, but only those sales activities related to Spine, Trauma, CMF, Biomaterials, and Power Tools sales forces shall be considered Covered Operations.

H. Section III.A.1 of the CIA, Compliance Officer, is revised to read as follows:

1. *Chief Compliance Officer.* DePuy Synthes shall maintain a chief compliance officer for the Covered Operations for the term of the CIA. The chief compliance officer for the Covered Operations (also referred to as Global Compliance Officer Synthes CIA) shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The chief compliance officer for the Covered Operations shall report to the DePuy Synthes Health Care Compliance Vice President. The chief compliance officer for the Covered Operations shall work with the J&J Chief Compliance Officer to ensure periodic (at least quarterly) reports are made regarding compliance matters directly to the Regulatory, Compliance, and Government Affairs Committee (RCGAC), a committee of the J&J Board of Directors.

The chief compliance officer for the Covered Operations shall not be, or be subordinate to, the legal or finance functions of DePuy Synthes. The chief compliance officer for the Covered Operations shall have and maintain direct access to the World Wide Chair, DePuy Synthes, as well as the President of Synthes, Inc. The chief compliance officer for the Covered Operations shall be responsible for monitoring the day-to-day compliance activities engaged in by the Covered Operations as well as for any reporting obligations created under this CIA. Any job responsibilities of the chief compliance officer for the Covered Operations not related to compliance functions shall be limited and must not interfere with the chief compliance officer's ability to perform the duties outlined in this CIA.

DePuy Synthes shall report to OIG, in writing, any changes in the identity or position description of the chief compliance officer for the Covered Operations, or any actions or changes that would affect the chief compliance officer's ability to perform the duties necessary to meet the obligations in this CIA, within 5 days after such a change.

I. Section III.A.2 of the CIA, Compliance Committee (initial paragraph) is revised to read as follows:

2. *Compliance Committee.* The Compliance Committee, which will be known as the DePuy Synthes Health Care Compliance (HCC) Committee, shall, at a minimum, include the Global Compliance Officer Synthes CIA and the members of senior management with responsibilities relevant to the requirements of this CIA, including the DePuy Synthes World Wide Chair, the DePuy Synthes Health Care Compliance Vice President, the Orthopaedic and Neuro Business Group leads, the Covered Operations presidents or equivalent positions, and the leads for the following functional departments: Finance, Operations, Human Resources, Science and New Technology, Regulatory Affairs, Clinical Affairs, Medical Affairs, Quality, and Legal. The DePuy Synthes Health Care Compliance Vice President will chair the DePuy Synthes HCC

Committee. Each Covered Operation will maintain a HCC Committee that will be composed of at least the Covered Operations Presidents or their equivalents, the Global Compliance Officer Synthes CIA, the Health Care Compliance Officer for the Covered Operation, and the leads for the following functional departments: Finance, Operations, Human Resources, Regulatory Affairs, Clinical Affairs, Medical Affairs, Quality, Legal, Sales, and Marketing. The Health Care Compliance Officer for the Covered Operation will chair the relevant HCC Committee.

J. Section III.A.3 of the CIA, Board of Directors Compliance Obligations, is revised to read as follows:

*3. Board of Directors Compliance Obligations.* The RCGAC is and shall continue to be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The RCGAC must include outside, independent (*i.e.*, non-executive) members.

The RCGAC shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee DePuy Synthes' Compliance Program, including but not limited to the performance of the Global Compliance Officer Synthes CIA and the Compliance Committee;
- b. reviewing the report on the effectiveness of DePuy Synthes' Compliance Program prepared by the Compliance Expert (described below) for each Reporting Period of the CIA. The RCGAC shall review the Compliance Program Review Report (described below) as part of the review and assessment of DePuy Synthes' Compliance Program; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each individual member of the RCGAC summarizing its review and oversight of DePuy Synthes' compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At a minimum, the resolution shall include the following language:

“the RCGAC has made a reasonable inquiry into the operations of the DePuy Synthes Compliance Program for the Covered Operations for the time period [insert time period], including the performance of the Global Compliance Officer Synthes CIA and the Compliance Committee. In addition, the RCGAC has reviewed the results of the Compliance Program Review, including the Compliance Program Review Report prepared by a Compliance Expert with expertise in compliance with Federal health care program and FDA requirements. Based on its inquiry and review, the RCGAC has concluded that to the best of its knowledge, DePuy Synthes has implemented an effective compliance program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

If the RCGAC is unable to provide such a conclusion in the resolution, the RCGAC shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective compliance program at DePuy Synthes.

