CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
JOHNSON & JOHNSON

I. PREAMBLE

Johnson & Johnson (J&J) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Contemporaneously with this CIA, J&J and certain J&J Pharmaceutical Affiliates are entering into Settlement Agreements with the United States. They will also enter into settlement agreements with various states (State Settlement Agreements) and J&J's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, J&J initiated certain compliance measures and established a compliance program governing the J&J Pharmaceutical Affiliates (as defined below) designed, among other things, to address its U.S. pharmaceutical operations and compliance with Federal health care program and FDA requirements (Compliance Program). J&J and the J&J Pharmaceutical Affiliates shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. J&J and the J&J Pharmaceutical Affiliates may modify the Compliance Program as appropriate. However, at a minimum, J&J and the J&J Pharmaceutical Affiliates shall ensure that during the term of this CIA, they shall comply with the obligations set forth in this CIA.

In April 2010, Ortho-McNeil-Janssen Pharmaceuticals, Inc.[1] entered a CIA with the OIG (the "Janssen CIA"). As set forth in more detail in Section II, this CIA shall supersede and replace the Janssen CIA.

[1] Following the Effective Date of the CIA with Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI), OMJPI changed its corporate name to Janssen Pharmaceuticals, Inc. (Janssen).

II. TERM AND SCOPE OF THE CIA

A. Janssen's obligations under the Janssen CIA shall continue through the Effective Date of this CIA at which point Janssen's obligations under the Janssen CIA shall be superseded by the terms of this CIA. The period of the compliance obligations assumed by J&J and the J&J Pharmaceutical Affiliates (as defined below in Section II.C) under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. The first Reporting Period shall be from the Effective Date through December 31, 2013, and shall include Janssen obligations from the beginning of the fourth Reporting Period of the Janssen CIA (April 28, 2013) through the Effective Date. The second through fifth Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years. The last (sixth) Reporting Period shall start on January 1, 2018 and end on the anniversary date of the Effective Date in 2018.

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) J&J's final Annual Report; or (2) any additional materials submitted by J&J pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "J&J Pharmaceutical Affiliates" shall include Janssen and all pharmaceutical subsidiaries and affiliates of J&J, and all other pharmaceutical entities that are majority owned or controlled, directly or indirectly, by J&J that market, sell, contract for, distribute, conduct research relating to, and/or promote Government Reimbursed Products (as defined below in Section II.C.4). As of the Effective Date, the term J&J Pharmaceutical Affiliates shall include, but not be limited to, the following entities: Janssen, Patriot Pharmaceuticals, Inc., Janssen Biotech, Inc. (including its Janssen Therapeutics division), Scios, Inc., Janssen Research and Development LLC, Johnson & Johnson Health Care Systems Inc., and JOM Pharmaceutical Services, Inc.

2. "Covered Persons" includes:

   a. all owners of J&J who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading) and all directors of J&J;

b. all owners of J&J Pharmaceutical Affiliates who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading) and all directors of J&J Pharmaceutical Affiliates;

c. all employees of J&J or any J&J Pharmaceutical Affiliate who are engaged in or supervise personnel who are engaged in any of the Covered Functions (as defined below in Section II.C.8); and

d. all contractors, subcontractors, agents, and other persons (including, but not limited to, third party vendors who provide services relating to the Covered Functions) who perform any Covered Function on behalf of J&J and/or any J&J Pharmaceutical Affiliate and who in that capacity either: (1) interact directly with health care professionals (HCPs), health care institutions (HCIs), or consumers; or (2) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Covered Person prior to execution or dissemination.

Notwithstanding the above, this term does not include 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, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

3. "Relevant Covered Persons" includes all Covered Persons who engage in any of the Covered Functions and all individuals who supervise Covered Persons who engage in Covered Functions.

4. "Government Reimbursed Products" refers to all human pharmaceutical products of any J&J Pharmaceutical Affiliate that are marketed or sold by any J&J Pharmaceutical Affiliate in the United States or pursuant to contracts with the United States that are reimbursed by Federal health care programs.

5. The term "Promotional Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government

Reimbursed Products, including those functions relating to any applicable Promotional Review Committee (PRC) process and any applicable review committees for promotional materials.

6. The term "Product Related Functions" includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs and HCIs about Government Reimbursed Products, including those functions relating to any applicable medical review committee(s) and to medical affairs/medical services of any J&J Pharmaceutical Affiliate; (b) contracting with HCPs and HCIs licensed in the United States to conduct post-marketing clinical trials, post-marketing investigator-initiated studies (IISs), and all other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to post-marketing clinical trials and other post-marketing studies for Government Reimbursed Products (including studies of investigational and other uses and indications outside the currently approved uses and conditions of use); and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as DrugDex or other compendia of information about Government Reimbursed Products).

7. The term "Managed Healthcare Related Functions" refers to Promotional Functions and Product Related Functions as they relate to interactions between J&J and/or J&J Pharmaceutical Affiliates and: (1) government payers, including the Federal government, state Medicaid programs, pharmacy benefits managers (PBMs), or other individuals or entities under contract with or acting on behalf of Medicaid, Medicare and other government payers; and (2) institutional purchasers or providers, institutional pharmacies, long-term care or specialty pharmacies, or other individual or entities under contract with or acting on behalf of institutional purchasers or providers and who are in a position to influence the use of Government Reimbursed Products in the institution. Managed Healthcare Related Functions include marketing, formulary, contracting, and rebate activities undertaken in connection with the sale of Government Reimbursed Products.

8. The term "Covered Functions" refers to "Promotional Functions," "Product Related Functions," and "Managed Healthcare Related Functions" collectively.

9. The term "Third Party Educational Activity" shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by a J&J Pharmaceutical Affiliate, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

10. The term "Third Party Personnel" shall mean personnel who perform Covered Functions who are employees of entities with whom J&J or a J&J Pharmaceutical Affiliate has or may in the future (during the term of this CIA) enter into agreements to co-promote a Government Reimbursed Product in the United States or to engage in joint promotional activities in the United States relating to such a product. J&J has represented that: (a) Third Party Personnel are employed by entities other than J&J or a J&J Pharmaceutical Affiliate; (b) J&J or a J&J Pharmaceutical Affiliate does not control the Third Party Personnel; and (c) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. J&J and/or the J&J Pharmaceutical Affiliates agree to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.5. Provided that J&J and the J&J Pharmaceutical Affiliate(s) comply with the requirements of Sections III.B.2, V.A.7, and V.B.5, J&J and the J&J Pharmaceutical Affiliate(s) shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

J&J shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officers and Committees.

1. *Compliance Officers*.

J&J Chief Compliance Officer. Prior to the Effective Date, J&J appointed a Covered Person to serve as its Chief Compliance Officer (hereafter "J&J Chief Compliance Officer" or "J&J CCO"). J&J shall maintain a J&J CCO for the term of the CIA. The J&J CCO 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 and FDA requirements.

The J&J CCO shall be a member of senior management of J&J, shall make periodic (at least quarterly) reports directly to the Chief Executive Officer of J&J, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Regulatory, Compliance, and Government Affairs Committee of the Board of Directors of J&J, and shall be authorized to report on such matters to the Regulatory, Compliance, and Government Affairs Committee of the Board of Directors at any time. The J&J CCO shall not be or be subordinate to the Chief Legal Officer or Chief Financial Officer. The J&J CCO shall be responsible for monitoring the day-to-day compliance activities engaged in by J&J as well as for any reporting obligations created under this CIA. Any

noncompliance job responsibilities of the J&J CCO shall be limited and must not interfere with the J&J CCO's ability to perform the duties outlined in this CIA.

NALT Compliance Officer. Prior to the Effective Date, the J&J Pharmaceutical Affiliates, through their leadership board referred to as the J&J Pharmaceutical Group North American Leadership Team (NALT) appointed a Compliance Officer (NALT Compliance Officer), and the NALT shall maintain a Compliance Officer during the term of the CIA. The NALT Compliance Officer shall be responsible for working with the J&J CCO to develop and implement policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements.

The NALT Compliance Officer shall be a member of senior management of the NALT and shall ensure periodic (at least quarterly) reports are made regarding compliance matters directly to the NALT, and shall be authorized to report on such matters to the NALT at any time. The NALT Compliance Officer also shall work with the J&J CCO to ensure periodic (at least quarterly) reports are made regarding compliance matters directly to the Regulatory, Compliance, and Government Affairs Committee of the J&J Board of Directors. The NALT Compliance Officer shall not be or be subordinate to the Chief Legal Officer or Chief Financial Officer for J&J, the NALT, or any J&J Pharmaceutical Affiliate. The NALT Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the J&J Pharmaceutical Affiliates as well as for assisting in fulfilling any reporting obligations created under this CIA. Any noncompliance job responsibilities of the NALT Compliance Officer shall be limited and must not interfere with the NALT Compliance Officer's ability to perform the duties outlined in this CIA.

J&J shall report to OIG, in writing, any change in the identity of the J&J CCO or the NALT Compliance Officer or any actions or changes that would affect either of the Compliance Officers' ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee*. Prior to the Effective Date, J&J, through the NALT, established a Compliance Committee with responsibility for compliance at the J&J Pharmaceutical Affiliates (NALT Compliance Committee). J&J shall ensure that this NALT Compliance Committee is maintained throughout the term of the CIA. The NALT Compliance Committee shall, at a minimum, include the NALT Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as legal, medical affairs/scientific, regulatory affairs, sales, marketing, human resources, research and development, audit, finance, and operations). The NALT Compliance Officer shall chair the NALT Compliance Committee and the Committee shall support the NALT

Compliance Officer and the J&J CCO in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations). The NALT Compliance Committee shall meet at least quarterly.

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

3. *Boards of Directors Compliance Obligations.*

J&J Board Obligations. Prior to the Effective Date, J&J formed the Regulatory, Compliance and Government Affairs Committee (RCGAC) as a subcommittee of its Board of Directors, and J&J shall maintain the RCGAC or an equivalent subcommittee of its Board of Directors during the term of this CIA. The RCGAC is and shall continue to be responsible for the review and oversight of matters related to the J&J Pharmaceutical Affiliates' 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 the Compliance Program, including but not limited to the performance of the J&J CCO and the NALT Compliance Committee;

b. reviewing the report on the effectiveness of the 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 the Compliance Program; and

c. for each Reporting Period of the CIA, adopting a resolution (described below), signed by each individual member of the RCGAC summarizing its review and oversight of the J&J Pharmaceutical Affiliates' compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The RCGAC has made a reasonable inquiry into the operations of the J&J Pharmaceutical Affiliates' Compliance Program for the time period [insert time period], including the performance of the J&J Chief Compliance Officer and the NALT Compliance Committee. In addition, the RCGAC has reviewed the results of a 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, the J&J Pharmaceutical Affiliates have 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 J&J.

NALT Compliance Obligations. The NALT shall also be responsible for the review and oversight of matters related to the J&J Pharmaceutical Affiliates' compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

The NALT 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 J&J Pharmaceutical Affiliates, including but not limited to the performance of the NALT Compliance Officer and NALT Compliance Committee;

b. arranging for the performance of a review of the effectiveness of the J&J Pharmaceutical Affiliates' Compliance Program (Compliance Program Review) by a Compliance Expert (described below) beginning in the second Reporting Period. The NALT shall review the Compliance Program Review Report (described below) as part of the review and assessment of the J&J Pharmaceutical Affiliates' Compliance Program. A copy of the Compliance Program Review Report shall be provided to OIG in each Annual Report submitted by J&J;

c. retaining, in connection with the Compliance Program Review, 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. providing a copy of the Compliance Program Review Report to the RCGAC to be considered in connection with each annual resolution of the RCGAC.

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

4. *Management Accountability and Certifications*. In addition to the responsibilities set forth in this CIA for all Covered Persons, the J&J CCO, members of the NALT, and certain officers or employees of each of the J&J Pharmaceutical Affiliates (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority. Each such Certifying Employee shall annually certify that the applicable J&J or J&J Pharmaceutical Affiliate business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the J&J CCO, the members of the NALT, and the presidents, vice presidents, and/or heads of business units at the J&J Pharmaceutical Affiliates that are engaged in Covered Functions; the Presidents of Janssen Pharmaceuticals, Inc., Janssen Biotech, Inc., Patriot Pharmaceuticals, Inc., and Scios, Inc.; the Vice-Presidents of Human Resources; Vice-Presidents of Strategic Customer Group; the Vice-Presidents of Commercial Analytics; Vice-Presidents of Medical Affairs; Vice-Presidents of Communication and Public Affairs; Vice-Presidents of New Business Development; Chief Scientific Officers; Vice-President(s) of Finance; and, to the extent that a business performs Covered Functions and is not covered by the certification of one of the above-listed individuals, such other presidents, vice presidents, and heads of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit at each J&J Pharmaceutical Affiliate.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and J&J policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of the [insert name of J&J Pharmaceutical Affiliate company] is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct*. To the extent not already accomplished, within 120 days after the Effective Date, J&J shall ensure that the J&J Pharmaceutical Affiliates develop, implement, and distribute a written Code of Conduct to all Covered Persons. J&J shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct shall, at a minimum, set forth:

a. J&J's commitment to full compliance by J&J and all J&J Pharmaceutical Affiliates with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to the Covered Functions;

b. J&J's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements, FDA requirements, and with Policies and Procedures of J&J and all applicable J&J Pharmaceutical Affiliates;

c. the requirement that all Covered Persons shall be expected to report to the J&J CCO, or other appropriate individual(s) designated by J&J, suspected violations of any Federal health

care program requirements, FDA requirements, or of J&J's or any Pharmaceutical Affiliate's own Policies and Procedures; and

d. the right of all individuals to use the Disclosure Program described in Section III.F, and J&J's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished within 180 days prior to the Effective Date, within 120 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by the J&J Pharmaceutical Affiliates' Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

J&J shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, either in writing or electronic format, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* To the extent not already accomplished, within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, J&J or a J&J Pharmaceutical Affiliate shall send, electronically or in hard copy format, a letter to each entity employing Third Party Personnel. The letter shall outline obligations under the CIA and J&J and the J&J Pharmaceutical Affiliates' commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of the Compliance Program. J&J or the J&J Pharmaceutical Affiliate shall include with the letter a copy of the Code of Conduct and shall request the entity employing Third Party Personnel to either: (a) make a copy of the Code of Conduct and a description of the Compliance Program available to its Third Party Personnel; or (b) represent to J&J or the J&J Pharmaceutical Affiliate that it has and enforces a substantively comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, J&J and/or each J&J Pharmaceutical Affiliate shall implement written Policies and Procedures regarding the operation of the compliance program, including the compliance program requirements outlined in this

CIA and compliance with Federal health care program requirements and FDA requirements. At a minimum, the Policies and Procedures must address the following:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

b. appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;

c. appropriate ways to conduct Product Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;

d. appropriate ways to conduct Managed Healthcare Related Functions in compliance with all applicable Federal healthcare program requirements (including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733)), FDA requirements, and other requirements;

e. the materials and information that may be distributed by J&J Pharmaceutical Affiliates' sales representatives about Government Reimbursed Products and the manner in which J&J Pharmaceutical Affiliates' sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives may not engage in off-label promotion (directly or indirectly) and must refer all requests for information about off-label uses of Government Reimbursed Products to the relevant medical affairs or the medical information & services department (collectively hereinafter "Medical Information and Services");

f. the materials and information that may be distributed by Medical Information and Services and the mechanisms through, and manner in which, Medical Information and Services receives and responds to requests for information about off-label uses of Government Reimbursed Products; the form and content of information disseminated in response to such requests; and the internal review and approval process for the information disseminated.

