

**U.S. Department of Justice** 

**Criminal Division** 

Fraud Section, Suite 4100, Bond Building 1400 New York Avenue, NW Washington, D.C. 20530

January 14, 2011

# RECEIVED

Eric A. Dubelier Reed Smith LLP 1301 K Street, N.W. Washington, DC 20005-3373

APR - 8 2011

Clerk, U.S. District & Bankruptcy Courts for the District of Columbia

Re: Johnson & Johnson

Dear Mr. Dubelier:

This letter sets out the Deferred Prosecution Agreement (the "Agreement") between Johnson & Johnson, its subsidiaries, and its operating companies (collectively, "J&J") and the United States Department of Justice, Criminal Division, Fraud Section (the "Department of Justice" or the "Department") relating to illegal conduct committed by certain J&J operating companies and subsidiaries.

1. Relevant Parties: J&J, by J&J's undersigned attorneys, pursuant to authority granted by J&J's Board of Directors, and the Department of Justice, enter into this Agreement, which shall bind J&J, its subsidiaries, and its operating companies, including but not limited to DePuy, Inc.; Cilag AG International; and Janssen Pharmaceutica N.V. The terms and conditions of this Agreement are as follows:

2. Criminal Information and Acceptance of Responsibility: J&J accepts and acknowledges that the United States will file a criminal Information in the United States District Court for the District of Columbia charging DePuy, Inc. with conspiracy to commit an offense against the United States, in violation of 18 U.S.C. § 371, that is, to violate the Foreign Corrupt Practices Act of 1977 ("FCPA"), as amended, 15 U.S.C. § 78dd-2 (Count One) and violating the FCPA, 15 U.S.C. § 78dd-2 and 18 U.S.C. § 2 (Count Two).

a. In so doing, J&J, on behalf of itself and DePuy, Inc., knowingly waives DePuy, Inc.'s right to indictment on these charges, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b). In addition, J&J, on behalf of itself and DePuy, Inc., consents to the filing of the Information and the Agreement in the United States District Court for the District of Columbia.

b. J&J admits, accepts, and acknowledges that it is responsible for the acts of its officers, employees and agents, and wholly-owned subsidiaries and operating companies, as set forth in the Statement of Facts attached hereto as "Attachment A," and incorporated by reference into this Agreement, and that the facts described in Attachment A are true and accurate.

Should the Department initiate the prosecution that is deferred by this Agreement, J&J agrees that neither it, DePuy, Inc., nor any J&J operating company or subsidiary will contest the admissibility of, or contradict, in any such proceeding, the Statement of Facts.

3. **Term of the Agreement**: This Agreement is effective for a period beginning on the date the Information is filed in United States District Court and ending three (3) years from that date (the "Term"). However, J&J agrees that, in the event the Department determines, in its sole discretion, that J&J has knowingly violated any provision of this Agreement, an extension or extensions of the term of the Agreement may be imposed by Department, in its sole discretion, for up to a total additional time period of one year. Any extension of the Agreement extends all terms of this Agreement for an equivalent period. Conversely, in the event the Department finds, in its sole discretion, that there exists a change in circumstances sufficient to eliminate the need for reporting and the other provisions of this Agreement have been satisfied, the Agreement may be terminated early.

4. **Relevant Considerations**: The Department enters into this Agreement based on the following factors:

a. J&J voluntarily and timely disclosed the majority of the misconduct described in the Information and Statement of Facts;

b. J&J conducted a thorough internal investigation of that misconduct;

- c. J&J reported all of its findings to the Department;
- d. J&J cooperated fully with the Department's investigation of this matter;

e. J&J has undertaken substantial remedial measures as contemplated by this Agreement;

f. J&J has agreed to continue to cooperate with the Department in any investigation of the conduct of J&J and its directors, officers, employees, agents, consultants, subsidiaries, contractors, and subcontractors relating to violations of the FCPA and related statutes;

g. J&J has cooperated and agreed to continue to cooperate with the Securities and Exchange Commission (the "SEC") and, at the direction of the Department, foreign authorities investigating the conduct of J&J and its directors, officers, employees, agents, consultants, subsidiaries, contractors, and subcontractors relating to corrupt payments;

h. J&J has cooperated and agreed to continue to cooperate with the Department in the Department's investigations of other companies and individuals in connection with business practices overseas in various markets; i. J&J has also agreed to resolve related cases being investigated by the SEC and the United Kingdom Serious Fraud Office (the "SFO"); and

j. Were the Department to initiate a prosecution of J&J or one of its operating companies and obtain a conviction, instead of entering into this Agreement to defer prosecution, J&J could be subject to exclusion from participation in federal health care programs pursuant to 42 U.S.C. § 1320a-7(a).

k. With respect to the corporate compliance reporting obligations set forth in paragraph 11, the Department based that element of this Agreement on the following representations by J&J:

- i. J&J has already engaged in significant remediation of the misconduct described in the statement of facts and reviewed and improved its compliance program and implementation thereof;
- ii. J&J conducted an extensive, global review of all of its operations to determine if there were problems elsewhere and has reported on any areas of concerns to the Department and the SEC;
- iii. J&J has and will undertake enhanced compliance obligations described in paragraph 10 and Attachment D;
- iv. J&J's cooperation during this investigation and its substantial assistance in investigations of others has been extraordinary; and
- v. J&J had a pre-existing compliance and ethics program that was effective and the majority of problematic operations globally resulted from insufficient implementation of the J&J compliance and ethics program in acquired companies.

5. **Cooperation:** During the Term of this Agreement, J&J agrees to cooperate fully with the Department, the SEC, and any other authority or agency, domestic or foreign, designated by the Department, in any investigation of J&J or any subsidiary or operating company thereof, or any of its present or former directors, officers, employees, agents, consultants, subsidiaries, contractors, or subcontractors, or any other party, in any and all matters relating to corrupt payments. J&J agrees that its cooperation shall include, but is not limited to, the following:

a. J&J shall truthfully disclose all non-privileged information with respect to the activities of J&J and its present and former directors, officers, employees, agents, subsidiaries, consultants, contractors, and subcontractors thereof, concerning all matters relating to corrupt payments, related false books and records, and related internal controls, about which J&J has any knowledge or about which the Department may inquire. This obligation of truthful disclosure includes the obligation of J&J to provide to the Department, upon request, any nonprivileged document, record, or other tangible evidence relating to such corrupt payments, books and records, and internal controls about which the Department may inquire of J&J.

b. Upon request of the Department, with respect to any issue relevant to its investigation of corrupt payments in connection with the operations of J&J, related books and records, and inadequate internal controls, J&J shall designate knowledgeable employees, agents, or attorneys to provide to the Department the information and materials described in Paragraph 6(a) above, on behalf of J&J. It is further understood that J&J must at all times provide complete, truthful, and accurate information.

c. With respect to any issue relevant to the Department's investigation of corrupt payments in connection with the operations of J&J, any of its present or former subsidiaries or affiliates, or any other company or individual, consistent with applicable law, J&J shall use all reasonable efforts to make available for interviews or testimony, as requested by the Department, present or former directors, officers, employees, agents, and consultants of J&J as well as the directors, officers, employees, agents, and consultants of contractors and subcontractors. This obligation includes, but is not limited to, sworn testimony before a federal grand jury or in federal trials, as well as interviews with federal law enforcement authorities. Cooperation under this paragraph will include identification of witnesses who, to the knowledge of J&J, may have material information regarding the matters under investigation.

d. With respect to any information, testimony, documents, records, or other tangible evidence provided to the Department pursuant to this Agreement, J&J consents to any and all disclosures to other governmental authorities, whether United States authorities or those of a foreign government, of such materials as the Department, in its sole discretion, shall deem appropriate.