K. Section III.A.4 of the CIA, Synthes Audit Committee Compliance Obligations, is revised to read as follows:

4. *Synthes Audit Committee Compliance Obligations.* The Audit Committee of the Synthes Inc. Board of Directors shall also be responsible for the review and oversight of matters related to DePuy Synthes' compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

The Synthes Audit Committee shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee the Compliance Program in place at the Covered Operations, including but not limited to the performance of the chief compliance officer for Covered Operations and the DePuy Synthes Health Care Compliance Committee;
- b. arranging for the performance of a review of the effectiveness of the DePuy Synthes Compliance Program (Compliance Program Review) by a Compliance Expert (described below) for the third, fourth, and fifth Reporting Periods of the CIA. The Synthes Audit Committee shall review the Compliance Program Review Report (described below) as part of the review and assessment of the DePuy Synthes Compliance Program. A copy of the Compliance Program Review Report shall be provided to OIG in each Annual Report submitted by DePuy Synthes;
- c. in connection with the Compliance Program Review, DePuy Synthes shall retain an independent individual or entity with expertise in compliance with Federal health care program and FDA requirements (Compliance Expert). The Compliance Expert shall create a work plan for the Compliance Program Review, and prepare a written report about the Compliance Program Review and the results of the review. The written report (Compliance Program Review Report) shall include a description of the review and shall include recommendations with respect to the Compliance Program; and
- d. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Synthes Audit Committee, summarizing its review and oversight of the DePuy Synthes' compliance with Federal health care program requirements, FDA requirements, and the obligations of the CIA.

DePuy Synthes shall report to OIG, in writing, any changes in the composition of the RCGAC or the Synthes Audit Committee, or any actions or changes that would affect the RCGAC's or the Synthes Audit Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

L. Section III.A.5 of the CIA, Management Accountability and Certifications, is revised to read as follows. In addition, the certifications will be revised to replace Synthes with the name of DePuy Synthes or the relevant Covered Operation.

*5 Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain individuals (“Certifying Employees”) are specifically expected to manage, monitor, and oversee activities within their areas of authority, including implementation of this CIA, and shall annually certify that the applicable DePuy Synthes component is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA. These Certifying Employees shall include the World Wide Chair, DePuy Synthes, the head of DePuy Synthes Finance, the head of DePuy Synthes operations, all Covered Operations presidents or their equivalent, any functional leads on the DePuy Synthes Management Board who have oversight of a Covered Operation, including Science and New Technology, Regulatory Affairs, Clinical Affairs, Medical Affairs, and Quality, and excluding Legal, and all members of the Covered Operations’ Management Boards and Leadership Teams. However, for the Second Reporting Period, only individuals in these positions who had a comparable position in legacy Synthes on June 13, 2012 are Certifying Employees.

M. Section III.D of the CIA, Review Procedures, is revised to add the following language:

Notwithstanding section III.D.1.b.i, a Systems Review for Covered Operations shall be performed in the Third Reporting Period instead of in the Fourth Reporting Period. Any material changes in the Covered Operations’ systems, processes, policies, and procedures relating to any of the Covered Functions after June 14, 2012 shall be reviewed during the System Review performed in the Third Reporting Period and shall not trigger a separate Systems Review. All other requirements of section III.D.1.b.i shall remain in effect.

The Transactions Reviews performed during the remaining term of the CIA will not apply to Clinical Investigations, IDE-Exempted Investigations, or Clinical Registries initiated by legacy DePuy Spine prior to December 7, 2012. The Transactions Reviews for the Third, Fourth, and Fifth Reporting Periods will apply only to Clinical Investigation, IDE-Exempted Investigation, and Clinical Registries initiated by Covered Operations of DePuy Synthes.

N. Section III.J.1.a of the CIA, Internal Monitoring Program, Observations, U.S. Compliance Review Program, is revised to add the following language:

The U.S. Compliance Review Program remains in effect for legacy Synthes employees, including legacy Synthes managers and their directly reporting legacy Synthes employees. After December 6, 2012, Section III.J.1.a shall apply only to the Covered Operations.

O. Section III.J.2 of the CIA, Consultant Monitoring Activities, is amended to include the following language:

The requirements of the first paragraph of this section remain in effect for Consultant agreements entered by legacy Synthes prior to June 14, 2012. Such requirements are waived for Consultant agreements entered into by legacy DePuy before December 6, 2012 and services performed pursuant to such agreements, regardless of the date of service. The Consultant

Program Audit requirements apply to HCP arrangements entered into by all Covered Operations on and after December 7, 2012.

The requirements of this Section are waived for HCPs as an attendee at a product training session.

The requirements of this Section are waived for HCPs who would be "Consultants" under this section only by virtue of having their expenses for training covered by DePuy Synthes.

### **III. EFFECTIVE AND BINDING AGREEMENT**

A. All terms and conditions of the CIA not modified in this Amendment shall remain in effect. The Effective Date of this Amendment shall be the date the final signatory signs this Amendment (Amendment Effective Date).

B. The undersigned Synthes and DePuy Synthes signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatories represent that they are signing this Amendment in their official capacities and that they are authorized to execute this Amendment.

C. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Amendment.

ON BEHALF OF SYNTHES, INC.

/Steve Murray/

10/31/2013

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Steve Murray  
President  
Synthes, Inc.

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Date

/Michel Orsinger/

10/31/2013

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Michel Orsinger  
Worldwide Chairman  
Depuy Synthes

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Date

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Jeffrey B. Miller  
Vice President  
Global Synthes CIA Compliance Officer

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Date

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Vickie L. McCormick  
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Vice President

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Date

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Jonathan L. Diesenhaus  
Hogan Lovells US LLP  
Counsel for Synthes, Inc.

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Jeffrey B. Miller  
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/Vickie L. McCormick/

Nov 1, 2013

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Vickie L. McCormick  
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Date

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Robert K. DeConti/

10/31/13

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Robert K. DeConti  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

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Date

/Lee Penninger/MER/

11/1/13

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Lee Penninger  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

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Date