The Policies and Procedures shall include a requirement that J&J Pharmaceutical Affiliates develop a database ("Inquiries Database") to track all requests for information about Government Reimbursed Products that are made to Medical Information and Services. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Government Reimbursed Products: (1) date of Inquiry; (2) form of Inquiry (e.g., fax, phone, etc.); (3) name of the requesting HCP, HCI, or other individual or entity (if applicable); (4) nature and topic of request (including exact language of the Inquiry if made in writing); (5) an evaluation of whether the Inquiry relates to information about an off-label use for the product; (6) nature/form of the response from the J&J Pharmaceutical Affiliate (including a record of the materials provided to the HCP or HCI in response to the request); and (7) the name of the J&J Pharmaceutical Affiliate representative who called on or interacted with the HCP, customer, or HCI, if known. The J&J Pharmaceutical Affiliates will record the date and name of the individual who reviewed the Inquiry, if applicable;

g. the materials and information that may be distributed or made available by any J&J Pharmaceutical Affiliate through social media and/or direct-to-consumer advertising. These policies and procedures shall be designed to ensure that the Affiliate's activities in this area and the information distributed or made available comply with all applicable Federal health care program and FDA requirements, and have been reviewed and approved by the applicable review committee before they are disseminated;

h. the manner and circumstances under which medical personnel from Medical Information and Services interact with or

participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Government Reimbursed Products;

i. the development, implementation, and review of call plans for sales representatives and other personnel of the J&J Pharmaceutical Affiliates who promote and sell Government Reimbursed Products (Call Plans). For each Government Reimbursed Product, the Policies and Procedures shall require that the J&J Pharmaceutical Affiliate review Call Plans for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the Call Plans. The Policies and Procedures shall also require that the Pharmaceutical Affiliate modify the Call Plans as necessary to ensure that the company is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The Call Plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

j. the development, implementation, and review of plans for the distribution, by J&J Pharmaceutical Affiliates, of samples of, or coupons or vouchers for, Government Reimbursed Products (collectively "Sample Distribution Plans"). This shall include a review of the bases upon, and circumstances under which, HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from the J&J Pharmaceutical Affiliate (including, separately, from sales representatives and from Medical Information and Services, or through other channels). Policies and Procedures shall also require that the J&J Pharmaceutical Affiliate modify the Sample Distribution Plan as necessary to ensure that the J&J Pharmaceutical Affiliates are promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;

k. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to speaker programs, speaker training programs, presentations, advisory boards, ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

l. programs to educate sales representatives, including but not limited to, mentorships, presentations by HCPs at sales meetings and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

m. sponsorship or funding of grants (including educational grants) and charitable contributions. These Policies and Procedures shall be designed to ensure that the J&J Pharmaceutical Affiliates' funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

n. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.9 above. These Policies and Procedures shall be designed to ensure that the J&J Pharmaceutical Affiliates' funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements;

The Policies and Procedures shall require that: (1) the J&J Pharmaceutical Affiliates disclose their financial support of the Third Party Educational Activity and, any financial

relationships with faculty, speakers, or organizers at such Activity; (2) as a condition of funding, the third party shall agree to disclose the J&J Pharmaceutical Affiliates' financial support of the Third Party Educational Activity and any financial relationships that the J&J Pharmaceutical Affiliates might have with faculty, speakers, or organizers at such Activity; (3) any faculty, speakers, or organizers at the Third Party Educational Activity disclose any financial relationship with the J&J Pharmaceutical Affiliates; (4) the Third Party Educational Activity have an educational focus; (5) the content, organization, and operation of the Third Party Educational Activity (including the faculty, educational methods, materials, and venue) be independent of the J&J Pharmaceutical Affiliates' control; (6) the J&J Pharmaceutical Affiliates support only Third Party Educational Activity that is non-promotional in tone/nature; and (7) the J&J Pharmaceutical Affiliate's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

o. review of promotional, reimbursement, and disease materials intended to be disseminated outside of J&J or the J&J Pharmaceutical Affiliates by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during the review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: (1) applicable review committees review all promotional materials prior to the distribution or use of such materials; (2) the copy review and approval process ensure that FDA communications relevant to the product are considered and appropriately reflected in promotional materials and in a repository or summary maintained for each product; and (3) deviations from the standard review committee practices and protocols (including timetables for the submission of

materials for review) shall be documented and referred for appropriate follow-up;

p. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Procedures shall be designed to ensure that the J&J Pharmaceutical Affiliates' funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;

q. compensation (including through salaries, bonuses, or other means) for Relevant Covered Persons who are sales representatives. These Policies and Procedures shall: (1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Government Reimbursed Products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate off-label promotion of Government Reimbursed Products.

As set forth in more detail in Section III.H below and in Appendix D, J&J and/or J&J Pharmaceutical Affiliates have established an Incentive Compensation Program. J&J and the J&J Pharmaceutical Affiliates shall continue this program, or a substantially equivalent program, during the term of the CIA;

r. J&J's and each J&J Pharmaceutical Affiliate's right to recoup or cause the forfeiture of annual performance pay of covered executives in accordance with the Executive Financial Recoupment Program described in more detail below in Section III.H and in Appendix D. J&J and the J&J Pharmaceutical Affiliates shall establish and continue this program, or a substantially equivalent program, during the term of the CIA;

s. the submission of information about any Government Reimbursed Product to any compendia such as DrugDex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This

includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (e.g., any changes based on the discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The Policies and Procedures shall include a requirement that the J&J Pharmaceutical Affiliate review, at the time of submission, all information submitted to any Compendia to ensure it is complete and accurate. In addition, the J&J Pharmaceutical Affiliate shall conduct an annual review, with respect to actively promoted Government Reimbursed Products of: (i) all information in the compendia about Government Reimbursed Products in order to ensure the information is complete and accurate; and (ii) all arrangements, processing fees, or other payments or financial support (if any) provided by the J&J Pharmaceutical Affiliate to any Compendia. J&J compliance personnel shall be involved in this review;

t. sponsorship of post-marketing clinical trials, post-marketing IISs, and all other post-marketing studies of Government Reimbursed Products (collectively, "Research"), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the support for publication of information about the Research results and outcomes; uses made of publications relating to Research;

Policies/Procedures regarding Research Decision-Making: To the extent not already accomplished, J&J Pharmaceutical Affiliates shall amend their Policies and Procedures and processes within 120 days after the Effective Date to require that Research be initiated, designed, reviewed, and approved by the medical and research and development organizations of J&J and/or the J&J Pharmaceutical Affiliates. Commercial personnel shall not participate in the approval of the publication of Research results. J&J and/or the J&J Pharmaceutical Affiliates represent that they require that all Research and any resulting publications address legitimate scientific questions or needs, and are intended to foster increased understanding of scientific, clinical or medical

issues. To the extent not already accomplished, J&J and/or the J&J Pharmaceutical Affiliates shall require as a condition of its funding that all researchers disclose in any publication of Research, support by J&J and/or any J&J Pharmaceutical Affiliate and any financial interest the researcher may have in J&J or any J&J Pharmaceutical Affiliate.

Registration of Studies and Publication of Study Results:

J&J Pharmaceutical Affiliates represent that they register all applicable clinical trials of Government Reimbursed Products sponsored by J&J and/or any J&J Pharmaceutical Affiliate and report results of such clinical trials on the National Institutes of Health (NIH) sponsored website (www.clinicaltrials.gov) in compliance with all Federal requirements. J&J Pharmaceutical Affiliates shall continue to comply with Federal requirements or other applicable requirements relating to the registration and results reporting of clinical studies throughout the term of this CIA. In addition, if there is a change in Federal requirements or other applicable requirements relating to registration and results reporting of clinical study information, J&J Pharmaceutical Affiliates shall fully comply with such requirements.

J&J Pharmaceutical Affiliates further represent that they make good faith efforts to publish Research results in peer-reviewed journals in a timely fashion and include specified timeframes for the submission of manuscripts following completion of the Research. To the extent not already accomplished, within 120 days after the Effective Date, J&J Pharmaceutical Affiliates shall amend their Policies and Procedures and their contracts with Researchers to require that the Researcher to exercise best efforts to publish the results of the Research in a timely fashion and to impose specified timeframes for the drafting and submission of manuscripts following the completion of a study.

To the extent not already accomplished, within 120 days after the Effective Date, J&J Pharmaceutical Affiliates shall establish policies and practices governing scientific engagement which shall include detailed directions regarding publications. Among other things, the policies and practices

shall require the implementation of data dissemination plans that establish prospective publication strategies for Research and address requirements for appropriateness, accuracy, and balance in publications of Research. In all publications about Research sponsored by J&J and/or a J&J Pharmaceutical Affiliate, J&J and/or the appropriate J&J Pharmaceutical Affiliate shall acknowledge its role as the funding source.

To the extent not already accomplished, within 120 days after the Effective Date, J&J Pharmaceutical Affiliates shall establish policies, systems, and practices designed to ensure that adverse event data regarding pharmaceutical products are properly reported to the FDA.

The standards, policies, and practices described above shall hereafter be referred to collectively as the "Research and Publication Practices." J&J and/or J&J Pharmaceutical Affiliates shall maintain their Research and Publication Practices (or standards and practices substantially equivalent to those set forth above) for studies initiated or completed after the Effective Date for the term of the CIA.

u. authorship of journal articles and other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and the J&J Pharmaceutical Affiliates; the identification of all authors or contributors (including professional writers); and the scope and breadth of research results be made available to each author or contributor.

Authorship Requirements: To the extent not already accomplished, within 120 days after the Effective Date, the J&J Pharmaceutical Affiliates shall require all authors of journal articles or other publications about Research sponsored by a J&J Pharmaceutical Affiliate to adhere to International Committee of Medical Journal Editors (ICMJE) requirements regarding authorship except when a particular journal requires an alternative procedure. In addition, J&J Pharmaceutical Affiliates shall require all authors of articles about Research sponsored by J&J Pharmaceutical Affiliates

to disclose any J&J Pharmaceutical Affiliates financial support for the study and any financial relationship with J&J (including any financial interest the author may have in a J&J or a J&J Pharmaceutical Affiliates product). Within 120 days after the Effective Date, the J&J Pharmaceutical Affiliates shall amend their policies and practices to ensure that individuals may be considered an "author" on a publication about Research sponsored by J&J Pharmaceutical Affiliates only if the individual has made substantial contributions to the study and has given final approval to the version of the publication ultimately published.

Within 120 days after the Effective Date, J&J Pharmaceutical Affiliates' policies and procedures shall be amended (if necessary) to prohibit guest/honorary/gift authorship and ghostwriting.

The standards, policies and practices described above shall be referred to collectively as "Authorship-Related Practices"; and

v. disciplinary policies and procedures for violations of J&J's and/or the J&J Pharmaceutical Affiliate's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), J&J and the J&J Pharmaceutical Affiliates shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education.

1. *General Training*. Within 120 days after the Effective Date, J&J and/or the J&J Pharmaceutical Affiliates shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain J&J's:

a. CIA requirements; and

b. Compliance Program, including the Code of Conduct and Policies and Procedures as they pertain to general compliance issues.

The J&J Pharmaceutical Affiliates' Covered Persons who received General Training after January 1, 2013, explaining the Janssen CIA requirements and the J&J Pharmaceutical Affiliates' compliance program, including its Code of Conduct, are not required to receive additional training referenced in Section III.C.1 until the second Reporting Period. However, within 30 days after the Effective Date, J&J and/or the J&J Pharmaceutical Affiliates shall notify all such Covered Persons (in writing or in electronic format) of the fact that J&J entered into the settlement referenced in the Preamble and this CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training*. Within 120 days after the Effective Date, J&J and/or the J&J Pharmaceutical Affiliates shall provide at least three hours of Specific Training to each Relevant Covered Person relating to his or her specific job responsibilities in addition to the General Training required above.

For Relevant Covered Persons engaged in Promotional Functions or Product Related Functions, this Specific Training shall include a discussion of:

a. all applicable Federal health care program requirements relating to Promotional Functions and Product Related Functions;

b. all applicable FDA requirements relating to Promotional Functions and Product Related Functions;

c. all applicable Policies and Procedures and other requirements applicable to Promotional Functions and Product Related Functions;

d. the personal obligation of each individual involved in Promotional Functions and Product Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;

e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and

f. examples of proper and improper practices related to Promotional Functions and Product Related Functions.

For Relevant Covered Persons engaged in Managed Healthcare Related Functions, this Specific Training shall include a discussion of topics a-f above, as well as:

g. all applicable Federal health care program requirements and FDA requirements relating to Managed Healthcare Related Functions;

h. all company systems and processes applicable to Managed Healthcare Related Functions;

i. all Policies and Procedures and other requirements applicable to Managed Healthcare Related Functions;

j. the personal obligation of each individual involved in Managed Healthcare Related Functions to ensure that all information provided or reported to Payers is complete, accurate and not misleading;

k. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and

l. examples of proper and improper practices relating to Managed Healthcare Related Functions.

New Relevant Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or becoming a Relevant Covered Person or within 120 days of the Effective Date, whichever is later. An employee of a J&J Pharmaceutical Affiliate who has completed the Specific Training shall oversee a new Relevant Covered Person's work, to the extent that the work relates to any of the Covered Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

The J&J Pharmaceutical Affiliates' Relevant Covered Persons, who received Specific Training after January 1, 2013 explaining areas addressed in Section III.C.2.a-f. above are not required to receive additional specific training until the second Reporting Period.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

3. *Compliance Training for Management*. Beginning in the second Reporting Period, in addition to General Training and in lieu of Specific Training, J&J and/or the J&J Pharmaceutical Affiliates shall provide to managers of employees at the J&J Pharmaceutical Affiliates who are performing Covered Functions and to supervisors of sales representatives at J&J Pharmaceutical Affiliates (collectively "Management") at least three hours of specialized compliance-related training applicable to the functional area of the manager (Management Compliance Training). This training shall address the topics addressed in the Specific Training (Section III.C.2) related to the functional area of the manager and the responsibility of Management to promote compliance and to identify and mitigate compliance-related risks.

Beginning in the second Reporting Period, new members of Management shall receive the Management Compliance Training within 30 days after becoming a member of Management.

After receiving the initial Management Compliance Training described in this Section in the second Reporting Period, each Management Relevant Covered Person shall receive at least three hours of Management Compliance Training in each subsequent Reporting Period.

4. *Board Member Training*. Within 120 days after the Effective Date, J&J shall provide at least two hours of training (Board Member Training) to each member of the RCGAC of the J&J Board, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the RCGAC shall receive the Board Member Training described above within 30 days after becoming a member of the RCGAC or within 120 days after the Effective Date, whichever is later.

5. *Certification.* Each individual who is required to complete training shall certify, in writing or in electronic form, that he or she has received such training. The certification shall specify the type of training received and the date received. The J&J CCO or (or designee) shall retain these certifications, along with all course materials. These shall be made available to OIG, upon request.

6. *Qualifications of Trainer.* Persons responsible for providing the training described above shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

7. *Update of Training.* J&J and the J&J Pharmaceutical Affiliates shall review their training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews, the risk assessment and mitigation planning program (discussed below in Section III.D), and any other relevant information.

8. *Computer-based Training.* J&J and/or the J&J Pharmaceutical Affiliates may provide the training required under this CIA through appropriate computer-based training approaches. If J&J and/or the J&J Pharmaceutical Affiliates chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training. In addition, if J&J and/or the J&J Pharmaceutical Affiliates choose to provide computer-based General or Specific Training, all applicable requirements to provide a number of "hours" of training in this section III.C. may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

D. Risk Assessment and Mitigation Planning Program.

J&J represents that, prior to the Effective Date, the J&J Pharmaceutical Affiliates implemented a standardized annual process to allow the J&J Pharmaceutical Affiliates legal, compliance, and other business unit leaders to identify and assess risks associated with the marketing and promotion of Government Reimbursed Products that have field force support in the United States. This process shall be referred to as the Risk Assessment and Mitigation Planning (or "RAMP") Program. The RAMP Program involves an annual evaluation and mitigation of risks associated with the marketing and promotion of Government Reimbursed Products. Based on the outcomes of the RAMP assessments, the J&J Pharmaceutical Affiliates develop and implement specific plans designed to mitigate or reduce the identified risks. The risk mitigation plans shall be developed annually and a plan shall be developed for each Government Reimbursed Product. The RAMP Program shall be reviewed by the IRO, and the IRO review of the RAMP Program is described in more detail in Appendix C. J&J and the J&J Pharmaceutical Affiliates shall maintain the RAMP process for the duration of the CIA.