6. **Payment of Monetary Penalty**: The Department and J&J agree that the application of the United States Sentencing Guidelines ("USSG" or "Sentencing Guidelines") to determine the applicable fine range yields the following analysis:

a. The 2006 USSG are applicable to this matter.

b. <u>Base Offense</u>. Based upon USSG §§ 2C1.1 and 8C4.1, the total offense level is 34, calculated as follows:

2C1.1(a)(2)	Base Offense Level	12
2C1.1(b)(1)	More than one bribe	+2
2C1.1(b)(2)	Value of benefit received more that \$20,000,000	+22
8C4.1	Substantial assistance in the prosecution of others	-2

TOTAL OFFENSE LEVEL 34

c. <u>Base Fine</u>. Based upon USSG § 8C2.4(a)(1) and (d), the base fine is \$28,500,000 (the fine indicated in the Offense Level Fine Table (\$28,500,000) is used where such number is greater than the pecuniary gain to the organization from the offense (approximately \$24,000,000)).

d. <u>Culpability Score</u>. Based upon USSG § 8C2.5, the culpability score is 5, calculated as follows:

(a)	Base Culpability Score	5
(b)(1)	Organization had 5,000 or more employees and an individual within high-level personnel of the organization participated in, condoned, or was wilfully ignorant of the offense	+5
(g)(1)	The organization, prior to an imminent threat of disclosure or government investigation, within a reasonably prompt time after becoming aware of the offense, reported the offense, fully cooperated, and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct;	-5
TOTAL CULPABILITY SCORE		5
Calculation of Fine Range.		
Base Fine \$28,500,000		

Fine Range \$28,500,000-\$57,000,000

1.0 (minimum)/2.0 (maximum)

Subject to the terms of Paragraph 8 below, J&J agrees to pay a monetary penalty in the amount of \$21,400,000, a 25 percent reduction off the bottom of the fine range, to the United States Treasury within ten days of the execution of this Agreement. J&J and the Department agree that this fine is appropriate given J&J's voluntary and thorough disclosure of the misconduct at issue, the nature and extent of J&J's cooperation in this matter, penalties related to the same conduct in the United Kingdom and Greece, J&J's cooperation in the Department's investigation of other companies, and J&J's extraordinary remediation. The \$21,400,000 penalty is final and shall not be refunded if the Department moves to dismiss the Information pursuant to this Agreement, or should the Department later determine that J&J has breached this Agreement and bring a prosecution against J&J. Furthermore, nothing in this Agreement shall be deemed an agreement by the Department that the \$21400,000 amount is the maximum penalty that may be imposed in

e.

Multipliers

any such prosecution, and the Department is not precluded from arguing that the Court should impose a higher fine, although the Department agrees that under those circumstances, it will recommend to the Court that the amount paid under this Agreement should be offset against any fine the Court imposes as part of a judgment.

7. **Conditional Release from Criminal Liability**: In return for the full and truthful cooperation of J&J or any of its wholly-owned or controlled subsidiaries and operating companies, and compliance with the terms and conditions of this Agreement, the Department agrees not to use any information related to the conduct described in the attached Statement of Facts against J&J in any criminal or civil case, except: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of Title 26 of the United States Code. In addition, the Department agrees, except as provided herein, that it will not bring any criminal or civil case against J&J, its subsidiaries, or its operating companies related to the conduct of present and former directors, officers, employees, agents, consultants, contractors, and subcontractors, as described in the attached Statement of Facts, or relating to any other conduct J&J disclosed to the Department prior to the date on which this Agreement was signed.

a. This paragraph does not provide any protection against prosecution for any corrupt payments or false accounting, if any, made after the effective date of this Agreement by J&J or any of its directors, officers, employees, agents, consultants, contractors, and subcontractors, irrespective of whether disclosed by J&J, pursuant to the terms of this Agreement.

b. This paragraph also does not provide any protection against prosecution for any corrupt payments made in the past which are not described in the attached Statement of Facts or which were not disclosed to the Department prior to the date on which this Agreement was signed. In addition, this paragraph does not provide any protection against criminal prosecution of any present or former director, officer, employee, shareholder, agent, or consultant of J&J for any violations of law committed by them.

8. **Corporate Compliance Program**: J&J represents that it has implemented and will continue to implement and maintain a compliance program designed to detect and prevent violations of the FCPA and other applicable anticorruption laws throughout its operations, including those of its affiliates, joint ventures, and contractors, with responsibilities that include interactions with foreign officials. Implementation of these policies and procedures shall not be construed in any future enforcement proceeding as providing immunity or amnesty for any crimes not disclosed to the Department as of the date of signing of this Agreement for which J&J would otherwise be responsible.

9. In order to address any deficiencies in its internal controls, policies, and procedures regarding compliance with the FCPA and other applicable anticorruption laws, J&J represents

that it has undertaken, or will undertake in the near future, in a manner consistent with all of its obligations under this Agreement, a review of its existing internal controls, policies, and procedures. Where necessary and appropriate, J&J will adopt new, or modify existing, internal controls, policies, and procedures in order to ensure that J&J maintains: (a) a system of internal accounting controls designed to ensure the making and keeping of fair and accurate books, records, and accounts; and (b) a rigorous anticorruption compliance system designed to deter and detect violations of the FCPA and other applicable anticorruption laws. The internal controls and compliance system will include, but not be limited to, the minimum elements set forth in Attachment C, which is incorporated by reference into this Agreement.

10. **Enhanced Compliance Undertakings:** J&J represents that it has or will undertake, at a minimum, the enhanced compliance obligations described in Attachment D, for the duration of this Agreement.

11. **Corporate Compliance Reporting**: J&J agrees that it will report to the Department periodically, at no less than six-month intervals, during a three-year term regarding remediation and implementation of the compliance measures described in Attachment C. J&J shall designate a senior company officer as the person responsible for overseeing J&J's corporate compliance reporting obligations. Should J&J discover credible evidence that questionable or corrupt payments or questionable or corrupt transfers of property or interests may have been offered, promised, paid, or authorized by any J&J entity or person, or any entity or person working directly for J&J, or that related false books and records have been maintained, J&J shall promptly report such conduct to the Department. During this three-year period, J&J shall: (1) conduct an initial review and submit an initial report, and (2) conduct and prepare at least five follow-up reviews and reports, as described below:

a. J&J shall submit to the Department a written report within 180 calendar days of the signing of this Agreement setting forth a complete description of its remediation efforts to date, its proposals reasonably designed to improve the internal controls, policies, and procedures of J&J for ensuring compliance with the FCPA and other applicable anticorruption laws, and the proposed scope of the subsequent reviews. The report shall be transmitted to Deputy Chief – FCPA Unit, Fraud Section, Criminal Division, U.S. Department of Justice, 10th and Constitution Ave., N.W., Bond Building, Fourth Floor, Washington, D.C., 20530. J&J may extend the time period for issuance of the report with prior written approval of the Department.

b. J&J shall undertake at least five follow-up reviews, after considering the Department's views and comments on J&J's prior reviews and reports, to further monitor and assess whether the policies and procedures of J&J are reasonably designed to detect and prevent violations of the FCPA and other applicable anticorruption laws.

c. The first follow-up review and report shall be completed by no later than 180 days after the initial review. Subsequent follow-up reviews and reports shall be completed by no later than 180 after the completion of the preceding follow-up review.

d. J&J may extend the time period for submission of any of the follow-up reports with prior written approval of the Department.

12. **Deferred Prosecution**: In consideration of: (a) the factors set forth in Paragraph 4 above; (b) the past and future cooperation of J&J described in Paragraphs 5 and 6 above; (b) J&J's payment of a monetary penalty of \$21.4 million; and (c) J&J's adoption and maintenance of remedial measures, and review and audit of such measures, including the compliance undertakings described in Paragraphs 9 through 11 above, the Department agrees that any prosecution of J&J or its subsidiaries or operating companies, including DePuy, Inc., for the conduct set forth in the attached Statement of Facts, and for the conduct relating to information that J&J disclosed to the Department prior to the signing of this Agreement, be and hereby is deferred for the Term of this Agreement. The Department further agrees that if J&J fully complies with all of its obligations under this Agreement, the Department will not continue the criminal prosecution against DePuy, Inc. described in Paragraph 2 and, after the Term, this Agreement shall expire and the Department will move to dismiss with prejudice the criminal Information pending against DePuy, Inc.

13. Breach of the Agreement: If, during the Term of this Agreement, the Department determines, in its sole discretion, that J&J (including DePuy, Inc. or any of J&J's wholly-owned subsidiaries or operating companies) has committed felony under federal law<sup>1</sup> subsequent to the signing of this Agreement; has, at any time, provided deliberately false, incomplete, or misleading information; or has otherwise breached the Agreement, J&J shall thereafter be subject to prosecution for any federal criminal violation of which the Department has knowledge. Any such prosecution may be premised on information provided by J&J. Any such prosecution that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against J&J notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, J&J agrees that the statute of limitations with respect to any prosecution that is not time-barred on the date of this Agreement shall be tolled for the Term plus one year. J&J acknowledges that the Department has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if J&J breaches this Agreement and this matter proceeds to judgment. J&J further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion. In the event that the Department determines that J&J has breached this Agreement:

a. All statements made by or on behalf of J&J to the Department or to the Court, including the attached Statement of Facts, and any testimony given by J&J before a grand jury or any tribunal, at any legislative hearings whether prior or subsequent to this Agreement, or any leads derived from such statements or testimony, shall be admissible in evidence in any and

<sup>&</sup>lt;sup>1</sup> The filing or unsealing of a qui tam action shall not, by itself, constitute a breach of this Agreement.

all criminal proceedings brought by the Department against J&J (including DePuy, Inc. and any of J&J's wholly-owned subsidiaries and operating companies); and

b. J&J shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule, that statements made by or on behalf of J&J prior or subsequent to this Agreement, and any leads derived therefrom, should be suppressed. The decision whether conduct or statements of any individual will be imputed to J&J for the purpose of determining whether J&J has violated any provision of this Agreement shall be in the sole discretion of the Department.