E. Review Procedures

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, J&J and/or the J&J Pharmaceutical Affiliates shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist the J&J Pharmaceutical Affiliates in assessing and evaluating their Covered Functions and the RAMP Program. More specifically, the IRO(s) shall conduct reviews that assess the J&J Pharmaceutical Affiliates' systems, processes, policies, procedures, and practices relating to the Covered Functions and the RAMP Program (collectively "IRO Reviews").

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by J&J and/or the J&J Pharmaceutical Affiliates shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained including expertise in the pharmaceutical industry with regard to risk identification and mitigation in relation to pharmaceutical product marketing and promotion. Each IRO shall assess, along with J&J and/or the J&J Pharmaceutical Affiliates, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendices B and C, the IRO Reviews shall consist of three components: (1) Systems Reviews and Transactions Reviews relating to the Covered Functions; (2) Systems Reviews and Transaction Reviews relating to the RAMP Program; and (3) Additional Items reviews. The Systems Reviews shall assess the J&J Pharmaceutical Affiliates systems, processes, policies, and procedures relating to the Covered Functions and the RAMP Program. If there are no material changes in relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the periods covering the second and fifth Reporting Periods. If a J&J Pharmaceutical Affiliate

materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform Systems Reviews for the Reporting Period in which such changes were made in addition to conducting a Systems Review for the second and fifth Reporting Periods, as set forth more fully in Appendices B and C.

The Transactions Reviews shall be performed annually and shall cover each of the six Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendices B and C, the Transactions Reviews shall include several components.

In addition, as set forth in Appendix B, the Transactions Reviews relating to Covered Functions shall also include a review of up to three additional areas or practices of the J&J Pharmaceutical Affiliates identified by the OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with the J&J Pharmaceutical Affiliates and may consider internal audit work conducted by the J&J Pharmaceutical Affiliates, the Government Reimbursed Product portfolio of J&J and the J&J Pharmaceutical Affiliates, the nature and scope of the J&J Pharmaceutical Affiliates' promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, the J&J Pharmaceutical Affiliates may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow the J&J Pharmaceutical Affiliates' internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify J&J and/or the J&J Pharmaceutical Affiliates of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each applicable Reporting Period. Prior to undertaking

the review of the Additional Items, the IRO and/or J&J and/or the J&J Pharmaceutical Affiliates shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

c. *Retention of Records.* The IRO and J&J and/or the J&J Pharmaceutical Affiliates shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and J&J and/or the J&J Pharmaceutical Affiliates) related to the IRO Reviews.

2. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in each IRO Review Report is described in Appendices B and C.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any of the IRO Reviews fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). J&J shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of reports submitted as part of J&J's final Annual Report shall be initiated no later than one year after J&J's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify J&J of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, J&J may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. J&J agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with J&J prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to J&J a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section

III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

F. Disclosure Program.

To the extent not already accomplished, within 90 days after the Effective Date, J&J shall ensure a Disclosure Program is established covering all J&J Pharmaceutical Affiliates that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the J&J CCO (or designee) or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with J&J's or any J&J Pharmaceutical Affiliate's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. J&J and/or the J&J Pharmaceutical Affiliates shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the J&J CCO (or designee) shall gather all relevant information from the disclosing individual. The J&J CCO (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, J&J and/or the J&J Pharmaceutical Affiliates shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The J&J CCO (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. This disclosure log shall be made available to OIG upon request.

G. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's System of Awards Management (available through the Internet at http://www.sam.gov).

2. *Screening Requirements.* J&J and/or the applicable J&J Pharmaceutical Affiliates shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements:

a. J&J or the applicable J&J Pharmaceutical Affiliate shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. to the extent not already accomplished within 180 days prior to the Effective Date, J&J or the applicable J&J Pharmaceutical Affiliate shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. J&J and/or the applicable J&J Pharmaceutical Affiliate shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in Section III.G affects J&J's or the applicable J&J Pharmaceutical Affiliate's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. J&J and the applicable J&J Pharmaceutical Affiliates understand that items or services furnished by excluded persons are not payable by Federal health care programs and that J&J and/or the applicable J&J Pharmaceutical Affiliate may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether J&J and/or the applicable J&J Pharmaceutical Affiliate meets the requirements of Section III.G.

3. *Removal Requirement*. If J&J or the applicable J&J Pharmaceutical Affiliate has actual notice that a Covered Person has become an Ineligible Person, J&J or the applicable J&J Pharmaceutical Affiliate shall remove such Covered Person from responsibility for, or involvement with, those business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If J&J or the applicable J&J Pharmaceutical Affiliate has actual notice that a Relevant Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Relevant Covered Person's employment or contract term, J&J or the applicable J&J Pharmaceutical Affiliate shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

H. Employee and Executive Incentive Compensation and Recoupment Policies and Practices.

The J&J Pharmaceutical Affiliates will maintain policies and procedures that shall be designed to ensure that financial incentives do not inappropriately motivate sales representatives or their direct managers to engage in improper promotion, sales, and marketing of Government Reimbursed Products (Incentive Compensation Program).

J&J represents that prior to the Effective Date, the J&J Pharmaceutical Affiliates included in the Incentive Compensation Program the "Qualifying the Customer Initiative" (QCI) and the "Sales Award Audit." The QCI is designed to ensure that sales representative compensation is based on compliant sales interactions with appropriate HCP targets and is part of the RAMP process detailed in Section III.D. All Government

Reimbursed Products that are actively promoted are subjected to a risk-based assessment for inclusion in QCI programs. The Sales Award Audit is an annual audit of top-performing sales representatives who may qualify for an award based on their performance (e.g., an incentive trip, monetary compensation). The Sales Award Audit is designed to ensure sales representatives' adherence to applicable health care compliance, travel, and entertainment policies and procedures in interactions with customers, and also is part of the RAMP process detailed in Section III.D.

Beginning in the second Reporting Period, the J&J Pharmaceutical Affiliates shall audit at least 5% of the sales representatives who are eligible for a performance based award as a part of the Sales Award Audit and shall ensure that all Government Reimbursed Products that are actively promoted are included in the sampling for the Sales Awards Audit. The J&J Pharmaceutical Affiliates may request adjustments to the number of sales representatives audited, and any such modifications must be approved by the OIG. The J&J Pharmaceutical Affiliates shall continue the QCI and Sales Award Audit, or substantially equivalent programs, for at least the duration of the CIA absent agreement otherwise by OIG.

Prior to the Effective Date, J&J endorsed the Principal Elements of a Leading Practices Recoupment Policy (the "Principles"). In accordance with those Principles, within 150 days after the Effective Date, J&J shall establish and maintain throughout the term of this CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual incentive compensation (including bonuses and equity awards) for a Covered Executive (as defined in Appendix D) based on significant misconduct relating to the sales or marketing of pharmaceutical products by the Covered Executive, or significant misconduct relating to the sales or marketing of pharmaceutical products in the business unit for which the Covered Executive had responsibility, in the circumstances described in Appendix D (Executive Financial Recoupment Program). This financial recoupment program shall apply to Covered Executives who are current and former executives of J&J or a J&J Pharmaceutical Affiliate at the time of a Recoupment Determination (as defined in Appendix D). The specific terms and conditions of the Executive Financial Recoupment Program are set forth in Appendix D. J&J commits to maintaining an Executive Financial Recoupment Program consistent with the terms of Appendix D for at least the duration of the CIA absent agreement otherwise by OIG.

I. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, J&J and/or the J&J Pharmaceutical Affiliates shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to J&J or to any J&J Pharmaceutical Affiliate conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that any J&J Pharmaceutical Affiliate has

committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. J&J and/or the J&J Pharmaceutical Affiliates shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

J. Reportable Events.

1. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a matter that a reasonable person would consider a probable violation by any J&J Pharmaceutical Affiliate of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to J&J or a J&J Pharmaceutical Affiliate);

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

d. the filing of a bankruptcy petition by J&J or a J&J Pharmaceutical Affiliate.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If J&J and/or the J&J Pharmaceutical Affiliates determine (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event involving a J&J Pharmaceutical Affiliate, J&J shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.J.1.a-c*. For Reportable Events under Sections III.J.1.a-c, the report to OIG shall include:

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;

b. a description of the actions J&J and/or the applicable J&J Pharmaceutical Affiliate has taken to correct the Reportable Event; and

c. any further that steps J&J and/or the applicable J&J Pharmaceutical Affiliates plan to take to address the Reportable Event and prevent it from recurring.

J&J and/or the J&J Pharmaceutical Affiliates shall not be required to report as a Reportable Event a matter which is the subject of an ongoing investigation or legal proceeding by a government entity or its agents previously disclosed under Section III.I above.

4. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

K. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between J&J and/or a J&J Pharmaceutical Affiliate and the FDA that materially discusses J&J's, a J&J Pharmaceutical Affiliate's or a Covered Person's actual or potential unlawful or improper promotion of Government Reimbursed Products (including any improper dissemination of information about off-label indications), J&J and/or the applicable J&J Pharmaceutical Affiliates shall provide a copy of the report, correspondence, or communication to the OIG. J&J and/or the applicable J&J Pharmaceutical Affiliates shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

L. Field Force Controls, Monitoring and Review Efforts.

1. *Compliance Controls*. Prior to the Effective Date, the J&J Pharmaceutical Affiliates developed and implemented internal compliance controls and processes to ensure that the J&J Pharmaceutical Affiliates' business activities are conducted in accordance with Federal health care program and FDA requirements (Compliance Controls). The J&J Pharmaceutical Affiliates represent that these Compliance Controls are based on requirements set forth in the J&J Pharmaceutical Affiliates' Policies and

Procedures and function as oversight and risk mitigation mechanisms designed to ensure that the Compliance Program operates effectively and that compliance concerns are detected and remedied in a systematic manner. The J&J Pharmaceutical Affiliates further represent that through a combination of: (i) the RAMP process (as described in Section III.D. above), (ii) transaction-specific Compliance Controls (as described in this Section III.L.1) and (iii) the Healthcare Compliance Monitoring program (as described in Section III.L.2 below), the Compliance Program reviews fair market value payments and needs assessments for Consultant arrangements, Researcher arrangements, and Publications activities, among other activities, to ensure that these arrangements or activities fulfill legitimate J&J Pharmaceutical Affiliates' business or scientific needs.

The J&J Pharmaceutical Affiliates review, and throughout the term of this CIA shall continue to review, the Compliance Controls on a routine and ongoing basis. As part of its review of the Compliance Controls, except as expressly set forth below, the J&J Pharmaceutical Affiliates will revise the Compliance Controls based on the business risks identified as a result of the annual RAMP process described in Section III.D of this CIA. The J&J Pharmaceutical Affiliates will summarize any revisions to Compliance Controls in Annual Reports submitted to OIG pursuant to Section V.B of this CIA.

a. *Speaker Program Controls.* The J&J Pharmaceutical Affiliates implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for speaker programs. The J&J Pharmaceutical Affiliates represent that these controls ensure, among other factors, that: (i) all speakers enter into written agreements describing the scope of work to be performed, the fees to be paid and the compliance obligations of the speakers (including requirements that speakers may only use the J&J Pharmaceutical Affiliates' approved materials and may not directly or indirectly promote the product for off-label uses); (ii) only eligible and qualified speakers (who have completed required training) participate in speaker programs; (iii) amounts paid to speakers are consistent with fair market value and tracked in connection with speaker programs conducted during each Reporting Period; (iv) appropriate venues are selected for speaker training and speaker programs; and (v) there is a legitimate need for the speaker program (collectively, the "Speaker Program Controls"). The J&J Pharmaceutical Affiliates shall manage each speaker program to ensure that the Speaker Program Controls are operating effectively and that speaker programs are conducted in accordance with J&J Pharmaceutical Affiliates Policies and Procedures, and prompt reporting of any instances of non-compliance.

b. *Consultant Arrangements Controls.* To the extent that the J&J Pharmaceutical Affiliates enter into contracts, agreements, or other arrangements with HCPs or HCIs that relate to Promotional Functions or Product Related Functions (e.g., as a member of an advisory board or to attend consultant meetings) other than for speaker programs, Research, or Publication activities (as defined below), such HCPs or HCIs

shall be referred to herein as "Consultants". The J&J Pharmaceutical Affiliates implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Consultant arrangements. The J&J Pharmaceutical Affiliates represent that these controls ensure, among other factors, that: (i) prior to retention of the Consultant, the J&J Pharmaceutical Affiliates define the scope of the proposed services to be performed by the Consultant, confirm that the Consultant is appropriately qualified to provide these proposed services and verifies that there is a legitimate business need for the Consultant's retention; (ii) amounts paid to Consultants are fair market value and for services rendered; (iii) all Consultants enter into written agreements describing the scope of work to be performed, the fees to be paid and the compliance obligations of the Consultants; and (iv) to the extent applicable, the J&J Pharmaceutical Affiliates received the work product generated by the Consultant (collectively, the "Consultant Arrangements Controls").

c. *Third Party Educational Activities Controls and Sponsorships Controls.* The J&J Pharmaceutical Affiliates implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Third Party Educational Activities (as defined in Section II.C.9). The J&J Pharmaceutical Affiliates represent that these controls ensure, among other factors, that: (i) all Third Party Educational Activity funding requests are reviewed, tracked, and evaluated by the Compliance organization to ensure that the requests meet compliance criteria; (ii) funding decisions are based on objective criteria such as: the qualifications of the requestor, the quality of the Third Party Educational Activity program, and the J&J Pharmaceutical Affiliates' pre-established educational goals; (iii) Third Party Educational Activity funding is provided only pursuant to a written agreement with the funding recipient and payments made to the Third Party Educational Activity funding recipient comply with the express terms of the written agreement; and (iv) the J&J Pharmaceutical Affiliates' staff are not involved in the development or implementation of Third Party Educational Activity programs funded by the J&J Pharmaceutical Affiliates (collectively, the "Third Party Educational Activity Controls").

In addition, the J&J Pharmaceutical Affiliates implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for sponsorships to ensure that the J&J Pharmaceutical Affiliates' sponsorships comply with all applicable Federal health care program and FDA requirements (Sponsorships Controls). The J&J Pharmaceutical Affiliates represent that the Sponsorships Controls ensure, among other factors, that: (i) a legitimate business purpose for the sponsorship exists; (ii) a tangible benefit for the sponsorship exists; (iii) proposed costs and fees are reasonable; and (iv) prior to the sponsorship being provided and paid, there is a fully executed agreement in place which sets forth the sponsorship to be provided.

d. *Publication Controls.* To the extent that the J&J Pharmaceutical Affiliates engage HCPs or HCIs as authors for articles or other publications relating to Research (Publications), such HCPs or HCIs shall be referred to as "Authors". The J&J Pharmaceutical Affiliates implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Publications. The J&J Pharmaceutical Affiliates represent that these controls ensure, among other factors, that: (i) prior to beginning the drafting of a Publication manuscript, Authors confirm in writing that they will participate in a manner consistent with the J&J Pharmaceutical Affiliates' requirements for Authors; (ii) during the Final Publication Approval process, Publications are reviewed and approved by noncommercial personnel of the J&J Pharmaceutical Affiliates with relevant expertise prior to submission to a journal or congress; (iii) Publications are developed in a transparent and collaborative manner in accordance with principles of scientific exchange; (iv) with certain limited exceptions, no compensation is paid to Authors for their time spent drafting or revising Publications; and (v) Authors confirm that they satisfy International Committee of Medical Journal Editors (ICMJE) authorship criteria, including providing final approval of the version of the Publication to be published (collectively, the "Publication Controls").

e. *Research Controls*. To the extent that the J&J Pharmaceutical Affiliates engage or provide support to HCPs or HCIs to conduct Research, such HCPs and HCIs will be referred to herein as "Researchers". The J&J Pharmaceutical Affiliates implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, Compliance Controls for Research. The J&J Pharmaceutical Affiliates represent that these controls ensure, among other factors, that: (i) all Researchers enter into written agreements describing the scope of work to be performed, the fees to be paid and the compliance obligations of the Researchers; (ii) if payment or funding is provided, that amounts paid are fair market value for services rendered; and (iii) prior to retention of the Researcher, the J&J Pharmaceutical Affiliates define the scope of the proposed Research, confirms that Researchers are appropriately qualified to perform the Research, and verifies that there is a legitimate business or scientific need for the Research (collectively, the "Research Controls").

2. *Healthcare Compliance Monitoring*. Prior to the Effective Date, the J&J Pharmaceutical Affiliates established a comprehensive Healthcare Compliance Monitoring (HCCM) program. The Healthcare Compliance Monitoring program is a formalized and ongoing process, in which appropriately trained personnel from the compliance organization or law, or other J&J Pharmaceutical Affiliate organizations, or agents acting on behalf of the Compliance organization, at the direction of the Compliance organization who are independent from the activity area being monitored (collectively "Monitoring Personnel") check and measure healthcare compliance-related performance pertaining to a specific function or department to ensure achievement of operational and/or compliance objectives. To the extent not already accomplished,

within 120 days after the Effective Date, the J&J Pharmaceutical Affiliates shall extend its Healthcare Compliance Monitoring program, including the Healthcare Compliance testing program to all business areas within the J&J Pharmaceutical Affiliates that perform Covered Functions under this CIA.

As described in more detail below, the Healthcare Compliance Monitoring program includes, and shall continue to include: 1) the development and execution of an annual plan that is based on an assessment of compliance risks and that identifies the types and volume of monitoring activities to be performed for each year (Monitoring Plan); 2) activities that evaluate compliance through a focus on processes, procedures, and documentation for various activities that are initiated and handled internally from the J&J Pharmaceutical Affiliates headquarters (Transactional Activities); and 3) activities that evaluate compliance through attendance at the site of a business activity, such as speaker programs and observations of sales representatives (Field-Based Activities). The J&J Pharmaceutical Affiliates implemented prior to the Effective Date, and shall continue to maintain throughout the term of this CIA, written procedures regarding the operation of the Healthcare Compliance Monitoring program and reporting and follow-up for any potential or suspected noncompliance with the J&J Pharmaceutical Affiliates' Policies and Procedures or legal requirements.

a. *Annual Monitoring Plan*. Prior to the Effective Date, the J&J Pharmaceutical Affiliates developed, and shall continue to maintain throughout the term of this CIA, annual Monitoring Plans based on relative assessment of risk in each calendar year, using the identified risk results from the RAMP, with consideration of external factors (e.g., regulatory changes, IRO findings) and internal factors (e.g., past monitoring results, management feedback). Pursuant to the applicable Monitoring Plan(s), during each year, the J&J Pharmaceutical Affiliates shall select Transactional Activities and Field-Based Activities for review and assessment, using both a risk-based targeting and sampling approach.

The J&J Pharmaceutical Affiliates represent that the Monitoring Plans for the period January 1, 2013 through December 31, 2013 and the second Reporting Period will include each of the types of Transactional Activities and Field Based Activities described in Sections III.L.2.b and III.L.2.c below (i.e., monitoring activities for Consultant arrangements, Researcher arrangements, Publication activities, Third Party Educational activities, speaker programs and Observations (hereafter, "CIA-required Monitoring Activities")). The J&J Pharmaceutical Affiliates further represent that the Monitoring Plans for the period January 1, 2013 through December 31, 2013 and the second Reporting Period requires the J&J Pharmaceutical Affiliates to conduct, at minimum, the numbers of CIA-required Monitoring Activities described in Sections III.L.2.b and III.L.2.c below.

On or before November 1, 2014, the J&J Pharmaceutical Affiliates shall submit to OIG the proposed Monitoring Plan for the period January 1, 2015 to December 31, 2015 (Monitoring Plan). The proposed Monitoring Plan shall include, at minimum, the numbers and types of CIA-required Monitoring Activities described in Sections III.L.2.b and III.L.2.c below. Thereafter, no later than November 1 of each calendar year beginning in 2015 through the end of the term of the CIA, the J&J Pharmaceutical Affiliates shall submit to OIG a summary and an explanation of: (i) any reductions in the number of CIA-required Monitoring Activities to be conducted in the upcoming calendar year, compared to the prior year's Monitoring Plan and (ii) any material modifications to the types of CIA-required Monitoring Activities to be conducted in the upcoming calendar year, compared to the prior year's Monitoring Plan. Each proposed Monitoring Plan shall also indicate whether transactions or activities at each and every J&J Pharmaceutical Affiliate will be subject to monitoring under the plan. To the extent that transactions or activities at a particular J&J Pharmaceutical Affiliate are not subject to monitoring under an annual Monitoring Plan, the proposed Monitoring Plan shall explain the rationale for the non-inclusion of all such Pharmaceutical Affiliate(s).

OIG shall have the right to object and/or propose changes to each annual proposed Monitoring Plan in the event it does not comply with requirements of Sections III.L.2.b and III.L.2.c, and OIG shall have the right to object and/or propose changes to any proposed reductions or modifications with respect to CIA-required Monitoring Activities for upcoming and subsequent years. In the event OIG does not notify the J&J Pharmaceutical Affiliates of any objection and/or proposed changes to the applicable proposed Monitoring Plan and/or proposed reductions or modifications submitted to the OIG from time to time, the J&J Pharmaceutical Affiliates may proceed to implement the Monitoring Plan and/or the proposed reductions and modifications submitted to OIG, as of January 1 of the following calendar year. In addition to the notifications to OIG under this Section III.L.2.a, the J&J Pharmaceutical Affiliates shall provide information regarding each year's Monitoring Plan to OIG as part of the Annual Reports in accordance with Section V.B.19 below.

Subject to the limitations of this Section III.L.2 the number of Transactional Activities and/or Field-Based Activities conducted by the J&J Pharmaceutical Affiliates each year may be increased or decreased from time to time based on the applicable Monitoring Plan as informed by the J&J Pharmaceutical Affiliates' annual RAMP.

b. *Transactional Activities*. Prior to the Effective Date, the J&J Pharmaceutical Affiliates developed, and shall continue to maintain throughout the term of this CIA, a process for monitoring Transactional Activities through which Monitoring Personnel review certain activities and complete monitoring assessments. The monitoring assessment will describe the risk area being examined, identify the Compliance Controls that form the basis of the Transactional Activity and ask a series of

questions designed to verify whether the Transactional Activity that was reviewed complied with the J&J Pharmaceutical Affiliates' Policies and Procedures. Monitoring assessments shall account for Compliance Controls based on requirements set forth in the J&J Pharmaceutical Affiliates' Policies and Procedures and shall ensure that Monitoring Personnel review documentation available for the Transactional Activity to assess whether the activities being monitored were conducted in a manner consistent with the J&J Pharmaceutical Affiliates' Policies and Procedures.

During the term of this CIA, except as otherwise set forth in this Section III.L.2, the J&J Pharmaceutical Affiliates, through Monitoring Personnel, shall conduct reviews of, and complete monitoring assessments for, the following Transactional Activities:

(i) *Consultant Arrangement Activities*. To the extent that the J&J Pharmaceutical Affiliates engage Consultants during the term of the CIA, the J&J Pharmaceutical Affiliates created, and shall maintain throughout the term of this CIA, monitoring assessments that evaluate compliance with the Consultant Arrangements Controls consistent with the J&J Pharmaceutical Affiliates' Policies and Procedures. Monitoring Personnel shall review, and complete monitoring assessments for, at least 50 Consultant arrangements with HCPs or HCIs in the period January 1, 2013 to December 31, 2013 and the Second Reporting period (January 1, 2014 to December 31, 2014). Beginning January 1, 2015, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall review, and complete monitoring assessments for, at least the number of Consultant arrangements with HCPs or HCIs selected in accordance with the applicable year's Monitoring Plan and as approved by OIG in accordance with Section III.L.2.a.

(ii) *Researcher Arrangement Activities*. To the extent that the J&J Pharmaceutical Affiliates engage Researchers during the term of the CIA, the J&J Pharmaceutical Affiliates created, and shall continue to maintain throughout the term of this CIA, monitoring assessments that evaluate compliance with the Research Controls consistent with the J&J Pharmaceutical Affiliates' Policies and Procedures.

Monitoring Personnel shall review, and complete monitoring assessments, for at least 30 Researcher arrangements with HCPs or HCIs in the period from January 1, 2013 to December 31, 2013, and the second Reporting Period. Beginning January 1, 2015, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall review, and complete monitoring assessments for, at least the number of Researcher arrangements with HCPs or HCIs selected in accordance with the applicable year's Monitoring Plan and as approved by OIG in accordance with Section III.L.2.a.

(iii) *Publication Activities*. To the extent that the J&J Pharmaceutical Affiliates engage Authors for Publication activities, the J&J

Pharmaceutical Affiliates created, and shall continue to maintain throughout the term of this CIA, monitoring assessments that evaluate compliance with the Publication Controls consistent with the J&J Pharmaceutical Affiliates' Policies and Procedures. Monitoring Personnel shall review, and complete monitoring assessments for, at least 20 Publication activities in the period January 1, 2013 through December 31, 2013, and for at least 30 Publication activities in the second Reporting Period. Beginning January 1, 2015, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall review, and complete monitoring assessments for, at least the number of Publication activities selected in accordance with the applicable Monitoring Plan and as approved by OIG in accordance with Section III.L.2.a.

(iv) *Third Party Educational Activities*. To the extent that the J&J Pharmaceutical Affiliates provide funding for Third Party Educational Activities, the J&J Pharmaceutical Affiliates created, and shall continue to maintain throughout the term of this CIA, monitoring assessments that evaluate compliance with the Third Party Educational Activity Controls governing the process through which requesters may seek or be awarded funding for Third Party Educational Activities from the J&J Pharmaceutical Affiliates. Monitoring Personnel shall review, and complete monitoring assessments for, at least 20 Third Party Educational Activities (i.e., Third Party Educational requests) in the period January 1, 2013 to December 31, 2013, and at least 30 Third Party Educational Activities in the second Reporting Period. Beginning January 1, 2015, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall review, and complete monitoring assessments for, at least the number of Third Party Educational Activities selected in accordance with the applicable Monitoring Plan and as approved by OIG in accordance with Section III.L.2.a.

(v) *Records Review*. As a component of its monitoring of Transactional Activities, the J&J Pharmaceutical Affiliates shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs in order to identify actual or potential compliance violations (Records Reviews). The J&J Pharmaceutical Affiliates created, and shall maintain throughout the term of this CIA, monitoring assessments that evaluate compliance with the J&J Pharmaceutical Affiliates' Policies and Procedures governing interactions between sales representatives and HCPs and HCIs. For each Reporting Period, the J&J Pharmaceutical Affiliates shall complete monitoring assessments based on Records Reviews for at least three Government Reimbursed Products in accordance with that year's Monitoring Plan, which shall result in Monitoring Personnel conducting a Records Review of sales representatives from across the J&J Pharmaceutical Affiliates' business units and United States geographic regions.

In the period January 1, 2013 through December 31, 2013 and the second Reporting Period, the Records Reviews shall include, at a minimum, a review of: (1) the

J&J Pharmaceutical Affiliates' required system of records for sales representatives (which includes call notes, if applicable); (2) requests for medical information; and (3) field conference reports describing field ride-alongs conducted by a field manager with a sales representative. Beginning January 1, 2015, through the Monitoring Plan as informed by the RAMP and subject to OIG approval of any reductions or modifications as referenced in Section III.L.2.a above, the J&J Pharmaceutical Affiliates shall determine the types of documentation completed by sales representatives in connection with their interactions with HCPs or HCIs that will permit the J&J Pharmaceutical Affiliates to assess most effectively the compliance of sales representatives with Policies and Procedures governing interactions with HCPs and HCIs in that Reporting Period. Following this determination, and as documented in the Monitoring Plan, Monitoring Personnel will review such documentation in order to complete the required monitoring assessments.

In connection with the development of the Monitoring Plan for each calendar year, the OIG shall have the discretion to identify the Government Reimbursed Products to be reviewed for each applicable Reporting Period. The OIG will select the products based on information about the J&J Pharmaceutical Affiliates' products provided by the J&J Pharmaceutical Affiliates, upon request by the OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, the J&J Pharmaceutical Affiliates shall select the products to be reviewed based on the Monitoring Plan.

c. *Field-Based Activities*. Prior to the Effective Date, the J&J Pharmaceutical Affiliates developed, and shall continue to maintain throughout the term of this CIA, a process for monitoring Field-Based Activities through which Monitoring Personnel complete monitoring assessments based on direct or indirect observations of sales representatives made at the site of a business activity and the documentation associated with such observations. As with Transactional Activities, Monitoring Personnel shall review, and complete monitoring assessments for, Field-Based Activities that account for the Compliance Controls based on requirements set forth in the J&J Pharmaceutical Affiliates' Policies and Procedures, guide Monitoring Personnel in making the necessary direct and indirect observations during the Field-Based Activity, and ensure that Monitoring Personnel review all documentation needed to assess whether the Field-Based Activity was conducted in a manner consistent with the J&J Pharmaceutical Affiliates' Policies and Procedures.

During the term of this CIA, except as otherwise set forth in this Section III.L.2, the J&J Pharmaceutical Affiliates, through Monitoring Personnel, shall review, and complete monitoring assessments for, the following Field-Based Activities:

(i) *Speaker Programs Activities*. Prior to the Effective Date, the J&J Pharmaceutical Affiliates conducted, and shall continue to conduct throughout the term of this CIA, monitoring of Field-Based Activities that require Monitoring Personnel to attend speaker programs (Speaker Monitoring Program). For each speaker program selected for the Speaker Monitoring Program, the relevant Monitoring Personnel shall complete a Speaker Program Assessment that requires the review of slides and other materials used as part of the speaker program, speaker statements made during the program, and the J&J Pharmaceutical Affiliates' representative activities during the program to assess whether the programs were conducted in a manner consistent with the J&J Pharmaceutical Affiliates' Policies and Procedures.

In the period January 1, 2013 through December 31, 2013, Monitoring Personnel shall attend and actively review at least 100 speaker programs. In the second Reporting Period, Monitoring Personnel shall attend and actively review at least 150 speaker programs. Beginning January 1, 2015, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall attend and review at least the number of speaker programs selected in accordance with the applicable Monitoring Plan and as approved by OIG in accordance with Section III.L.2.a.

(ii) *Field-Ride Observations*. Prior to the Effective Date, the J&J Pharmaceutical Affiliates conducted, and shall continue to conduct throughout the term of this CIA, observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with the J&J Pharmaceutical Affiliates' Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Field-Ride Observations) by Monitoring Personnel, and each Observation shall consist of the relevant Monitoring Personnel observing all meetings between a sales representative and HCPs during the workday. In the period from January 1, 2013 through December 31, 2013, and the second Reporting Period, the J&J Pharmaceutical Affiliates shall conduct at least 50 Observations, which shall result in Monitoring Personnel conducting Field Observations of sales representatives across the J&J Pharmaceutical Affiliates' business units and United States geographic regions. Beginning January 1, 2015, and for each subsequent calendar year in the remainder of the term of the CIA, Monitoring Personnel shall conduct at least the number of Field-Ride Observations selected in accordance with the applicable Monitoring Plan and as approved by OIG in accordance with Section III.L.2.a, which shall result in Monitoring Personnel conducting Observations of sales representatives across the J&J Pharmaceutical Affiliates' business units programs and United States geographic regions.