14. **Sale or Merger of J&J**: J&J agrees that in the event it sells, merges, or transfers all or substantially all of its business operations as they exist as of the date of this Agreement, whether such sale is structured as a stock or asset sale, merger, or transfer, it shall include in any contract for sale, merger, or transfer a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement.

15. **Public Statements by J&J**: J&J expressly agrees that it shall not, through present or future attorneys, directors, officers, employees, agents, or any other person authorized to speak for J&J make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by J&J set forth above or the facts described in the attached Statement of Facts. Any such contradictory statement shall, subject to cure rights of J&J described below, constitute a breach of this Agreement and J&J thereafter shall be subject to prosecution as set forth in Paragraphs 12 and 13 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to J&J for the purpose of determining whether they have breached this Agreement shall be at the sole discretion of the Department. If the Department determines that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the Department shall so notify J&J, and J&J may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. Consistent with the obligations of J&J as set forth above, J&J shall be permitted to raise defenses and to assert affirmative claims in civil and regulatory proceedings relating to the matters set forth in the Statement of Facts. This paragraph does not apply to any statement made by any present or former employee of J&J in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is then specifically authorized to speak on behalf of J&J. J&J shall not issue a press release in connection with this Agreement unless it first determines that the text of the release is acceptable to the Department.

16. **Limitations on Binding Effect of Agreement**: This Agreement is binding on J&J and the Department but specifically does not bind any other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, although the Department will bring the cooperation of J&J and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by J&J.

17. **Complete Agreement:** This Agreement sets forth all the terms of the Deferred Prosecution Agreement between J&J and the Department. No amendments, modifications, or additions to this Agreement shall be valid unless they are in writing and signed by the Department and a duly authorized representative of J&J.

18. Notice: Any notice to the Department under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, in each case, for the Department, addressed to Deputy Chief - FCPA, Fraud Section, Criminal Division, U.S. Department of Justice, 1400 New York Avenue, N.W., Washington, D.C. 20005 and, for J&J, addressed to William Craco, Senior Counsel, Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey, 08933. Notice shall be effective upon actual receipt by the Department or J&J.

AGREED:

FOR JOHNSON & JOHNSON :

ERIC A. DUBELIER Reed Smith LLP Counsel for Johnson & Johnson

RUSSELL C. DEYO

Vice President and General Counsel Johnson & Johnson

FOR THE DEPARTMENT OF JUSTICE:

PAUL PELLETIER Principal Deputy Chief, Fraud Section

By:

KATHLEEN M HAMANN Trial Attorney, Fraud Section Criminal Division United States Department of Justice 1400 New York Avenue, NW Washington, D.C. 20530 (202) 305-7413

Filed at Washington, D.C., on this day of april 2011.

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#### **OFFICER'S CERTIFICATE**

I have read this Agreement and carefully reviewed every part of it with counsel for Johnson & Johnson, its subsidiaries, and its operating companies (collectively, "J&J"). I understand the terms of this Agreement and voluntarily agree, on behalf of J&J, to each of its terms. Before signing this Agreement, I consulted with the attorney for J&J. The attorney fully advised me of the rights of J&J, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed this Agreement with the Board of Directors of Johnson & Johnson. I have advised, and caused outside counsel for J&J to advise, that Board fully of the rights of J&J, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into the Agreement.

No promises or inducements have been made other than those contained in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of J&J, in any way to enter into this Agreement. I am alsosatisfied with the attorney's representation in this matter. I certify that I am an officer of Johnson & Johnson and that I have been duly authorized by Johnson & Johnson to execute this Agreement on behalf of J&J.

Date: <u>April 6</u>, 2011

Johnson & Johnson

By:

Vice President and General Counsel Johnson & Johnson

#### **CERTIFICATE OF COUNSEL**

I am counsel for Johnson & Johnson, its subsidiaries, and its operating companies (collectively "J&J") in the matter covered by this Agreement. In connection with such representation, I have examined relevant J&J documents and have discussed this Agreement with the Johnson & Johnson Board of Directors. Based on my review of the foregoing materials and discussions, I am of the opinion that: the representative of Johnson & Johnson has been duly authorized to enter into this Agreement on behalf of J&J and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of J&J and is a valid and binding obligation of J&J. Further, I have carefully reviewed this Agreement with the Board of Directors and General Counsel of Johnson & Johnson. I have fully advised them of the rights of J&J, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement. To my knowledge, the decision of J&J to enter into this Agreement is an informed and voluntary one.

Date: <u>April 6</u>, 2011

Eric A. Dubelier

Eric A. Dubeller Reed Smith, LLP Counsel for Johnson & Johnson

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## ATTACHMENT A

# STATEMENT OF FACTS

The following Statement of Facts is incorporated by this reference as part of the Deferred Prosecution Agreement (the "Agreement") between the United States Department of Justice, Criminal Division, Fraud Section (the "Department") and Johnson & Johnson, its subsidiaries, and its operating companies (collectively, "J&J") and the parties hereby agree and stipulate that the following information is true and accurate. As set forth in Paragraph 2 of the Agreement, J&J accepts and acknowledges that it is responsible for the acts of its officers, employees and agents as set forth below.

Should the Department initiate the prosecution that is deferred by this Agreement, J&J agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding.

# BACKGROUND

# The Foreign Corrupt Practices Act

1. The Foreign Corrupt Practices Act of 1977 ("FCPA"), as amended, Title 15, United States Code, Sections 78dd-1, *et seq.*, was enacted by Congress for the purpose of, among other things, making it unlawful for certain classes of persons and entities to act corruptly in furtherance of an offer, promise, authorization, or payment of money or anything of value to a foreign government official for the purpose of securing any improper advantage, or of obtaining or retaining business for, or directing business to, any person. The FCPA also requires that any issuer of securities shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the issuer.

# The United Nations Oil-for-Food Program

2. On or around August 6, 1990, days after Iraq's invasion of Kuwait, the U.N. adopted Security Council Resolution 661, which prohibited U.N. member states from transacting business with Iraq, except for the purchase and sale of humanitarian supplies. Resolution 661 prohibited virtually all direct financial transactions with the government of Iraq.

3. On or around April 15, 1995, the U.N. adopted Security Council Resolution 986, which provided a limited exception to the Iraq sanctions regime in that it allowed Iraq to sell its oil, but required that the proceeds of oil sales be used by the Iraqi government to purchase humanitarian supplies for the Iraqi people, including food and medicine. Hence, this program became known as the Oil for Food Program ("OFFP"). Payments made to the Iraqi government which were not approved by the U.N. and which were outside the strict contours of the OFFP were prohibited. From in or around December 1996 through March 2003, the United States

government prohibited United States companies and individuals from engaging in transactions with the government of Iraq, unless such transactions were authorized by the U.N. pursuant to the OFFP. 31 C.F.R. § 575.201, *et seq*.

4. Under the provisions of the OFFP, a supplier of humanitarian goods contracted with a ministry or other department of the Iraqi government to sell goods to the Iraqi government. Once that contract was finalized, the contract was submitted to a U.N. Committee (the "661 Committee") which reviewed the contracts to ensure that their terms complied with all OFFP and Iraqi sanction regulations.

5. Beginning in approximately August 2000, the Iraqi government demanded that suppliers of humanitarian goods pay a kickback, usually valued at 10% of the contract price, to the Iraqi government in order to be awarded a contract by the government. These kickbacks violated U.N. OFFP regulations and U.N. sanctions which prohibited payments to the Iraqi government which were not expressly approved by the U.N. and which were not contemplated by OFFP guidelines.

6. Typically, these kickbacks were included in the contract price submitted by the supplier to the U.N. without disclosing to the U.N. the fact that the contract contained an extra 10% which would be kicked back to the Iraqi government. Including the 10% in the submitted contract price allowed the supplier to avoid paying the 10% out of its profits; instead, the suppliers caused the U.N., unknowingly, to fund the kickbacks to the Iraqi government.