At the completion of each Field-Ride Observation, Monitoring Personnel shall complete a Field Observation Assessment that includes at a minimum:

1) the identity of the sales representative;
2) the identity of the J&J Pharmaceutical Affiliate Monitoring Personnel;
3) the date and duration of the Field-Ride Observation;
4) the product(s) promoted during the Field-Ride Observation;
5) an overall assessment of compliance with applicable Policies and Procedures; and
6) the identification of any potential off-label promotional activity or other improper conduct by the sales representative.

d. *Reporting and Follow-Up*. Monitoring personnel's assessments and documentation of the results from monitoring Transactional Activities and Field-Based Activities shall be compiled, retained, and reported to the Compliance organization and other appropriate organizations within the J&J Pharmaceutical Affiliates for review and follow-up as appropriate.

In the event that a finding of a monitoring assessment indicates that an activity has raised one or more potential compliance concerns or issues for follow-up, a member of the Compliance organization shall review and assess the significance of the finding. If the finding is determined by the Compliance organization to present a potential significant compliance issue, the finding shall be reported to the NALT Compliance Officer. The finding shall also be referred to the appropriate department within the Compliance organization or the J&J Pharmaceutical Affiliates, including but not limited to, the Compliance organization's Internal Investigations program to respond to the finding consistent with established policies and procedures for the triage and handling of potential noncompliance and to ensure all necessary and appropriate responsive (including disciplinary) and corrective actions are taken, including the disclosure of Reportable Events pursuant to Section III.J, if applicable.

Any compliance issues identified during monitoring assessments, and any corrective action taken as a result of the findings identified in the course of the monitoring of Transactional Activities or Field-Based Activities, shall be recorded in the files of the Compliance organization. The J&J Pharmaceutical Affiliates shall include in each Annual Report a summary of the Healthcare Compliance Monitoring program and the results of the monitoring activities conducted for Transactional Activities and Field-Based Activities. The J&J Pharmaceutical Affiliates shall make documents relating to its monitoring of Transactional Activities and Field-Based Activities available to the OIG upon request.

M. Notices to Health Care Providers, Entities, Payers. Within 90 days after the Effective Date, J&J shall send, by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth below to all HCPs and HCIs that

personnel from the J&J Pharmaceutical Affiliates currently detail. This notice shall be dated and shall be signed by J&J's North American Pharmaceutical Company Group Chair. The body of the letter shall state the following:

> As you may be aware, Johnson & Johnson (J&J) and certain of its pharmaceutical affiliates recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and use of three of its products. This letter provides you with additional information about the settlement, explains the commitments of J&J and certain of its pharmaceutical affiliates going forward, and provides you with access to information about those commitments.
>
> In general terms, the Government alleged that J&J and certain of its pharmaceutical affiliates unlawfully promoted Risperdal, Invega, and Natrecor for uses not approved by the Food & Drug Administration (FDA) and that J&J and certain pharmaceutical affiliates engaged in other improper conduct relating to the drugs which constituted violations of the False Claims Act. To resolve these matters, Janssen Pharmaceuticals, Inc. pled guilty to one misdemeanor criminal violation of the Federal Food, Drug & Cosmetic Act and agreed to pay a criminal fine and forfeiture of $400 million. In addition, the Government alleged that J&J and certain of its pharmaceutical affiliates violated the False Claims Act, and J&J and certain of its pharmaceutical affiliates entered into civil settlements to resolve these allegations pursuant to which J&J and certain of its pharmaceutical affiliates agreed to pay $1.6 billion to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: [The letter shall include links to the Department of Justice and J&J websites.]
>
> As part of the global settlement, J&J also entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is available at https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp. Under this agreement, J&J agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by any of J&J's representatives to J&J's Compliance Department or the FDA using the information set forth below.
>
> Please call J&J at [insert phone number] or visit us at [insert web link] if

you have questions about the settlement referenced above or to report any instances in which you believe that a J&J representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a J&J representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to [insert applicable FDA phone number.]

The J&J CCO (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notice shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, J&J shall provide to the OIG a summary of the calls and messages received.

N. Reporting of Physician Payments.

1. *Reporting of Payment Information.*

Quarterly Reporting: On or before March 1, 2014, J&J shall ensure that the J&J Pharmaceutical Affiliates post in a prominent position on their respective websites, as well as on the J&J website (through a link or other appropriate means), an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.N.2, below) directly or indirectly from the applicable J&J Pharmaceutical Affiliate during the last quarter of 2013 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, each J&J Pharmaceutical Affiliate shall post on its respective website and on the J&J website (through a link or other appropriate means) a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

Annual Reporting: On or before May 1, 2014, J&J shall ensure that the J&J Pharmaceutical Affiliates post on their respective websites and the J&J website (through a link or other appropriate means) a report of the cumulative value of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from the applicable J&J Pharmaceutical Affiliate during the prior applicable calendar year. For subsequent calendar years during the term of the CIA, the annual report shall be posted 60 days after the end of each prior calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.N shall include a complete list of all individual physicians or Related Entities to whom or which the J&J Pharmaceutical Affiliate made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician has provided to the J&J Pharmaceutical Affiliate for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

2. *Definitions and Miscellaneous Provisions.*

(i) J&J shall continue to ensure that each annual listing and the most recent quarterly listing of Payments are available on its own website (through a link or other appropriate means) and the J&J Pharmaceutical Affiliates' respective websites during the term of the CIA. J&J and/or the applicable J&J Pharmaceutical Affiliates shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.N affects the responsibility of J&J and/or any J&J Pharmaceutical Affiliate to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

(ii) For purposes of Section III.N.1, "Payments" is defined to include all "payments or other transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom a J&J Pharmaceutical Affiliate would otherwise report a Payment if

made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by a J&J Pharmaceutical Affiliate or by a vendor retained by a J&J Pharmaceutical Affiliate to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iii) For purposes of its annual and quarterly website postings as described above, and only with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act, J&J may delay the inclusion of such payments on its website and the websites of the J&J Pharmaceutical Affiliates listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(iv) The term "Payments" does not include transfers of value or other items that are not included in or are excluded from the definition of "payment" as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

(v) For purposes of this Section III.N, the term "Related Entity" is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

O. Other Transparency/Disclosure Initiatives.

To the extent not already accomplished, within 120 days after the Effective Date of the CIA, J&J shall ensure that the J&J Pharmaceutical Affiliates shall post the following information on their respective websites and the J&J website (through a link or other appropriate means) annual reports about grants and charitable contributions to U.S.-based HCPs and HCIs: (1) the ultimate recipients organization's name, to the extent known by J&J Pharmaceutical Affiliates; (2) a brief description of the program for which the grant or charitable contribution was requested; and (3) the amount of the grant or charitable contribution. The J&J Pharmaceutical Affiliates shall continue to post (and provide updates to) the above-described information about grants and charitable contributions throughout the term of this CIA. The J&J Pharmaceutical Affiliates shall notify the OIG in writing at least 60 days prior to any change in the substance of their

policies regarding the funding of grants and charitable contributions or posting of the above-referenced information relating to such funding.

To the extent not already accomplished, within 120 days after the Effective Date, J&J shall ensure that all J&J Pharmaceutical Affiliates require all Consultants to comply fully with all applicable disclosure obligations relating to their relationship with the J&J Pharmaceutical Affiliates that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. J&J and J&J Pharmaceutical Affiliates shall maintain these requirements throughout the term of this CIA. Within 120 days after the Effective Date, the J&J Pharmaceutical Affiliates shall, if necessary, amend their policies relating to Consultants to explicitly state that the J&J Pharmaceutical Affiliates require all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with the companies that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 120 days following the Effective Date, the J&J Pharmaceutical Affiliates shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. J&J and/or J&J Pharmaceutical Affiliates shall continue these disclosure requirements throughout the term of this CIA.

To the extent not already accomplished, within 120 days after the Effective Date, J&J shall ensure that the J&J Pharmaceutical Affiliates require all Authors of biomedical manuscripts to fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with the applicable J&J Pharmaceutical Affiliate and to disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 120 days after the Effective Date, the applicable J&J Pharmaceutical Affiliates, if necessary, shall amend their policies relating to Authors to explicitly state the companies' requirement about full disclosure by Authors consistent with the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts with Authors and in any new contracts with Authors entered into after 120 days following the Effective Date, the applicable J&J Pharmaceutical Affiliate shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with the applicable J&J Pharmaceutical Affiliate, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

To the extent not already accomplished, within 120 days after the Effective Date, J&J shall ensure that the J&J Pharmaceutical Affiliates have registered all clinical studies and report results of such clinical studies on the National Institutes of Health (NIH) sponsored website (www.clinicaltrials.gov) in compliance with all current federal requirements. The applicable J&J Pharmaceutical Affiliate shall continue to comply with Federal health care program requirements, or other applicable requirements relating to the registration and results reporting of clinical studies throughout the term of this CIA. In addition, if there is a change in Federal health care program requirements, FDA requirements, NIH requirements or other applicable requirements relating to registration and results reporting of clinical study information, J&J and/or the applicable J&J Pharmaceutical Affiliate shall fully comply with such requirements.

To the extent not already accomplished, within 120 days after the Effective Date, J&J shall ensure that the J&J Pharmaceutical Affiliates link, post, or make available information on their website(s) and on the J&J website (through a link or other appropriate means) about FDA postmarketing commitments (PMCs). The applicable website(s) shall provide access to general information about the PMC process, descriptions of ongoing studies, and information about the nature and status of the post-marketing commitments. The J&J Pharmaceutical Affiliates shall continue to post or make available the above-described information about PMCs on their websites and the J&J website or links included therein throughout the term of this CIA.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, J&J or a J&J Pharmaceutical Affiliate changes locations or closes a business unit or location related to or engaged in any of the Covered Functions, J&J and/or the J&J Pharmaceutical Affiliates shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, J&J or a J&J Pharmaceutical Affiliate purchases or establishes a new business unit or location related to or engaged in any of the Covered Functions, J&J and/or the J&J Pharmaceutical Affiliates shall notify OIG no later than five days after the date that the purchase or establishment of the new business unit or location is publicly disclosed by J&J or the J&J Pharmaceutical Affiliate. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which J&J or the J&J Pharmaceutical Affiliate currently submits claims (if applicable). Each new

business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, J&J or a J&J Pharmaceutical Affiliate proposes to sell any or all of its business units or locations that are subject to this CIA, J&J and/or the J&J Pharmaceutical Affiliates shall notify OIG of the proposed sale no later than five days after the sale is publicly disclosed by J&J or the J&J Pharmaceutical Affiliate. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, J&J shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the J&J CCO and the NALT Compliance Officer required by Section III.A.1, and a summary of any other noncompliance job responsibilities either of the Compliance Officers may have;

2. the names and positions of the members of the NALT Compliance Committee required by Section III.A.2;

3. the names of the members of the J&J RCGAC and the NALT who are responsible for satisfying the compliance obligations described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;

5. a copy of J&J Pharmaceutical Affiliates' Code of Conduct required by Section III.B.1;

6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

7. (a) a copy of the letter (including all attachments) required by Sections II.C.10 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotions and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to J&J or the J&J Pharmaceutical Affiliates' letter;

8. a summary of all Policies and Procedures required by Section III.B.3 (copies of such Policies and Procedures shall be made available to OIG upon request);

9. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between J&J and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to J&J;

11. a description of the Disclosure Program required by Section III.F;

12. a description of the process by which J&J and the J&J Pharmaceutical Affiliates fulfill the requirements of Section III.G regarding Ineligible Persons;

13. a certification by the NALT Compliance Officer that the notice required by Section III.M was mailed to each HCP and HCI, the number of HCPs and HCIs to whom or which the notice was mailed, a sample copy of the notice required by Section III.M, and a summary of the calls or messages received in response to the notice;

14. a certification from the NALT Compliance Officer that, to the best of his/her knowledge, information regarding Payments has been posted on the J&J and J&J Pharmaceutical Affiliates' websites as required by Section III.N;

15. a list of all J&J and J&J Pharmaceutical Affiliate locations engaged in Covered Functions (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which J&J or a J&J Pharmaceutical Affiliate currently submits claims (if applicable);

16. a description of J&J's corporate structure, including identification of all J&J Pharmaceutical Affiliates, and any relevant parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. J&J shall submit to OIG annually a report with respect to the status of, and findings regarding, J&J's Compliance Program, and the compliance activities of the J&J's Pharmaceutical Affiliates, for each of the six Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the J&J CCO, the NALT Compliance Officer, and any change in the membership of the NALT Compliance Committee, the RCGAC, the NALT, or the group of Certifying Employees described in Sections III.A.2-4;

2. a copy of the resolution by the RCGAC required by Section III.A.3;

3. a summary of any changes or amendments to the J&J Pharmaceutical Affiliates' Code of Conduct required by Section III.B.1 and the reasons for such changes, along with a copy of the revised Code of Conduct;

4. the number of individuals required to review the J&J Pharmaceutical Affiliates' Code of Conduct and complete the certifications required by Section III.B.1, the percentage of individuals who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

5. (a) a copy of the letter (including all attachments) required by Sections II.C.10 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotions and other applicable agreements with the party employing the

Third Party Personnel; and (c) a description of the entities' responses to J&J or the J&J Pharmaceutical Affiliates' letter;

6. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.3 and the reasons for such changes (e.g., change in applicable requirements);

7. the following information regarding each type of training required by Section III.C:

a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

b. the number of individuals required to complete each type of training specified in Section III.C, percentage of individuals who completed the training, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

8. a summary of any significant changes to the Risk Assessment and Mitigation Planning Program required by Section III.D;

9. a complete copy of all reports prepared pursuant to Section III.E, and Appendices B-C along with a copy of the IRO's engagement letters;

10. J&J and/or the applicable J&J Pharmaceutical Affiliate's response to the reports prepared pursuant to the reviews outlined in Section III.E and Appendices B-C, along with corrective action plan(s) related to any issues raised by the reports;

11. a summary and description of any and all current and prior engagements and agreements between J&J and the IRO (if different from what was submitted as part of the Implementation Report);

12. certifications from the IRO regarding its professional independence and objectivity with respect to J&J;

13. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products;

14. any changes to the process by which J&J and/or any J&J Pharmaceutical Affiliate fulfills the requirements of Section III.G regarding Ineligible Persons;

15. a summary of any changes to the Incentive Compensation Program or the Executive Financial Recoupment Program required by Section III.H and Appendix D and the information regarding Triggering Events and Recoupment Determinations required to be reported pursuant to Appendix D;

16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

17. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

18. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.K. This summary shall include a description of the matter and the status of the matter;

19. a summary of the Field Force Controls, Monitoring, and Review Efforts and the results of the HCCM reviews required by Section III.L, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that the J&J Pharmaceutical Affiliates took as a result of such determinations;

20. a summary of the calls and messages received in response to the notice required by Section III.M and the disposition of those calls and messages;

21. a certification from the NALT Compliance Officer that information regarding Payments has been posted on the respective websites of the J&J Pharmaceutical Affiliates and that a link or other relevant notifying information has been posted on the J&J website as required by Section III.N;

22. a description of all changes to the most recently provided list of J&J's locations and those of J&J's Pharmaceutical Affiliates (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers of each location's Federal health care program provider and/or supplier number (if applicable), and the name and address of each Federal health care program contract to which J&J or a J&J Pharmaceutical Affiliate

currently submits claims (if applicable);

23. a description of any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.3.s; and a description of all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia evaluated during the annual review described in Section III.B.3.s; and

24. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 120 days after the end of the first Reporting Period. To the extent that certain information has been provided in the Implementation Report or certain obligations do not begin until the second reporting period, J&J need not include that information in the first Annual Report (i.e., the information required by sections V.B.1-8, 11-12, 14-15, 20-22, and 24). Subsequent Annual Reports shall include all of the information required by section V.B and be received by OIG no later than 30 days prior to the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. Certifying Employees: In each Annual Report, J&J shall include the certifications of Certifying Employees as required by Section III.A.4;

2. Compliance Officer: In the Implementation Report and each Annual Report, J&J shall include a certification by the J&J CCO that:

a. to the best of his or her knowledge, except as otherwise described in the report, J&J and the J&J Pharmaceutical Affiliates are in compliance with the requirements of this CIA;

b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;

c. J&J and the J&J Pharmaceutical Affiliates, as applicable, have maintained the Incentive Compensation Program and the Executive Financial Recoupment Program in accordance with the terms set forth above in Section III.H and Appendix D;

d. the applicable J&J Pharmaceutical Affiliate's: (1) Policies

and Procedures as referenced in Section III.B above; (2) templates for standardized contracts and other similar documents; and (3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, the applicable J&J Pharmaceutical Affiliate's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside the company have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by J&J and/or the J&J Pharmaceutical Affiliate and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

e. the Call Plans for the Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.i) and, for each product, the Call Plans were found to be consistent with the Policies and Procedures as referenced above in Section III.B.3.i.

D. Designation of Information. J&J and/or the J&J Pharmaceutical Affiliates shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. J&J and/or the J&J Pharmaceutical Affiliates shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

J&J:
John T. Crisan
Chief Compliance Officer
Johnson & Johnson
410 George Street
New Brunswick, NJ 08901
Telephone: 732.524.2483
Facsimile: 732.524.2337

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, J&J may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of J&J's or any J&J Pharmaceutical Affiliate's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of J&J's locations or any J&J Pharmaceutical Affiliate's location for the purpose of verifying and evaluating: (a) J&J's and the Pharmaceutical Affiliates' compliance with the terms of this CIA; and (b) J&J's and J&J Pharmaceutical Affiliates' compliance with the requirements of the Federal

health care programs in which they participate and with all applicable FDA requirements. The documentation described above shall be made available by J&J and/or the applicable J&J Pharmaceutical Affiliate to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of J&J's or of any J&J Pharmaceutical Affiliate's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. J&J and the J&J Pharmaceutical Affiliates shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. J&J's or J&J Pharmaceutical Affiliates employees may elect to be interviewed with or without a representative of J&J or J&J Pharmaceutical Affiliates present.

VIII. DOCUMENT AND RECORD RETENTION

J&J and J&J Pharmaceutical Affiliates shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify J&J prior to any release by OIG of information submitted by J&J and/or the J&J Pharmaceutical Affiliates pursuant to their obligations under this CIA and identified upon submission as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, J&J and the J&J Pharmaceutical Affiliates shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

J&J and the J&J Pharmaceutical Affiliates are expected to fully and timely comply with all of the CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, J&J and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day J&J fails to establish and implement any of the following obligations as described in Section III:

a. a J&J CCO and the NALT Compliance Officers as required in Section III.A.1;

b. a NALT Compliance Committee as required in Section III.A.2;

c. all Board and NALT compliance obligations, including the resolution from the RCGAC as required in Section III.A.3;

d. the management accountability and certification obligations outlined in Section III.A.4;

e. a written Code of Conduct as required in Section III.B.1;

f. written Policies and Procedures as required in Section III.B.3;

g. the training of Covered Persons, Relevant Covered Persons, Management, and J&J Board Members as required in Section III.C;

h. a Risk Assessment and Mitigation Planning Program as required in Section III.D and Appendix C;

i. a Disclosure Program as required in Section III.F;

j. Ineligible Persons screening and removal requirements as required in Section III.G;

k. the Incentive Compensation Program and the Executive Financial Recoupment Program required by Section III.H and Appendix D;

l. notification of Government investigations or legal proceedings as required by Section III.I;

m. reporting of Reportable Events as required in Section III.J;

n. notification of written communications with FDA as required

by Section III.K;

o. a program for Compliance Controls, monitoring, and auditing as required by Section III.L;

p. notifications to HCPs and HCIs as required by Section III.M;

q. posting of any Payment information as required by Section III.N; and

r. posting or making available other information required by Section III.O.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day J&J fails to engage and use an IRO as required in Section III.E and Appendices A-C.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day J&J fails to submit the Implementation Report or any Annual Report to OIG in accordance with the requirements of Section V of the CIA by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day J&J fails to submit any IRO Review report in accordance with the requirements of Sections III.E and Appendices A-C.

5. A Stipulated Penalty of $1,500 for each day J&J fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date J&J fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of J&J as part of its Implementation Report, or any Annual Report, additional documentation to a report, or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day J&J fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to J&J stating the specific grounds for its determination that J&J has failed to comply fully and adequately with the CIA obligation(s) at issue and steps J&J shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty

under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. J&J and/or the J&J Pharmaceutical Affiliates may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after J&J fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after J&J receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that J&J has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify J&J of: (a) J&J's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, J&J shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event J&J elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until J&J cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination*. Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that J&J has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the

provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach*. A material breach of this CIA means:

a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure to report a Reportable Event and take corrective action as required in Section III.J of the CIA;

c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A-C;

d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; and

e. a failure of the J&J Board (through the RCGAC) to issue the resolutions in accordance with Section III.A.3 of the CIA.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by J&J and/or a J&J Pharmaceutical Affiliate constitutes an independent basis for the exclusion of the J&J Pharmaceutical Affiliates from participation in the Federal health care programs. Upon a determination by OIG that J&J and/or a Pharmaceutical Affiliate has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify J&J of: (a) J&J's and/or the J&J Pharmaceutical Affiliate(s)' material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure*. J&J shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. J&J and/or the J&J Pharmaceutical Affiliate(s) are in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30 day period, but that: (i) J&J and/or the J&J Pharmaceutical Affiliate(s) have begun to take action to cure the material breach; (ii) J&J and/or the J&J Pharmaceutical Affiliate(s) are pursuing such action with due diligence; and (iii) J&J and/or a J&J Pharmaceutical Affiliate(s) have provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, J&J and/or the J&J Pharmaceutical Affiliates fail to satisfy the requirements of Section X.D.3, OIG may exclude the J&J Pharmaceutical Affiliates from participation in the Federal health care programs. OIG shall notify J&J in writing of its determination to exclude the J&J Pharmaceutical Affiliates (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of J&J's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, the J&J Pharmaceutical Affiliates may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to J&J of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, J&J and/or the J&J Pharmaceutical Affiliate(s) shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether J&J

and/or the J&J Pharmaceutical Affiliate(s) were in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. J&J and/or the J&J Pharmaceutical Affiliate(s) shall have the burden of proving their full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders J&J to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless J&J and/or the J&J Pharmaceutical Affiliate(s) requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether J&J and/or the J&J Pharmaceutical Affiliate(s) were in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) J&J and/or the J&J Pharmaceutical Affiliate(s) had begun to take action to cure the material breach within that period; (ii) J&J and/or the J&J Pharmaceutical Affiliate(s) has pursued and is pursuing such action with due diligence; and (iii) J&J and/or the J&J Pharmaceutical Affiliate(s) provided to OIG within that period a reasonable timetable for curing the material breach and J&J and/or the J&J Pharmaceutical Affiliate(s) has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for J&J and/or the J&J Pharmaceutical Affiliate(s), only after a DAB decision in favor of OIG. J&J's and/or a J&J Pharmaceutical Affiliate(s)' election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude the J&J Pharmaceutical Affiliate(s) upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that J&J and/or the J&J

Pharmaceutical Affiliate(s) may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. J&J and/or the J&J Pharmaceutical Affiliate(s) shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of J&J and/or the J&J Pharmaceutical Affiliate(s), the J&J Pharmaceutical Affiliate(s) shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

J&J and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of J&J.

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

D. The undersigned J&J signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

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

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ON BEHALF OF JOHNSON & JOHNSON

/John T. Crisan/ 10/31/13

JOHN T. CRISAN DATE
Chief Compliance Officer
Johnson & Johnson

/Mark Jensen, Esq./ 10/31/13

MARK JENSEN, ESQ. DATE
King & Spalding LLP
Counsel for Johnson & Johnson

/Christopher A. Wray, Esq./ 10/31/13

CHRISTOPHER A. WRAY, ESQ. DATE
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BRANDT LEIBE, ESQ. DATE
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Counsel for Johnson & Johnson

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

/Robert K. DeConti/ 10/31/13

ROBERT DECONTI
Assistant Inspector General for Legal Affairs
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MARY E. RIORDAN
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Office of the Inspector General

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GEETA W. KAVETI
Senior Counsel
Office of the Inspector General

DATE

Appendix A to CIA for Johnson & Johnson

Independent Review Organization

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement.

J&J and/or the J&J Pharmaceutical Affiliates shall engage an IRO (or IRO(s)) that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.10 of the CIA or any additional information submitted by J&J and/or the J&J Pharmaceutical Affiliates in response to a request by OIG, whichever is later, OIG will notify J&J and/or the J&J Pharmaceutical Affiliates if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, J&J and/or the J&J Pharmaceutical Affiliates may continue to engage the IRO.

If J&J and/or the J&J Pharmaceutical Affiliates engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, J&J and/or the J&J Pharmaceutical Affiliates shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by J&J and/or the J&J Pharmaceutical Affiliates at the request of OIG, whichever is later, OIG will notify J&J and/or the J&J Pharmaceutical Affiliates if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, J&J and/or the J&J Pharmaceutical Affiliates may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and have expertise in applicable Federal health care program and FDA requirements that relate to the Covered Functions. The assigned individuals shall also be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care programs under which J&J Pharmaceutical Affiliates' products are reimbursed;

2. assign individuals to design and select the samples for the IRO Transactions Reviews who are knowledgeable about appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each component of each IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, request clarification from the appropriate authority (e.g., CMS or FDA);

4. respond to all OIG inquiries in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendices B and C to the CIA.

D. Independence and Objectivity.

The IRO must perform the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination.

1. *Termination of IRO*. If J&J and/or the J&J Pharmaceutical Affiliates terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, J&J and/or the J&J Pharmaceutical Affiliates must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. J&J and/or the J&J Pharmaceutical Affiliates must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of the termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or

objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require J&J and/or the J&J Pharmaceutical Affiliates to engage a new IRO in accordance with Paragraph A of this Appendix. J&J and/or the J&J Pharmaceutical Affiliates must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring J&J and/or the J&J Pharmaceutical Affiliates to engage a new IRO, OIG shall notify J&J and/or the J&J Pharmaceutical Affiliates of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, J&J and/or the J&J Pharmaceutical Affiliates may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with J&J and/or the J&J Pharmaceutical Affiliates prior to requiring J&J and/or the J&J Pharmaceutical Affiliates to terminate the IRO. However, the final determination as to whether or not to require J&J and/or the J&J Pharmaceutical Affiliates to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA for Johnson & Johnson

Independent Review Organization Reviews

I. Covered Functions Review, General Description

As specified more fully below, J&J and/or the J&J Pharmaceutical Affiliates shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist the J&J Pharmaceutical Affiliates in assessing and evaluating systems, processes, policies, procedures, and practices related to certain of the Covered Functions. The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. J&J and/or the J&J Pharmaceutical Affiliates may engage, at their discretion, a single IRO to perform both components of the IRO Reviews provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in the applicable systems, processes, policies, and procedures of the J&J Pharmaceutical Affiliates relating to the Covered Functions, the IRO shall perform the Systems Review for the second and fifth Reporting Periods. If the J&J Pharmaceutical Affiliate materially changes its systems, processes, policies, and procedures relating to the Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the second and fifth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Review

A. Description of Reviewed Policies and Procedures

The Systems Review shall be a review of systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) of the J&J Pharmaceutical Affiliates relating to certain of the Covered Functions. Where practical, J&J Pharmaceutical Affiliates personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by the J&J Pharmaceutical Affiliates in accordance with the preceding sentence.

Specifically, the IRO shall review systems, processes, policies, and procedures of the J&J Pharmaceutical Affiliates associated with the following (hereafter "Reviewed Policies and Procedures"):

1) the manner in which sales representatives and personnel from Medical Information and Services handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (i.e., off-label) uses of Government Reimbursed Products) and the dissemination of materials relating to the uses of these products. This review shall include:

a) the manner in which J&J Pharmaceutical Affiliate sales representatives handle requests for information about off-label uses of Government Reimbursed Products (i.e., by referring all such requests to relevant Medical Information and Services personnel);

b) the manner in which Medical Information and Services personnel, including those at the J&J Pharmaceutical Affiliate's headquarters, handle and respond to requests for information about off-label uses of Government Reimbursed Products (including tracking the requests and using pre-approved materials for purposes of responding to the request);

c) the form and content of information and materials related to Government Reimbursed Products disseminated to HCPs and HCIs (as defined in Section II.C.2 of the CIA), , payers, and formulary decision-makers by the J&J Pharmaceutical Affiliates;

d) the systems, processes, policies, and procedures (including the Inquiries Database) of the J&J Pharmaceutical Affiliates to track requests to Medical Information and Services for information about off-label uses of products and responses to those requests;

e) the manner in which the J&J Pharmaceutical Affiliates collect and support information reported in any systems used to track and respond to requests to Medical Information and Services

for Government Reimbursed Product information, including its Inquiries Database;

f) the processes and procedures by which Medical Information and Services, a compliance officer, or other appropriate individuals within J&J and/or the J&J Pharmaceutical Affiliates identify situations in which it appears that off-label or other improper promotion may have occurred; and

g) the processes and procedures of the J&J Pharmaceutical Affiliates for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

2) the manner and circumstances under which the J&J Pharmaceutical Affiliates' Medical Information and Services personnel participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of the Medical Information and Services personnel at such meetings or events;

3) the J&J Pharmaceutical Affiliates' internal review of promotional materials related to Government Reimbursed Products disseminated to HCPs, HCIs and Payers and individuals or entities (e.g., PBMs) acting on behalf of HCPs, HCIs or government payers;

4) the development and review of the J&J Pharmaceutical Affiliates processes relating to incentive compensation for Relevant Covered Persons who are prescriber-facing sales representatives and their direct managers, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. These systems, policies, and procedures shall be consistent with the Incentive Compensation Program required under Section III.H of the CIA. To the extent that the J&J Pharmaceutical Affiliate establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

5) the development and review of the Executive Financial Recoupment Program described in Section III.H of the CIA and in Appendix D;

6) the development and review of the J&J Pharmaceutical Affiliates' Call Plans (as defined in Section III.B.2.i of the CIA) for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the Call Plans based on expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

7) the development and review of Sample Distribution Plans (as defined in Section III.B.2.j of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from the J&J Pharmaceutical Affiliates (including, separately, from J&J Pharmaceutical Affiliate sales representatives and other J&J personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by J&J Pharmaceutical Affiliates through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

8) the systems (including any centralized electronic systems), processes, policies, and procedures of the J&J Pharmaceutical Affiliates' speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

9) the systems, processes, policies, and procedures of the J&J Pharmaceutical Affiliates relating to engagement of non-speaker related consultants or other fee-for-service arrangements (including, but not limited to, presentations, advisory boards, preceptorships, mentorships, and ad hoc advisory activities, and any other financial engagement) that the J&J Pharmaceutical Affiliates entered into with HCPs or HCIs and all events and expenses associated with such activities;

10) the systems, processes, policies, and procedures of the J&J Pharmaceutical Affiliates' funding, directly or indirectly, of Third Party Educational Activities (as defined in Section II.C.9 of the CIA) and all events and expenses relating to such activities;

11) the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a

Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information, (e.g., any changes based on J&J's Pharmaceutical Affiliates discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia). The review shall also assess J&J's Pharmaceutical Affiliates processes relating to J&J's Pharmaceutical Affiliates annual review with respect to actively promoted Government Reimbursed Products, of information in the Compendia about the Government Reimbursed Products and J&J's Pharmaceutical Affiliates review all arrangements, processing fees, or other payments or financial support (if any) provided to any Compendia;

12) Research and Publication Practices (as described in Section III.B.3.t of the CIA), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes; and uses made of publications relating to such Research;

13) Authorship-Related Practices (as described in Section III.B.3.u of the CIA), including, but not limited to, the disclosure of any and all financial relationships between the author and the J&J Pharmaceutical Affiliate, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

14) the form and content of information and materials disseminated by a J&J Pharmaceutical Affiliate to payers and payer subcontractors, e.g. PBMs, and the systems, policies, processes, and procedures of J&J the J&J Pharmaceutical Affiliates relating to the internal review and approval of information and materials related to Government Reimbursed Products disseminated to payers and payer subcontractors by a J&J Pharmaceutical Affiliate; and

B. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

1) a description of the documentation (including policies) reviewed and any personnel interviewed;

2) a detailed description of systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-14 above, including a general description of the control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-14 above are made known or disseminated within the J&J Pharmaceutical Affiliates;

4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Database);

5) a detailed description of the incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined. To the extent that the J&J Pharmaceutical Affiliates may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

6) findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. IRO Transactions Review

As described more fully below in Sections III.A-F, the Transactions Review shall include: (1) a review of Call Plans and the Call Plan review process; (2) a review of Sampling Events as defined below in Section III.C; (3) a review of records relating to a

sample of the Payments that are reported by the J&J Pharmaceutical Affiliates pursuant to Section III.N of the CIA; (4) a review of Research and Publication Practices and Authorship-Related Practices; and (5) a review of up to three additional items identified by the OIG in accordance with Section III.E.1.b of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. IRO Review of Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of the J&J Pharmaceutical Affiliates' review of its Call Plans for Government Reimbursed Products as set forth in Section III.B.3.i of the CIA. The J&J Pharmaceutical Affiliates shall provide the IRO with: i) a list of Government Reimbursed Products promoted by any J&J Pharmaceutical Affiliate during the Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) the Call Plans for each such product. The J&J Pharmaceutical Affiliates shall also provide the IRO with information about the reviews of Call Plans that the J&J Pharmaceutical Affiliate conducted during the relevant Reporting Period and any modifications to the Call Plans made as a result of the J&J Pharmaceutical Affiliates' reviews.