# Relevant Entities

7. Johnson & Johnson ("J&J") was incorporated in New Jersey and had its principal place of business in New Brunswick, New Jersey. It issued and maintained a class of publicly-traded securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934 (15 U.S.C. § 781), which traded on the New York Stock Exchange. As such, it was required to file periodic reports with the United States Securities and Exchange Commission under Section 13 of the Securities Exchange Act (15 U.S.C. § 78m). Accordingly, J&J was an "issuer" within the meaning of the Foreign Corrupt Practices Act ("FCPA"), 15 U.S.C. § 78dd-1(a). By virtue of its status as an issuer, J&J was required to make and keep books, records, and accounts which, in reasonable detail, accurately and fairly reflected the transactions and disposition of assets of J&J and its subsidiaries, including those described below, which were incorporated into the books, records, and accounts of J&J.

8. DePuy, Inc. ("DePuy"), a wholly-owned subsidiary of J&J, together with related companies, was a global manufacturer and supplier of orthopedic medical devices. DePuy, Inc. was incorporated in Delaware and headquartered in Warsaw, Indiana, and maintained operations in a number of foreign countries. DePuy was a "domestic concern" as that term is defined by the FCPA, 15 U.S.C. § 78dd-2(h)(1)(B).

9. DePuy International, a wholly-owned subsidiary of J&J, was a global supplier of orthopedic medical devices and handled the sale of DePuy products in Europe, Asia, the Middle East, and Africa. DePuy International was incorporated in the United Kingdom and headquartered in Leeds, United Kingdom, and maintained operations in a number of foreign countries. As such, DePuy International was an agent of a domestic concern under the FCPA.

10. "Company X," based in Athens, Greece, was an agent and distributor for DePuy and its subsidiaries in Greece until February 2001, when it was acquired by DePuy. After Company X was acquired, it became DePuy Medec, and was later renamed DePuy Hellas ("DePuy Hellas"). As such, Company X was an agent of a domestic concern under the FCPA.

11. "Company Y," based in the Isle of Man, was a consultant for DePuy International in Greece until May 1999.

12. Johnson & Johnson Poland Sp. z.o.o. ("J&J Poland"), a wholly-owned subsidiary of J&J, was a supplier of orthopedic medical devices in Poland. J&J Poland was headquartered in Warsaw, Poland.

13. Johnson & Johnson d.o.o. ("J&J Romania"), a wholly-owned subsidiary of J&J, was a supplier of pharmaceuticals in Romania. J&J Romania was headquartered in Bucharest, Romania.

14. Janssen Pharmaceutica, NV ("Janssen"), a wholly-owned subsidiary of Johnson & Johnson, was a global manufacturer and supplier of pharmaceuticals. It was headquartered in Beerse, Belgium, and maintained operations in a number of foreign countries.

15. Cilag AG International ("Cilag"), a wholly-owned subsidiary of Johnson & Johnson, was a global manufacturer and supplier of pharmaceuticals. It was headquartered in Schaffhausen, Switzerland, and maintained operations in a number of foreign countries.

16. Janssen and Cilag sold pharmaceutical products under the Oil for Food program through their joint representative office in Beirut, Lebanon ("JC-Lebanon").

# Relevant Individuals

17. "Executive A," a British citizen, was an officer and senior executive in charge of DePuy at the time it was purchased by J&J, and retained that position until 1999, when he became a senior executive at J&J, retaining control of DePuy and its related operating companies.

18. "Executive B," a U.S. citizen, was an officer and senior executive of DePuy.

19. "DPI VP Marketing," a British citizen, was Vice President of Marketing and Development for DePuy International.

20. "DPI VP Finance," a British citizen, was Vice President of Finance for DePuy International.

21. "DPI President," a British citizen, was a President of DePuy International.

22. "DPI Counsel," a British citizen, was in-house counsel for DePuy International.

23. "DPI Accountant," a British citizen, was an accountant for DePuy International.

24. "Greek Agent A," a Greek national, was the beneficial owner of both Company X and Company Y, and acted as a distributor for and a consultant to DePuy International and DePuy Hellas.

25. "Greek Agent B," a Greek national, acted as a consultant to DePuy International and DePuy Hellas.

26. "DePuy Hellas MD," a Greek national, was an employee of Company X until it was acquired by J&J, when she became the Managing Director of DePuy Hellas.

27. "JC-Lebanon Agent," a Lebanese citizen, was the agent for both Janssen and Cilag in Iraq. He was based in Beirut, Lebanon.

# GREECE

# Background

28. Greece has a national healthcare system wherein most Greek hospitals are publicly owned and operated. Health care providers who work at publicly-owned hospitals ("HCPs") are government employees, providing health care services in their official capacities. Therefore, such HCPs in Greece are "foreign officials" as that term is defined in the FCPA, 15 U.S.C. 78dd-2(h)(2)(A).

29. In November 1998, J&J acquired DePuy, including its subsidiary, DePuy International. At the time of the acquisition, DePuy International had a distribution agreement with Company X, which provided that Company X would be DePuy's exclusive distributor of medical devices in Greece. DePuy continued to distribute its products through Company X and maintained its consulting contract with Company Y after acquisition. DePuy maintained the relationship with Company X and/or its principal or a successor agent until in or around late 2005.

## Payments Through Company X

30. From in or around 1998 to in or around May 1999, Company X received a 35% discount in the price it paid for DePuy's products for sale into the Greek market. At the same time, DePuy International had an agreement with Company Y, which provided that DePuy International would pay Company Y 25% of all net invoiced sales to Company X. In fact, DePuy International actually paid Company Y 35% of net sales to Company X. These payments to Company Y were made into an account in the Isle of Man.

31. On or around March 22, 1999, an employee of a J&J umbrella company sent an email to the manager of J&J operations in Greece, stating that, "it is clear that [Greek Agent A] has managed over the year to build off-shore accounts through various representations he has, which in turn helped him to have significant competitive advantage when dealing with Greek surgeons," and describing instances in which Greek Agent A had made payments to Greek surgeons to induce the purchase of products he distributed.

32. In or around May 1999, DePuy International terminated its contract with Company Y.

# Acquisition of Company X

33. On or around January 10, 2000, Greek Agent A wrote a letter to Executive A and others regarding Greek Agent A's ongoing relationship with DePuy International and DePuy International's "decision to terminate the market support," in which Greek Agent A requested an urgent meeting with Executive A.

34. On or around January 20, 2000, DPI VP Marketing, DPI VP Finance, DPI President, and Executive A met in Dublin, Ireland to discuss the contract with Company X. The three DePuy International employees recommended that the relationship with Greek Agent A be terminated, in part because Greek Agent A was making cash payments to Greek surgeons to induce the purchase of DePuy products. In that meeting, Executive A agreed to terminate the relationship with Greek Agent A and Company X.

35. Subsequent to that meeting, also on or around January 20, 2000, Executive A and DPI President met with representatives of Company X, at which time Executive A suggested that J&J acquire Company X and retain Greek Agent A as a consultant, notwithstanding Executive A's earlier agreement to terminate the relationship with Greek Agent A and Company X.

36. On or around February 8, 2000, Greek Agent A sent an email to DPI President, copying Executive A, DPI VP Marketing, and DPI VP Finance, regarding an upcoming meeting, in which email Greek Agent A noted the need to "negotiate a new service agreement" similar to the agreement with Company X, as well as a need "to negotiate a mechanism to cover up for sales promotional costs," which he characterized as "cash incentives."

37. On or around March 13, 2000, DPI VP Marketing emailed a report on the status of the acquisition of Company X, copying DPI VP Finance. In the report, DPI VP Marketing stated that they planned to "pay a 30% sales commission to [Greek Agent A]," and that Greek Agent A "would take his personal remuneration and any other local support payments that he needed from this sum."

38. On or around April 17, 2000, DPI VP Finance, Greek Agent A, and others met in Greece to discuss acquisition of Company X, during which meeting, Greek Agent A stated that "any adverse changes to [Company X's] way of dealing would negatively affect [his] ability to make sales."

39. On or around April 17, 2000, DPI Counsel called Executive B in Indiana to discuss the Company X acquisition and due diligence on Greek Agent A.

40. On or around April 21, 2000, DPI VP Finance sent an email to Executive B in Indiana, recommending various ways to ensure that Greek Agent A received the funds needed "to secure the business" in a manner that would "pass[] the red face test," and noting that "we cannot accommodate \$2.3 million in special payments and hide them in the acquisition deal or consultancy agreement." He added that the prior distribution model could not be reinstated because "it requires significant offshore payments and [Greek Agent A] would have to falsify expenses to make the payments...," that Greek Agent A could use his consultancy fees "to fund the special payments \$8 [million]," and that he and Executive B should talk to DPI VP Marketing and decide what to say to Executive A.

41. On or around April 27, 2000, Executive A sent an email from New Jersey to other J&J employees noting that termination of agreements with Greek Agent A would result in the loss of half of J&J's business in Greece, stating, "to lose approximately \$4m in sales in end user terms to the competition is totally unacceptable," and stating that they were trying to find an alternate solution that included acquiring Company X and finding a way to "handle the in market customer practices."