For each Call Plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the Call Plan. For each Call Plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by the J&J Pharmaceutical Affiliates in conducting their review and/or modifying the Call Plan. The IRO shall seek to determine whether the J&J Pharmaceutical Affiliates followed their criteria and Policies and Procedures in reviewing and modifying the Call Plan.

The IRO shall note any instances in which it appears that the sampled HCPs or HCIs on a particular Call Plan are inconsistent with the J&J Pharmaceutical Affiliates' criteria relating to the Call Plan and/or the J&J Pharmaceutical Affiliates' Policies and Procedures. The IRO shall also note any instances in which it appears that the J&J Pharmaceutical Affiliates failed to follow their criteria or Policies and Procedures.

B. IRO Review of the Distribution of Samples of J&J Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. The J&J Pharmaceutical Affiliates shall provide the IRO with: i) a list of Government Reimbursed Products for

which J&J distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) information about the J&J Pharmaceutical Affiliates' Sample Distribution Plans. The J&J Pharmaceutical Affiliates shall also provide the IRO with information about the reviews of Sample Distribution Plans that the J&J Pharmaceutical Affiliates conducted during the Reporting Period as set forth in Section III.B.3.j of the CIA and any modifications to the Sample Distribution Plans made as a result of these reviews.

For each Government Reimbursed Product for which J&J the J&J Pharmaceutical Affiliate distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which the J&J Pharmaceutical Affiliates provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the samples provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual J&J Pharmaceutical Affiliates sales representatives or other J&J Pharmaceutical Affiliates personnel provided the sample to the HCP or HCI; and 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to the J&J Pharmaceutical Affiliates).

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA and whether the sample was distributed by a J&J Pharmaceutical Affiliates' representative in a manner consistent with the Sample Distribution Plan for the product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by a representative of J&J or the J&J Pharmaceutical Affiliates other than a sales representative, the IRO shall review the proof of receipt form signed by the HCP or HCI. If no proof of receipt form is available, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a J&J Pharmaceutical Affiliate sales representative, conversation with a J&J Pharmaceutical Affiliate representative at headquarters, independent research, or knowledge of the HCP or HCI).

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the Government Reimbursed Product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the Government Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by the J&J Pharmaceutical Affiliates in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that the J&J Pharmaceutical Affiliates failed to follow their Sample Distribution Plans for the Government Reimbursed Product(s) provided during the Sampling Event.

C. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

For purposes of the IRO Review as set forth in this Section III.C, each annual listing of physicians and Related Entities who received Payments (as defined in Section III.N of the CIA) from the J&J Pharmaceutical Affiliate shall be referred to as the "Physician Payment Listing" or "Listing." For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician's full name; ii) name of Related Entity (if applicable); iii) city and state of the physician's practice or the Related Entity; and (iv) the aggregate value of the Payment(s) in the preceding year(s).

For purposes of this IRO Review, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for a sampled physician and/or Related Entity. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by field personnel or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. Selection of Sample for Review

For each IRO Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this

discretion, it shall notify the IRO at least 90 days prior to the end of the Reporting Period of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in the Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;

b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in the J&J Pharmaceutical Affiliate's policies;

c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payments(s) reflected in the Control Documents; and

d) Whether the Control Documents reflect that the J&J Pharmaceutical Affiliates' policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with all applicable policies).

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:

i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or

ii. the IRO cannot confirm that the J&J Pharmaceutical Affiliates otherwise followed applicable policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or

b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with the J&J Pharmaceutical Affiliates' policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but the J&J Pharmaceutical Affiliates have initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that the J&J Pharmaceutical Affiliates otherwise followed their policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

D. IRO Review of Research and Publications Practices and Authorship-Related Activities

Beginning in the second Reporting Period, the IRO shall conduct a review and assessment of J&J's Research and Publications Practices and Authorship-Related activities as described in Sections III.B.3.t-u of the CIA.

Review of Research Activities:

The J&J Pharmaceutical Affiliates shall provide the IRO with a list of all Research activities (as defined in Section III.B.3.t of the CIA) that occurred during the Reporting Period. The IRO shall select a sample of 25 HCPs or HCIs involved in such activities, which sample shall include a review of each type of Research (i.e., post-marketing clinical trials, other post-marketing studies, and post-marketing investigator-initiated studies (IISs)). The IRO shall review samples of each type of Research in proportion to the relative number of each type of Research that occurred during the reporting period. The J&J Pharmaceutical Affiliates shall provide the IRO with documents relating to the Research activities sufficient for the IRO to conduct the reviews outlined below.

For each sampled Research activity, the IRO will review whether: (i) the activity was approved consistent with the J&J Pharmaceutical Affiliates' standards, policies, procedures and processes regarding sponsorship or support of Research, including obtaining required approval for the Research and ensuring that the J&J Pharmaceutical Affiliates funded the Research in order to address a legitimate scientific question or need; (ii) there is an executed written agreement with the Researcher that meets the requirements of the J&J Pharmaceutical Affiliates' standards, policies and procedures and, among other things, requires the Researcher to disclose in any publication of Research, the J&J Pharmaceutical Affiliates' support and any financial interest the researcher may have in J&J and/or the J&J Pharmaceutical Affiliates; and (iii) the Research was initiated, designed, reviewed, approved and/or funded by the J&J Pharmaceutical Affiliates' medical or research and development organizations pursuant to J&J Pharmaceutical Affiliates' policies.

Review of Publication Activities:

The J&J Pharmaceutical Affiliates shall provide the IRO with a list of Publication activities (as defined in Section III.L.1 of the CIA) that that occurred during the Reporting Period, and the IRO shall select a sample of 25 Publication Activities for Review (Reviewed Publication Activities). The J&J Pharmaceutical Affiliates shall provide the IRO with copies of the publications and documents and information relating to each of the Reviewed Publication Activities sufficient for the IRO to conduct the reviews outlined below.

The IRO will assess each of the Reviewed Publication Activities to test whether the reviewed Publication Activity was conducted in a manner consistent with the J&J Pharmaceutical Affiliates' standards, policies, procedures and processes, including those that require: i) registration and reporting of trial results from applicable clinical trials on the NIH sponsored website in compliance with the J&J Pharmaceutical Affiliates' policies and procedures; ii) publication (or attempted publication) of the results of Research studies in peer-reviewed journals within applicable timeframes; and iii)

compliance with J&J's policies and procedures regarding publications (including standards relating to appropriateness, accuracy, balance, and acknowledgement of the J&J Pharmaceutical Affiliates' role as the funding source for the Research).

Review of Authorship-Related Activities:

For each of the Reviewed Publication Activities, the IRO shall also assess the activity to test whether the activity was conducted in a manner consistent with the J&J Pharmaceutical Affiliates' standards, policies, procedures and processes relating to authorship, including those that require: i) authors of journal articles about Research to adhere to ICMJE authorship requirements; ii) authors of articles on Research to disclose any J&J Pharmaceutical Affiliates financial support for the study and any financial relationship with the J&J Pharmaceutical Affiliates; and iii) authors of a publication about Research to make substantial contributions to the study and give final approval to the version of the publication ultimately published.

E. IRO Review of Additional Items

As set forth in Section III.E.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify J&J and/or the J&J Pharmaceutical Affiliates of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or J&J and/or the J&J Pharmaceutical Affiliates shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in the J&J Pharmaceutical Affiliates' systems, processes, policies, and procedures based on its review of each Additional Item).

The J&J Pharmaceutical Affiliates may propose to the OIG that its internal audit(s) be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow J&J Pharmaceutical Affiliates' internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of the J&J Pharmaceutical Affiliates' planned internal audit work, the results

of the Transactions Review(s) during prior Reporting Period(s), and the J&J Pharmaceutical Affiliates' demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies the J&J Pharmaceutical Affiliates' request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, J&J and/or the J&J Pharmaceutical Affiliates shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of the J&J Pharmaceutical Affiliates' internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by the J&J Pharmaceutical Affiliates in its internal audits.

F. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1) General Elements to Be Included in Report

a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Transaction Review Report:

(Relating to the Call Plan Reviews)

a) a list of the Government Reimbursed Products promoted by the J&J Pharmaceutical Affiliate during the Reporting Period and a summary of the FDA-approved uses for such products;

b) for each Government Reimbursed Product which was promoted during the Reporting Period: i) a description of the criteria used the J&J Pharmaceutical Affiliate in developing or reviewing the Call Plans and for including or excluding specified types of HCPs or HCIs from the Call Plans; ii) a description of the review conducted by the J&J Pharmaceutical Affiliate of the Call Plans and an indication of whether the J&J Pharmaceutical Affiliate reviewed the Call Plans as required by Section III.B.3.i of the CIA; iii) a description of all instances for each Call Plan in which it appears that the HCPs and HCIs included on the Call Plan are inconsistent with the J&J Pharmaceutical Affiliates' criteria relating to the Call Plan and/or Policies and Procedures; and iv) a description of all instances in which it appears that the J&J Pharmaceutical Affiliate failed to follow its criteria or Policies and Procedures relating to Call Plans or the review of the Call Plans;

c) the findings and supporting rationale regarding any weaknesses in the J&J Pharmaceutical Affiliates' systems, processes, policies, procedures, and practices relating to Call Plans or the review of the Call Plans, if any;

d) recommendations, if any, for changes in the J&J Pharmaceutical Affiliates' systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Call Plans or the review of the Call Plans;

(Relating to the Sampling Event Reviews)

e) for each Government Reimbursed Product distributed during the Reporting Period: i) a description of Sample Distribution Plans (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with

the uses of the product approved by the FDA. This description shall include a description of the process followed by the J&J Pharmaceutical Affiliate in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that the J&J Pharmaceutical Affiliate failed to follow its Sample Distribution Plans for the Government Reimbursed Product(s) provided during the Sampling Event;

f) the findings and supporting rationale regarding any weaknesses in the J&J Pharmaceutical Affiliates' systems, processes, policies, procedures, and practices relating to the distribution of samples of Government Reimbursed Products, if any;

g) recommendations, if any, for changes in the J&J Pharmaceutical Affiliates' systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

h) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;

i) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable J&J Pharmaceutical Affiliate policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that the J&J Pharmaceutical Affiliates' policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) disciplinary action was undertaken in those instances in which the J&J Pharmaceutical Affiliates' policies were not followed;

j) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;

k) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Research, Publication, and Authorship-Related Activities)

l) a description of each sampled Research activity reviewed, including an identification of the types of documents and information reviewed in connection with each sampled Research activity;

m) an assessment of whether, for each sampled Research activity: (i) the activity was approved consistent with the J&J Pharmaceutical Affiliates' standards, policies, procedures and processes regarding sponsorship or support of Research; (ii) there is an executed written agreement with the Researcher that meets the requirements of the J&J Pharmaceutical Affiliates' standards, policies and procedures; and (iii) the Research was initiated, directed and/or funded by the J&J Pharmaceutical Affiliates' medical or research and development organizations pursuant to the J&J Pharmaceutical Affiliates' policies. If a sampled Research activity failed to meet the J&J Pharmaceutical Affiliates' standards, policies, procedures and processes, an explanation of the deficiency;

n) a description of each reviewed Publication Activity assessed by the IRO, including an identification of the types of documents and information reviewed in connection with each reviewed Publication Activity;

o) an assessment of whether for each reviewed Publication Activity: i) authors of journal articles about Research adhered to ICMJE requirements; ii) authors of articles on Research disclosed any J&J Pharmaceutical Affiliates financial support for the study and any financial relationship with J&J and/or the J&J Pharmaceutical

Affiliates; and iii) authors of a publication about Research made substantial contributions to the study and gave final approval to the version of the publication ultimately published;

p) if any reviewed Publication Activity or Authorship-Related activity failed to meet the J&J Pharmaceutical Affiliates' standards, policies, procedures and processes, an explanation of the deficiency;

q) the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in the J&J Pharmaceutical Affiliates' systems, processes, policies, procedures, and practices relating to the J&J Pharmaceutical Affiliates' Research and Publications Practices and Authorship-Related activities, if any;

r) recommendations, if any, for changes in the J&J Pharmaceutical Affiliates' systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Research and Publications Practices and Authorship-Related activities;

(Relating to the Review of Additional Items)

s) for each Additional Item reviewed, a description of the review conducted;

t) for each Additional Item reviewed, the IRO's findings based on its review;

u) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in the J&J Pharmaceutical Affiliates' systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

v) for each Additional Item reviewed, recommendations, if any, for changes in the J&J Pharmaceutical Affiliates' systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

Appendix C to CIA for Johnson & Johnson

IRO Reviews of Risk Assessment and Mitigation Planning Program

I. General Description of the Risk Assessment and Mitigation Planning Program

J&J, through the J&J Pharmaceutical Affiliates, represents that prior to Effective Date, the J&J Pharmaceutical Affiliates implemented a standardized process to allow the J&J Pharmaceutical Affiliates' business, compliance, and legal personnel to identify and assess risks associated with the marketing and promotion of Government Reimbursed Products by therapeutic area, and to devise and implement specific measures to mitigate the identified risks (Risk Assessment and Mitigation Planning Program (RAMP Program)).

The RAMP Program shall focus on identifying risks associated with each Government Reimbursed Product, including in the areas of: marketing, sales, promotion issues (including the risk of off-label promotion), and healthcare compliance risks. J&J and/or the J&J Pharmaceutical Affiliates shall undertake the risk assessment process annually. As part of the process, J&J and/or the J&J Pharmaceutical Affiliates shall solicit information about each Government Reimbursed Product and information relating to risks or potential risks associated with each such product from all relevant business units and functions (e.g., the sales and marketing function; regulatory affairs; medical affairs/scientific affairs; legal; audit, and compliance).