42. In or around October 2000, DePuy International finalized acquisition terms with Company X, including payment of a consultancy fee to Greek Agent A, totaling 27% of net sales, to be paid in advance on a quarterly basis.

43. On or around November 13, 2000, DPI Accountant received an email from Greek Agent A's accountant requesting that DPI Accountant speak with DPI VP Finance regarding the 35% owed to Greek Agent A on sales since termination of the agreement with Company X. The email stated, "as you are aware... these [sic] money are cash incentives and are paid net to the recipients."

44. On or around December 11, 2000, Greek Agent A's accountant sent a memorandum to DPI VP Marketing, DPI VP Finance, DPI Accountant, and Greek Agent A's assistant (who later became DePuy Hellas MD), in which he objected to a delay in the first payment on closing, stating, "This payment of USD 1.6 million is absolutely necessary for [Greek Agent A] because he has to pay cash incentives for sales up to the end of January 2001."

45. On or around December 11, 2000, DPI VP Finance responded to all recipients of Agent A's accountant's December 11, 2000 email, stating, "I [am] very disappointed to read in your proposal that it contains references to [Greek Agent A's] activities which cannot be mentioned in written correspondence with [DePuy International]."

46. On or around December 13, 2000, Agent A's accountant replied to the December 11, 2000 email from DPI VP Finance, asking to what DPI VP Finance was objecting, to which DPI VP Finance responded, "[Greek Agent A] need for prepayment," and stated that he "cannot file this document."

47. On or around December 17, 2000, Greek Agent A's accountant emailed DPI Accountant again, noting "the goods that are imported from [DePuy, Inc.] are overstated by 35% to cover the value of 'cash incentives."

48. In or around early December 2000, Company X issued \$1.4 million in dividends, to be paid to Greek Agent A by DePuy International subsequent to closing.

49. On or around December 20, 2000, immediately prior to the closing of the acquisition, Company X signed an agreement with Greek Agent A. The agreement provided for the payment to Greek Agent A of 27% of net invoiced sales in Greece, to be paid quarterly in advance.

50. On or around January 30, 2001, Greek Agent A signed a final consulting agreement with DePuy Hellas.

51. On or around February 23, 2001, DePuy International acquired Company X and it became DePuy Medec (later renamed DePuy Hellas). On the instruction of Executive A, DePuy Hellas MD was made Managing Director of DePuy Hellas.

52. On or around June 5, 2001, Greek Agent A sent a memorandum to DPI VP Marketing, stating, "The existence of cash incentives to surgeons is common knowledge in Greece. One of the intentions of this new law is to face this problem. This makes the necessity for an effective application of the arms-length precaution even greater than ever." Greek Agent A noted that, under a consulting arrangement, the consulting fee should be "sufficient to cover [DePuy International] and J&J cash incentives' cost and the relevant tax, plus a reasonable profit for the Consultant's services." He then noted that under a distributor arrangement, "selling price must be carefully calculated so that the distributor's profit would be sufficient to pay cash incentives." He concluded, "J&J cash incentives are estimated at 30% on sales, based on the information [Greek Agent A] has from several surgeons. This percentage represents the actual cash received by the surgeons...."

53. On or around June 29, 2001, Greek Agent A sent a letter to DePuy Hellas MD complaining about delays in the payment of his consultancy fees, because it forced him to make "costly" arrangements to "secure the amounts necessary to provide the sales of new company's products...." DePuy Hellas MD forwarded this letter to DPI VP Marketing, DPI VP Finance, and DPI Accountant.

54. On or around October 1, 2001, DPI President emailed to Executive A in New Brunswick, New Jersey, financial information on the 2002 business plan for Greece, including the ongoing payments to Greek Agent A.

55. On or around October 1, 2001, DePuy International and DePuy Hellas signed new agreements with Greek Agent A, splitting his commission such that DePuy International paid 15% and DePuy Hellas paid 12%, to increase to 16% in 2003.

56. On or around October 10, 2003, DePuy International decided to terminate Greek Agent A's consultancy agreement effective October 15, 2003.

57. From in or around April 2001 to in or around October 2003, Greek Agent A was paid approximately €7,987,540, a significant portion of which was used to pay cash incentives to Greek HCPs to induce the purchase of DePuy products.

# Change of Agents

58. On or around October 29, 2003, DePuy International signed a memorandum of understanding with Greek Agent B, providing for payments to Greek Agent B of 15% of net invoiced sales of J&J's medical devices in Greece.

59. Also on October 29, 2003, DePuy Hellas signed a consulting agreement with Greek Agent B, providing for payment to Greek Agent B of 16% of net invoiced sales.

60. On or around May 11, 2004, DePuy Hellas's outside auditors issued a report stating that the services provided by Greek Agent A were insufficiently described in tax documentation, noting, "the description of services is not sufficient as it does not describe the services at all."

61. On or around May 11, 2004, JJH's accountant wrote DPI Accountant, stating that he could "change the wording in the documents of [Greek Agent A] as well in [sic] [Greek Agent B]...," repeating that he had "the books of [the agents], so I can make certain changes in the invoices for the wording if this is important."

62. On February 9, 2005, DPI VP Marketing responded to an email from DPI Counsel regarding training on the Eucomed Code of Business Practice, stating that everyone in the industry provided improper incentives to HCPs, and if DePuy did not do so, "we'd lose 95% of our business [in Greece] by the end of the year."

63. In or around late February 2005, Executive A instructed DPI VP Marketing that J&J would not exit the Greek market and that all intermediary relationships should be terminated.

64. In or around early 2005, DPI Accountant, while in the United Kingdom, called Executive B in Indiana and told him that there were problems in Greece and that he should investigate.

65. In or around spring 2005, Executive B traveled to the United Kingdom from Indiana. While in the United Kingdom, both DPI Accountant and DPI VP Marketing encouraged Executive B to investigate problems in Greece.

66. Executive B continued to communicate with DPI VP Marketing by telephone and email regarding the status of discussions at DPI relating to business planning for 2006 that would not involve the use of a sales intermediary in Greece. However, Executive B did not conduct an investigation of past problems in Greece or take any steps to halt improper payments being made in Greece at the time.

67. On or around September 27, 2005, Executive B, in Indiana, emailed DPI VP Marketing, in the United Kingdom, asking for an update on the status of the Greek business, to which DPI VP Marketing responded that "when we abandon the consultancy, we might as well abandon the business."

68. On or around December 31, 2005, all agreements with Greek Agent B were terminated.

69. From in or around October 2003 to in or around December 2005, Greek Agent B was paid approximately €7,303,754, a significant portion of which was used to pay cash incentives to Greek HCPs to induce the purchase of DePuy products.

70. From in or around 2002 to in or around 2006, in addition to the payments to the Greek agents, approximately  $\in$  500,000 was withdrawn by DePuy Hellas MD and others and repaid within days. DePuy Hellas MD used these withdrawals to cover payments owed to HCPs by the agents but not yet paid.

#### Total Improper Payments in Greece

71. In total, from in or around 1998 to in or around 2006, DePuy, DePuy International, and their subsidiaries and employees authorized the payment, directly or indirectly, of approximately \$16.4 million to Greek Agent A and Greek Agent B, knowing that a significant portion was used to pay cash incentives to publicly-employed Greek HCPs to induce the purchase of DePuy products.

#### POLAND

### Background

72. Poland has a national healthcare system. Most Polish hospitals are owned and operated by the government and most Polish HCPs are government employees providing health care services in their official capacities. Therefore, most HCPs in Poland are "foreign officials" as defined by the FCPA, 15 U.S.C. § 78dd-1(f).

73. Polish hospitals purchase their medical products through a tender process, whereby suppliers of medical products compete for business by submitting bids to tender committees. Each tender committee may be associated with one or more hospitals.

74. In general, the tender committees evaluate the competitive bids and select the winning supplier for each purchase. Because most Polish hospitals are government owned, the tender committees effectively determine, on behalf of the government, from whom the government will purchase medical products.

75. J&J Poland made payments and provided things of value to publicly-employed Polish HCPs, in the form of "civil contracts," travel sponsorships, and donations of cash and equipment, to corruptly influence the decisions of HCPs on tender committees to purchase medical products from J&J Poland.

# Civil Contracts

76. J&J Poland engaged in professional services contracts with publicly-employed Polish HCPs, known as "civil contracts." The contracts were purportedly for professional services including lecturing, leading workshops, and conducting clinical trials.

77. For civil contracts in excess of approximately \$5,000, approval of J&J Poland's Managing Director or the Finance Director was required.

78. J&J Poland did not require that its sales representatives provide proof that the work, for which payment had been made, was actually ever performed.

79. From January 2000 until June 2006, J&J Poland awarded civil contracts to publicly-employed Polish HCPs to corruptly influence them, in their official capacities as members of tender committees, in order to induce those HCPs to select, or favorably influence the selection of, J&J Poland as the winning supplier in tender processes.

80. Several sales representatives of J&J Poland requested that civil contracts be awarded to particular HCPs in return for the HCPs taking action favorable to J&J Poland in tender processes. These requests were approved by the immediate supervisor, and, when valued at more than \$5,000, by J&J Poland's Managing Director or Finance Director.

81. Between in or around January 2000 and in or around June 2006, there were approximately 4,400 civil contracts for which the company paid HCPs approximately \$3.65 million, some of which were used to make improper payments to HCPs. Examples of such civil contracts requests for publicly-employed Polish HCPs included a request for a "key decision maker in the sutures tender for 2002, which will be concluded soon;" a civil contract valued at "5% of the value of the tender for transplantology which we have won in the hospital;" and for a publicly-employed Polish HCP who "was very helpful in relation to our winning of the tender for clips and… will be also helpful in the next one." Some contracts were valued into the thousands of dollars, up to \$2,456.

# Travel

82. At J&J Poland, any decision to sponsor a Polish HCP to attend a medical conference generally originated with an email request by a sales representative to a supervisor for approval. Requests that exceeded \$5,000 require approval of J&J Poland's Managing Director or Finance Director.

83. J&J Poland sponsored some publicly-employed Polish HCPs to attend conferences in order to corruptly influence them, in their official capacities as members of tender committees, in order to induce the HCPs to select, or favorably influence the selection of, J&J Poland as the winning supplier in tender processes.

84. Between in or around 2000 through in or around 2006, J&J Poland made approximately 15,000 payments to sponsor travel for publicly-employed Polish HCPs, totaling approximately \$7.6 million, a portion of which were improper. Examples of such travel included approval of sponsorship of a publicly-employed HCP that "has been a member of the tender committee and he contributed significantly to our win..." and that the sponsorship requested "is our fulfillment of the post tender obligations;" travel requested by a publicly-employed Polish HCP who had made it possible for J&J Poland to win a three-year tender at his hospital; and a trip to a conference in London for four publicly-employed Polish HCPs because it"has a great importance in relation to the support that may be given us during a tender for sutures in this hospital." Travel cost into the thousands of dollars, including up to \$9,690.

#### Total Improper Payments in Poland

85. In total, from in or around 2000 to in or around 2007, J&J Poland and its employees authorized the payment, directly or indirectly, of approximately \$775,000 in improper payments, including direct payments and travel, to publicly-employed Polish HCPs to induce the purchase of J&J products.

#### ROMANIA

# Background

86. The national healthcare system in Romania is almost entirely state-run. The healthcare system is funded by the National Health Care Insurance Fund ("CNAS"), to which employers and employees make mandatory contributions. Most Romanian hospitals are owned and operated by the government and most HCPs in Romania are government employees. Therefore, most HCPs in Romania are "foreign officials" as defined by the FCPA, 15 U.S.C. § 78dd-1(f).

87. The Ministry of Health controls pricing and profit margins for imported and domestically produced pharmaceuticals. Every year, the Ministry of Health and the CNAS compile a list of prescription drugs that are covered by public health insurance funds.

88. Typically, a doctor will prescribe a drug and give the prescription to the patient. The patient must obtain approval for reimbursement from the local insurance office, and with that approval, will then go to a pharmacy to have the prescription filled.

89. J&J Romania supplied pharmaceuticals to the Romanian market through one or more local distributors.

90. Prior to 2005, J&J Romania had only one general purpose distributor ("Romania Distributor"). Since then, it has added three additional distributors, while still maintaining the relationship with Romania Distributor.

91. From in or around 2005 through in or around 2008, J&J Romania employees made arrangements with J&J Romania distributors for the distributors, on behalf of J&J Romania, to provide cash payments and gifts to publicly-employed Romanian HCPs in exchange for prescribing certain pharmaceuticals manufactured by J&J subsidiaries and operating companies.

#### Cash Payments and Gifts

92. J&J Romania began making improper payments and gifts to publicly-employed Romanian HCPs through the Romania Distributor, but subsequently extended its practices of making such payments through all three additional distributors.

93. J&J Romania employees worked with distributors to deliver envelopes of cash to the publicly-employed Romanian HCPs in exchange for prescriptions; the amounts varied from 3% to 5% of sales value.

94. The HCP then issued a prescription and gave it directly to the distributor; the distributor delivered the drug and a percentage of the price to the doctor; the doctor kept the cash, and gave the drug directly to the patient; the distributor took the prescription, had it approved by the local state insurance office, and then delivered it to the pharmacy; the pharmacy then paid the distributor for the drug, and submitted the prescription for reimbursement.

95. J&J Romania sales representatives worked with distributors to identify HCPs that the distributors should target for corrupt payments, which took the form of cash, laptops, electronics, and other gifts to induce the prescription of pharmaceuticals manufactured by J&J subsidiaries and operating companies.

96. These improper cash payments and gifts were funded through discounts given to the distributors. Review of the agreements with the distributors revealed a 10-12% discount on each sales invoice, along with an additional discount of up to 10% in the form of free goods.

97. On some occasions, J&J Romania sales representatives, rather than the distributors, personally delivered cash to the HCPs. Even when payments were delivered to HCPs by the distributors, these payments were funded by J&J Romania through the arranged discounts with the distributors.

# Travel

98. Beginning in or around late 2007 and continuing until in or around mid-2008, as a result of the J&J internal investigation, J&J Romania's distributors largely stopped using cash as incentives for prescribing J&J products, and instead began sponsoring travel for the publicly-employed Romanian HCPs. J&J Romania sponsored the travel of publicly-employed Romanian HCPs to conferences either in exchange for promises from the HCPs to write a minimum number of prescriptions for J&J pharmaceuticals or based on the number of past prescriptions of J&J pharmaceuticals.

99. In addition to funding the travel itself, J&J Romania sales representatives made arrangements with some travel agents to overcharge for travel. The excess money was then used

for publicly-employed Romanian HCPs' expenses beyond the limited amount allowed by J&J Healthcare Compliance rules, such as spouse and family travel and "pocket money."

100. On some occasions, J&J Romania sponsored travel for publicly-employed Romanian HCPs that was unrelated to any conference or other business-related purpose.

# Total Improper Payments in Romania

101. In total, from in or around July 2005 to in or around mid-2008, J&J Romania and its employees authorized the payment, directly or indirectly, of approximately \$140,000 in incentives to publicly-employed Romanian HCPs to induce the purchase of pharmaceuticals manufactured by J&J subsidiaries and operating companies.

# THE UNITED NATIONS OIL FOR FOOD PROGRAM

102. Between in or around December 2000 and in or around March 2003, Janssen and Cilag were awarded 18 contracts for the sale of pharmaceuticals to the Iraqi Ministry of Health State Company for Marketing Drugs and Medical Appliances ("Kimadia") under the OFFP, with a total contract value of approximately \$9.9 million, which generated approximately \$6.1 million in profits. Janssen and Cilag secured these contracts through the payment of approximately \$857,387 in kickbacks to the government of Iraq.

103. The kickbacks were paid to the government of Iraq through JC-Lebanon Agent. The kickbacks were concealed from the United Nations by inflating Janssen and Cilag's contract prices by 10%.

104. From in or around February 2001 to in or around June 2004, Janssen and Cilag agreed to make payments to JC-Lebanon Agent that included the 10% kickback payments to the Iraqi government.

105. On or around October 24, 2000, JC-Lebanon Agent wrote to JC-Lebanon's Executive Manager for Corporate Affairs, informing him that "Kimadia is asking companies to pay them a 16 to 18% commission on each invoice. This subject will be discussed during your visit to Baghdad...".

106. While in or about November 2000, JC-Lebanon Agent signed a document stating that he would not pay commissions to Kimadia, JC-Lebanon Agent did in fact pay such commissions, and on or around February 22, 2001, Janssen and Cilag raised JC-Lebanon Agent's commissions on sales in Iraq by 10%, from the previous 12%, to 22%. This increase allowed JC-Lebanon Agent to pay kickbacks to Kimadia on Jansen and Cilag contracts.

107. On or around June 29, 2004, after the invasion of Iraq had obviated the need to pay kickbacks, Janssen and Cilag signed an amendment to JC-Lebanon Agent's contract, revoking the 10% increase.

108. Examples of such contracts include:

Contract 900868 - Cilag AG International

109. On or around May 27, 2001, Cilag was awarded Contract 900868, to supply quantities of the drug Sultrin, with a total contract price of  $\notin$ 1,376,023, which included an extra 10% fee. This fee was concealed in contracts and correspondence with the U.N. and in Cilag's books and records and was intended to be used to pay a kickback to the Iraqi government through JC-Lebanon Agent.

110. On or around January 8, 2002, the New York branch of BNP-Paribas sent, via an international electronic wire communication, a notice to the Central Bank of Iraq in Baghdad, Iraq, notifying it of the issuance of a letter of credit to Credit Suisse (First Boston) in Zurich, Switzerland, authorizing the eventual payment of  $\in 1,376,023$  from the OFFP escrow fund maintained at BNP-Paribas to Cilag, which represented payment for Contract 900868.

111. On or around June 2, 2001, JC-Lebanon Agent transferred approximately \$107,180 to the Iraqi government, representing the kickback on contract 900868.

112. On or around March 8, 2002, the inspection company sent from Iraq to the U.N. in New York, via international wire communication, notification that Cilag products purchased pursuant to Contract 900868 had been received and inspected by the inspection company in Iraq, thereby triggering payment by the U.N. to Cilag for Contract 900868.

Contract 1001745 - Janssen Pharmaceutica N.V.

113. On or around November 15, 2001, Janssen was awarded Contract 1001745, to supply quantities of the drugs Sporanox and Nizarol, with a total contract price of  $\in$ 1,045,189, which included an extra 10% fee. This fee was concealed in contracts and correspondence with the U.N. and in Janssen's books and records and was intended to be used to pay a kickback to the Iraqi government through JC-Lebanon Agent.

114. On or around June 3, 2002, the New York branch of BNP-Paribas sent, via an international electronic wire communication, a notice to the Central Bank of Iraq in Baghdad, Iraq, notifying it of the issuance of a letter of credit to Fortis Bank in Brussels, Belgium, authorizing the eventual payment of  $\notin$ 1,045,189 from the OFFP escrow fund maintained at BNP-Paribas to Janssen, which represented payment for Contract 1001745.

115. In or around summer 2002, JC-Lebanon Agent transferred approximately \$99,911 to the Iraqi government, representing the kickback on contract 1001745.

116. On or around August 8, 2002, the inspection company sent from Iraq to the U.N. in New York, via international wire communication, notification that Janssen products purchased pursuant to Contract 1001745 had been received and inspected by the inspection company in Iraq, thereby triggering payment by the U.N. to Janssen for Contract 1001745.

# **BOOKS AND RECORDS**

117. In order to conceal the payments to the Greek, Polish, and Romanian HCPs on the books and records of J&J and its subsidiaries, the payments were misrepresented as, among other things, "commissions," "civil contracts," "travel," "donations," and "discounts."

118. In order to conceal the kickback payments made to the Iraqi government through JC-Lebanon Agent for contracts under the OFFP on the books and records of Janssen and Cilag, the payments were misrepresented as "commissions."

119. At the end of J&J's fiscal year from in or around 1998 to in or around 2007, the books and records of DePuy International, DePuy Hellas, J&J Poland, J&J Romania, Janssen, and Cilag, including those containing false characterizations of kickback and bribe payments given to the Iraqi government and Greek, Polish, and Romanian officials, were incorporated into the books and records of J&J for purposes of preparing J&J's year-end financial statements, which were filed with the Securities and Exchange Commission in Washington, D.C.

ATTACHMENT B

Johnson-Johnson

#### **CERTIFICATE OF CORPORATE RESOLUTION**

I, DOUGLAS K. CHIA, do hereby certify that I am SECRETARY of JOHNSON & JOHNSON (the "Company"), a New Jersey corporation, and that the following is a true, correct, and accurate copy of resolutions duly adopted by unanimous vote at a Special Meeting of the Board of Directors the Company on April 4, 2011:

**WHEREAS**, the Company has been engaged in discussions with the United States Department of Justice, Criminal Division, Fraud Section (the "Department") in connection with issues arising in relation to certain corrupt payments to foreign officials to obtain and retain business for the Company;

**WHEREAS**, in order to resolve such issues, it is proposed that the Company enter into a certain agreement with the Department; and

**WHEREAS** the Company's Vice President, General Counsel, together with outside counsel for the Company, have advised the Board of Directors of the Company's rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Department;

Therefore, this Board hereby **RESOLVES** that:

1. The Company, on its own behalf and on behalf of its subsidiaries and operating companies, including DePuy, Inc., (a) consents to the filing in the United States District Court for the District of Columbia of an Information charging DePuy, Inc. with conspiracy to commit an offense against the United States in violation of 18 U.S.C. § 371, namely, to violate the Foreign Corrupt Practices Act ("FCPA") (15 U.S.C. § 78dd-2); and the violation of the FCPA, 15 U.S.C. § 78dd-2 and 18 U.S.C. § 2 (Count Two); (b) waives indictment on such charges and enters into a Prosecution Agreement with Deferred the Department; and (c) agrees to pay a monetary penalty of \$21,400,000 to the United States Treasury with respect to the conduct described in the Information and the Statement of Facts:

- 2. The Vice President, General Counsel, or his delegate, is hereby authorized, empowered, and directed, on behalf of the Company, to execute the Deferred Prosecution Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the Vice President, General Counsel, or his delegate, may approve;
- 3. The Vice President, General Counsel, or his delegate, is hereby authorized, empowered, and directed to take any and all actions as may be necessary or appropriate, and to approve the forms, terms, or provisions of any agreement or other documents as may be necessary or appropriate to carry out and effectuate the purpose and intent of the foregoing resolutions; and
- 4. All of the actions of the Vice President, General Counsel, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

This Board hereby further **RESOLVES** that Russell C. Deyo, the Vice President, General Counsel of the Company, be and hereby is authorized to act on behalf of the Corporation, and in his sole discretion, to negotiate, approve, and make the offer of settlement of the Company, attached hereto, to the United States Securities and Exchange Commission ("Commission") in connection with the investigation conducted by the Commission; in this connection, the aforementioned Officer be and hereby is authorized to undertake such actions as he may deem necessary and advisable, including the execution of such documentation as may be required by the Commission, in order to carry out the foregoing.

I further certify that the aforesaid resolutions have not been amended or revoked in any respect and remain in full force and effect. IN WITNESS WHEREOF, I have executed this Certificate as a sealed instrument this day of April 6, 2011.

#### JOHNSON & JOHNSON

By: Name: Douglas K. Chia Title: Secretary

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 6, 2011.

# ATTACHMENT C

# CORPORATE COMPLIANCE PROGRAM

In order to address deficiencies in its internal controls, policies, and procedures regarding compliance with the Foreign Corrupt Practices Act ("FCPA"), 15 U.S.C. §§ 78dd-1, *et seq.*, and other applicable anticorruption laws, Johnson & Johnson and its subsidiaries and operating companies (collectively, "J&J") agree to continue to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, policies, and procedures.

Where necessary and appropriate, J&J agrees to adopt new or to modify existing internal controls, policies, and procedures in order to ensure that it maintains: (a) a system of internal accounting controls designed to ensure that J&J makes and keeps fair and accurate books, records, and accounts; and (b) a rigorous anticorruption compliance code, standards, and procedures designed to detect and deter violations of the FCPA and other applicable anticorruption laws. At a minimum, this should include, but not be limited to, the following elements:

1. A clearly articulated corporate policy against violations of the FCPA, including its anti-bribery, books and records, and internal controls provisions, and other applicable counterparts (collectively, the "anticorruption laws").

2. Promulgation of compliance standards and procedures designed to reduce the prospect of violations of the anticorruption laws and J&J's compliance code. These standards and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of J&J in a foreign jurisdiction, including but not limited to, agents, consultants, representatives, distributors, teaming partners, and joint venture partners (collectively, "agents and business partners");

3. The assignment of responsibility to one or more senior corporate executives of J&J for the implementation and oversight of compliance with policies, standards, and procedures regarding the anticorruption laws. Such corporate official(s) shall have the authority to report matters directly to J&J's Board of Directors or any appropriate committee of the Board of Directors;

4. Mechanisms designed to ensure that the policies, standards, and procedures of J&J regarding the anticorruption laws are effectively communicated to all directors, officers, employees, and, where appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors, officers, and employees, and, where necessary and appropriate, agents and business partners; and (b) annual certifications by all such directors, officers, and employees, and, where necessary and appropriate, agents, and business partners; and appropriate, agents, and business partners; certifying compliance with the training requirements;

5. An effective system for reporting suspected criminal conduct and/or violations of the compliance policies, standards, and procedures regarding the anticorruption laws for directors, officers, employees, and, where necessary and appropriate, agents and business partners;

6. Appropriate disciplinary procedures to address, among other things, violations of the anticorruption laws and J&J's compliance code by J&J's directors, officers, and employees;

7. Appropriate due diligence requirements pertaining to the retention and oversight of agents and business partners;

8. Standard provisions in agreements, contracts, and renewals thereof with all agents and business partners that are reasonably calculated to prevent violations of the anticorruption laws, which may, depending upon the circumstances, include: (a) anticorruption representations and undertakings relating to compliance with the anticorruption laws; (b) rights to conduct audits of the books and records of the agent or business partner to ensure compliance with the foregoing; and (c) rights to terminate an agent or business partner as a result of any breach of anticorruption laws, and regulations or representations and undertakings related to such matters; and

9. Periodic testing of the compliance code, standards, and procedures designed to evaluate their effectiveness in detecting and reducing violations of anticorruption laws and J&J's compliance code.

### ATTACHMENT D

### ENHANCED COMPLIANCE OBLIGATIONS

In addition to and building upon the commitments enumerated in Attachment C, Johnson & Johnson and its subsidiaries and operating companies (collectively, "J&J") agree that they have or will undertake the following, at a minimum, for the duration of this Agreement:

#### General

- 1. J&J will:
  - a. Appoint a senior corporate executive with significant experience with compliance with the FCPA, including its anti-bribery, books and records, and internal controls provisions, as well as other applicable anticorruption laws and regulations (hereinafter "anticorruption laws and regulations") to serve as Chief Compliance Officer. The Chief Compliance Officer will have reporting obligations directly to the Audit Committee of the Board of Directors.
  - b. Appoint heads of compliance within each business sector and corporate function. These compliance heads will have reporting obligations to the Chief Compliance Officer and the Audit Committee.
  - c. Maintain a global compliance leadership team, including regional compliance leaders and business segment compliance leaders, with responsibility for overseeing its company-wide compliance program. That leadership team will have reporting obligations directly to the Chief Compliance Officer.

2. J&J shall institute gifts, hospitality, and travel policies and procedures in each jurisdiction that are appropriately designed to prevent violations of the anticorruption laws and regulations. At a minimum, these policies shall contain the following restrictions regarding government officials, including but not limited to public health care providers, administrators, and regulators:

- a. Gifts must be modest in value, appropriate under the circumstances, and given in accordance with anticorruption laws and regulations, including those of the government official's home country;
- b. Hospitality shall be limited to reasonably priced meals, accommodations, and incidental expenses that are part of product education and training programs, professional training, and conferences or business meetings;

- c. Travel shall be limited to product education and training programs, professional training, and conferences or business meetings; and
- d. Gifts, hospitality, and travel shall not include expenses for anyone other than the official.

# Complaints, Reports, and Compliance Issues

3. J&J shall maintain its mechanisms for making and handling reports and complaints related to potential violations of anticorruption laws and regulations, including referral for review and response to a standing committee that includes internal audit, legal, and compliance personnel, and will ensure that reasonable access is provided to an anonymous, toll-free hotline as well as to an anonymous electronic complaint form, where anonymous reporting is legally permissible.

4. J&J will ensure that its Sensitive Issue Triage Committee reviews and responds to FCPA and corruption issues promptly and consistently; this Triage Committee will include members from J&J's internal audit, legal, and compliance functions.

# Risk Assessments and Audits

5. J&J will conduct risk assessments of markets where J&J has government customers and/or other anticorruption compliance risks on a staggered, periodic basis. Such risk assessments shall occur at reasonable intervals and include a review of trends in interactions with government officials, including health care providers, to identify new risk areas. On the basis of those assessments, as needed, J&J will modify compliance implementation to minimize risks observed through the risk assessment process.

6. J&J will conduct periodic audits specific to the detection of violations of anticorruption laws and regulations ("FCPA Audits"). Specifically, J&J will identify no less than five operating companies<sup>2</sup> that are high risk for corruption because of their sector and location and will conduct FCPA Audits of those operating companies at least once every three years. High risk operating companies shall be identified based on J&J's risk assessment process in consultation with the Chief Compliance Officer, sector compliance leaders, corporate internal audit, and the Law Department, taking into account multiple risk factors including, but not limited to: a high degree of interaction with government officials; the existence of internal reports of potential corruption risk; a high corruption risk based on certain corruption indexes;

<sup>&</sup>lt;sup>2</sup> For purposes of this agreement, "operating company" shall mean a pharmaceutical, medical device or consumer company located in a single country that may include multiple J&J franchises.

and financial audit results. The list of high risk operating companies shall be reviewed annually and updated as necessary. FCPA Audits of other operating companies that pose corruption risk shall occur no less than once every five years.<sup>3</sup> Each FCPA Audit shall include:

- a. On-site visits by an audit team comprised of qualified auditors who have received FCPA and anticorruption training;
- b. Where appropriate, participation in the on-site visits by personnel from the compliance and legal functions;
- c. Review of a statistically representative sample appropriately adjusted for the risks of the market, of contracts with and payments to individual health care providers;
- d. Creation of action plans resulting from issues identified during audits; these action plans will be shared with appropriate senior management, including the Chief Compliance Officer, and will contain mandatory undertakings designed to enhance anticorruption compliance, repair process weaknesses, and deter violations; and
- e. Where appropriate, feasible, and permissible under local law, review of the books and records of distributors which, in the view of the audit team, may present corruption risk.

# Acquisitions

7. J&J will ensure that new business entities are only acquired after thorough FCPA and anticorruption due diligence by legal, accounting, and compliance personnel. Where such anticorruption due diligence is not practicable prior to acquisition of a new business for reasons beyond J&J's control, or due to any applicable law, rule, or regulation, J&J will conduct FCPA and anticorruption due diligence subsequent to the acquisition and report to the Department any corrupt payments, falsified books and records, or inadequate internal controls as required by Paragraph 11 of the Deferred Prosecution Agreement.

8. J&J will ensure that J&J's policies and procedures regarding the anticorruption laws and regulations apply as quickly as is practicable, but in any event no less than one year post-closing, to newly-acquired businesses, and will promptly:

<sup>&</sup>lt;sup>3</sup> For those operating companies that are determined not to pose corruption risk, J&J will conduct periodic FCPA Audits, or will incorporate FCPA components into financial audits.

- a. Train directors, officers, employees, agents, consultants, representatives, distributors, joint venture partners, and relevant employees thereof, who present corruption risk to J&J, on the anticorruption laws and regulations and J&J's related policies and procedures; and
- b. Conduct an FCPA-specific audit of all newly-acquired businesses within 18 months of acquisition.

# Relationships with Third Parties

9. J&J will conduct due diligence reviews of sales intermediaries, including agents, consultants, representatives, distributors, and joint venture partners. At a minimum, such due diligence shall include:

- a. A review of the qualifications and business reputation of the sales intermediaries;
- b. A rationale for the use of the sales intermediary; and
- c. A review of FCPA risk areas.

10. Such due diligence will be conducted by local businesses and reviewed by local healthcare compliance officers. New intermediaries that have not worked for the company prior to the date of this agreement, or where due diligence raises any red flags, shall be reviewed by a regional compliance officer with specific knowledge of and responsibility for anticorruption due diligence of sales intermediaries. Due diligence will be conducted prior to retention of any new agent, consultant, representative, distributor, or joint venture partner and for all such intermediaries will be updated no less than once every three years.

11. Where necessary and appropriate and where permitted by applicable law, J&J shall include standard provisions designed to prevent violations of the FCPA and other applicable anticorruption laws and regulations in agreements, contracts, grants, and renewals thereof with agents, distributors, and business partners, including:

- a. Anticorruption representations and undertakings relating to compliance with the anticorruption laws and regulations;
- b. Rights to conduct audits of the books and records of the agent, distributor, or business partner that are related to their business with J&J; and
- c. Rights to terminate the agent, distributor, or business partner as a result of any breach of anticorruption laws and regulations or representations and undertakings related to such anticorruption laws and regulations.

#### Training

- 12. J&J shall provide:
  - a. Annual training on anticorruption laws and regulations to directors, officers, executives, and employees who could present corruption risk to J&J.
  - b. Enhanced and in-depth FCPA training for all internal audit, financial, and legal personnel involved in FCPA audits, due diligence reviews, and acquisition of new businesses.
  - c. Training as necessary based on risk profiles to relevant third parties acting on the company's behalf that may interact with government officials at least once every three years.

13. J&J shall implement a system of annual certifications from senior managers in each of J&J's corporate-level functions, divisions, and business units in each foreign country confirming that their local standard operating procedures adequately implement J&J's anticorruption policies and procedures, including training requirements, and that they are not aware of any FCPA or other corruption issues that have not already been reported to corporate compliance.