Using the results of the risk-identification component of the RAMP Program, the J&J Pharmaceutical Affiliates' business, compliance, and legal personnel shall develop a specific plan for risk assessment and mitigation planning (RAMP) for each actively promoted Government Reimbursed Product that is designed, at a minimum, to mitigate or reduce the identified risks. The development of RAMPs shall also include input from the commercial/business components of the J&J Pharmaceutical Affiliate with responsibility for the product covered by the RAMP. The RAMP Program and the RAMPs shall also be used by the J&J CCO and/or the NALT Compliance Officer to inform the risk-based selection of products as required by the monitoring program described in CIA Section III.L.

A. *Risk Mitigation Plans*

Each annual RAMP shall outline standard risk mitigation activities to be performed and tracked for each actively promoted product. Risk mitigation activities will include, at a minimum, monitoring activities to be conducted for each actively promoted Government Reimbursed Product in the upcoming year, such as monitoring of speaker programs, speaker training, advisory boards, sampling, verbatim reviews, medical information requests and ride-alongs with sales personnel.

Each RAMP shall identify and explain: (i) the risk areas identified for mitigation; (ii) the risk mitigation activity or activities to address each risk area, including sufficient detail regarding scope and timing of mitigation activities; and; (iii) a responsible individual for each mitigation activity. The RAMPs shall be reviewed and approved by the respective business unit leadership teams.

B. *Risk Mitigation Plan Tracking*

RAMP activities (including risk monitoring activities and risk mitigation activities) shall be tracked and reported to the NALT Compliance Officer as a part of a reporting process where the results of mitigation efforts against the RAMPs are reviewed and evaluated in order to ensure risks are mitigated as planned on at least a quarterly basis. The status of the RAMPs shall be tracked and reported to the NALT Compliance Committee and the respective business unit leadership teams and compliance personnel at the J&J Pharmaceutical Affiliates at least quarterly and to the J&J CCO on an annual basis.

II. IRO RAMP Reviews, General Description

A. As specified more fully below, J&J and/or the J&J Pharmaceutical Affiliates shall retain an IRO to assist in assessing and evaluating the systems, processes, policies, procedures, and practices relating to the RAMP Program (RAMP Review). The RAMP Review shall consist of two components -- a systems review (RAMP Systems Review) and a transactions review (RAMP Transactions Review) as described more fully below. J&J and/or the J&J Pharmaceutical Affiliates may engage, at their discretion, a single IRO to perform both components of the RAMP Review provided that the entity has the necessary expertise and capabilities to perform both.

B. If there are no material changes in J&J Pharmaceutical Affiliates' systems, processes, policies, and procedures relating to RAMP Program, the IRO shall perform the RAMP Systems review for the second and fifth Reporting Periods. If the J&J Pharmaceutical Affiliates materially change their systems, processes, policies, and procedures relating to RAMP Program, the IRO shall perform a RAMP Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the second and fifth Reporting Periods. The additional RAMP Systems Review(s) shall consist of: (1) an identification of the material changes; (2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and (3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the RAMP Transactions Review for all Reporting Periods of the CIA.

III. RAMP Systems Review

A. The RAMP Systems review shall consist of the following:

1. A review of the processes by which the J&J Pharmaceutical Affiliates annually develop and evaluate RAMPs, including the sources of information (e.g., the individual personnel, departments or functional areas, and/or any systems involved) used to compile the RAMPs; the types of underlying data and information that are considered or evaluated during the development of the RAMPs; and the timing for development of RAMPs (including modifications to the RAMPs in the event of significant new developments);

2. An assessment of whether, in developing the RAMPs: (i) additional or different sources of information; (ii) additional or different types of data or information; and (iii) additional or different timing cycles should be utilized;

3. A review of the experience and background of the personnel responsible for development of the RAMPs and an assessment of the completeness and appropriateness of the training, policies, procedures, standard operating procedures, and guidance such individuals receive regarding the development of the RAMPs;

4. An assessment of whether the risk monitoring and mitigation activities included in RAMPs are designed to: (i) adequately monitor and mitigate all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential risk; and/or (iii) ensure that the activity associated with an identified risk does not occur in the future;

5. An assessment of whether risk mitigation activities that may be included in RAMPs should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; or (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed; and

6. A review of the systems, policies, procedures, and processes by which the J&J Pharmaceutical Affiliates track and manage RAMP activities

and an assessment of whether the systems, policies, procedures and processes ensure that the RAMPs are appropriately implemented (including by identifying individuals responsible for the follow-up or action items).

B. The IRO shall prepare a report based upon each Systems Review performed (System Review Report). The Systems Review Report shall include the IRO's findings, recommendations, observations, and comments on items 1-6 above and, to the extent not otherwise addressed, an assessment of the following: (i) whether the RAMPs identify relevant risks; (ii) whether the risk monitoring and risk mitigation activities identified in the RAMPs address identified risks; (iii) whether sufficient controls exist to ensure that all risk mitigation steps (including monitoring activities and risk mitigation activities) are completed in accordance with the RAMPs; (iv) whether the options for risk monitoring activities and risk mitigation activities identified in the RAMPs address and potentially mitigate identified risks; and (v) whether sufficient controls exist to ensure that all agreed-upon risk monitoring activities and risk mitigation activities are completed in accordance with the RAMPs.

IV. RAMP Transactions Review

A. At least thirty (30) days prior to the end of each Reporting Period, the J&J Pharmaceutical Affiliates shall submit to OIG a list of all Government Reimbursed Products for which RAMPs were developed. The J&J Pharmaceutical Affiliates shall also notify OIG about the risks identified for each product and the types of risk mitigation activities undertaken for each product. Prior to the end of the applicable Reporting Period, OIG shall select 3 Government Reimbursed Products (each a "Selected Product" and together the "Selected Products") to be reviewed in connection with the RAMP Transactions Review.

B. For each Reporting Period and for each Selected Product, the IRO shall conduct a review of: (i) the applicable RAMP; (ii) documents and materials related to the development of the RAMP; and (iii) documents and materials relating to the implementation of the RAMP. The IRO shall also interview the personnel responsible for the development of the RAMPs and the individual(s) responsible for the implementation of the risk monitoring and mitigation activities specified in the RAMP.

The objective of the IRO shall be to: (i) understand the processes used in developing the RAMP for each Selected Product; (ii) determine whether, based on the information contained in the RAMP (including as to the included risk monitoring and mitigation activities) was developed for the Selected Product; and (iii) assess the J&J Pharmaceutical Affiliate's implementation and tracking of the implementation of the RAMP for the Selected Product(s).

C. The IRO shall prepare a report based on each RAMP Transactions Review performed (Transactions Review Report). The Transactions Review Report shall include the following:

1. an identification of the Selected Products and a description of the documents and information reviewed in connection with each Selected Product;

2. for each Selected Product, a description of: (i) the standards and process followed in developing the RAMP; and (ii) the types of identified risks associated with the Selected Product;

3. for each Selected Product, an assessment of whether, based on the information contained in the RAMP, appropriate risk mitigation activities were developed for the Selected Product;

4. for each Selected Product, a description of the expertise and backgrounds of the personnel who were responsible for the development of the RAMP;

5. for each Selected Product, a description of the following items set forth in the RAMP: (i) identification and explanation of risk areas identified for mitigation; (ii) the risk mitigation activity or activities to address each risk area, including sufficient detail regarding scope and timing of mitigation activities; (iii) a responsible individual for each mitigation activity; and (iv) if the RAMP did not specify each of the items set forth above, a description of any deficiencies;

6. for each Selected Product, a description of whether risk monitoring activities specified in the RAMP were implemented and tracked in accordance with the RAMP and the applicable J&J Pharmaceutical Affiliates' policies and procedures, and a description of any deficiencies;

7. for each Selected Product, a description of whether risk mitigation activities (including any action items) specified in the RAMP were implemented and tracked in accordance with the RAMP and applicable to the J&J Pharmaceutical Affiliates' policies and procedures, and a description of any deficiencies;

8. for each Selected Product a description of: (i) any recommendations made by the IRO regarding the RAMP or any risk monitoring activities and risk mitigation activities included in the RAMP; (ii) whether, and in what manner, the J&J Pharmaceutical Affiliates implemented the recommendations from the IRO; and (iii) if the J&J Pharmaceutical Affiliates did not implement the IRO recommendations, a description of the rationale for the J&J Pharmaceutical Affiliates' decision not to implement the recommendations; and

9. the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in the J&J Pharmaceutical Affiliates' systems, processes, policies, procedures, and practices relating to the RAMP program, if any; and recommendations, if any, for changes in the J&J Pharmaceutical Affiliates' systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the RAMP program.

Appendix D to CIA for Johnson & Johnson

Executive Financial Recoupment Program

To the extent not already accomplished, within 150 days after the Effective Date of the CIA, Johnson & Johnson (J&J) and the J&J Pharmaceutical Affiliates shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual incentive compensation (including bonuses and Equity Awards) for any Covered Executive (defined below in Paragraph A) who is the subject of an Affirmative Recoupment Determination (as defined below in Paragraph C). This program shall be known as the Executive Financial Recoupment Program. This recoupment program shall apply to Covered Executives who are either current J&J or J&J Pharmaceutical Affiliate employees or who are former J&J or J&J Pharmaceutical Affiliate employees at the time of a Recoupment Determination.

(A) Description of Executive Financial Recoupment Program. To the extent not already accomplished, within 150 days after the Effective Date of the CIA, J&J and the J&J Pharmaceutical Affiliates shall establish policies and procedures (and modify employment and other contracts as necessary) to provide that annual incentive compensation for each Covered Executive is at risk of forfeiture in the event of misconduct that is discovered by J&J or the J&J Pharmaceutical Affiliates before the bonus is paid. In the event of misconduct by any J&J or J&J Pharmaceutical Affiliate Covered Executive, J&J and the J&J Pharmaceutical Affiliates shall also reserve the right and full discretion to void and forfeit any unvested stock options, unvested stock appreciation rights, unvested deferred share units, and other unvested rights to receive company common stock (collectively, "Equity Awards"). If J&J or a J&J Pharmaceutical Affiliate discovers any misconduct that would implicate the forfeitures described in this Paragraph by a Covered Executive, it shall evaluate the situation and make a determination about whether any forfeiture, and the terms of such forfeiture, shall be implemented.

In addition, to the extent not already accomplished, within 150 days after the Effective Date of the CIA, J&J and the J&J Pharmaceutical Affiliates shall modify and supplement their annual bonus plans applicable to a Covered Executive (and any employment agreements, as appropriate) by imposing the following eligibility and repayment conditions on future bonuses and Equity Awards and making the additional remedies discussed below applicable to all J&J and J&J Pharmaceutical Affiliate executives at the level of Vice President 2 (pay grade 51) or above (collectively, "Covered Executives"). J&J and the J&J Pharmaceutical Affiliates shall implement Policies and Procedures and, as necessary, shall modify contracts with Covered Executives so that beginning no later than calendar year 2015 the bonuses and Equity

Awards may be recouped if an Affirmative Recoupment Determination is made. The forfeiture and recoupment rights described in this Paragraph shall apply prospectively to Covered Executives beginning no later than the calendar year 2015 bonus plan and Equity Award years.

(i) **Executive Bonus Eligibility and Repayment Conditions.** J&J and J&J Pharmaceutical Affiliates shall implement an eligibility and repayment condition on annual bonuses that shall be designed to survive both the payment of the bonus and the separation of a Covered Executive's employment. This will allow J&J and the J&J Pharmaceutical Affiliates, as a consequence of a Triggering Event, to pursue repayment from the Covered Executive of all or any portion of the bonus monies paid to the Covered Executive. To the extent permitted by controlling law, these bonus eligibility and repayment conditions will survive the payment of the Covered Executive's bonus and the separation of the Covered Executive's employment for a period of 3 years from the payment of the bonus for the plan year. If payment of any portion of a bonus is deferred on a mandatory or voluntary basis, the 3 year period shall be measured from the date the bonus would have been paid in the absence of deferral.

If an Affirmative Recoupment Determination is made, J&J and the J&J Pharmaceutical Affiliates shall endeavor to collect repayment of any bonus from the Covered Executive through reasonable and appropriate means according to the terms of its bonus plan (or executive contract if applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary and appropriate to collect the repayment, J&J or the J&J Pharmaceutical Affiliate shall file suit against the Covered Executive unless good cause exists not to do so. For purposes of the Executive Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Covered Executive to repay any recoupment amount or J&J or the J&J Pharmaceutical Affiliates' inability to bring such a suit under the controlling law of the relevant jurisdiction.

(ii) **Equity Awards and Repayment Conditions.** J&J and J&J Pharmaceutical Affiliates shall implement an eligibility and repayment condition on J&J and J&J Pharmaceutical Affiliates' Equity Awards designed to survive the separation of a Covered Executive's employment. More specifically, to the extent necessary, J&J and J&J Pharmaceutical Affiliates shall implement an eligibility and repayment condition on J&J's Equity Awards in order to clarify that, as a consequence of a Triggering Event, J&J and J&J Pharmaceutical Affiliates may pursue repayment by a Covered Executive who is a former employee of all or any portion of the last 3 years' worth of any Equity Awards that were granted preceding the Affirmative Recoupment Determination.

If an Affirmative Recoupment Determination is made, J&J and J&J Pharmaceutical Affiliates shall endeavor to collect repayment of all or a portion of the

Equity Awards for the 3 years prior to an Affirmative Recoupment Determination from a Covered Executive through reasonable and appropriate means (including by means of filing suit against the executive, as may be appropriate) to the extent permitted by controlling law of the jurisdiction in which the Covered Executive works.

(iii) **Additional Remedies.** If, after expiration of the time period specified in Paragraphs A(i)-(ii) above, the Recoupment Committee determines that a Triggering Event has occurred, J&J and J&J Pharmaceutical Affiliates shall make a determination as to whether to pursue available remedies (e.g., filing suit against the Covered Executive) existing under statute or common law to the extent available.

(B) Definition of Triggering Events. The forfeiture and repayment conditions described above shall be triggered upon a Recoupment Determination that finds:

(i) significant misconduct (i.e., significant violation of a J&J or J&J Pharmaceutical Affiliate policy or regulation or law) relating to the manufacturing, sales or marketing of pharmaceutical products by the Covered Executive that, if discovered prior to payment, would have made the Covered Executive ineligible for a bonus or Equity Award in that plan year or subsequent plan years; or

(ii) significant misconduct (as defined above) relating to the manufacturing, sales or marketing of pharmaceutical products by subordinate employees in the business unit for which the Covered Executive had responsibility that does not constitute an isolated occurrence and which the Covered Executive knew or should have known was occurring that, if discovered prior to payment, would have made the Covered Executive in question ineligible for a bonus or Equity Awards in that plan year or subsequent plan years.

(C) Administration of Recoupment Programs. J&J and J&J Pharmaceutical Affiliates shall engage in a standardized, formal process to determine, in their sole discretion, whether a Triggering Event has occurred, and, if so, the extent of bonus monies, and Equity Awards that will be subject to repayment or forfeiture by the Covered Executive, and the most appropriate method for securing recoupment of relevant monies previously paid to a Covered Executive. The findings and conclusions resulting from this process shall be referred to as the "Recoupment Determination." A determination that bonus and/or Equity Award amounts shall be forfeited by or recouped from a Covered Executive shall be referred to as an "Affirmative Recoupment Determination."

(i) **Initiation.** J&J and/or any J&J Pharmaceutical Affiliate shall initiate the Recoupment Determination process upon: (1) discovery of potential significant misconduct that may rise to the level of a Triggering Event, or (2) written

notification by a United States federal government agency to J&J's or a J&J Pharmaceutical Affiliates' compliance officer of a situation that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal healthcare programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (e.g., a description of the alleged misconduct and the applicable time period) to allow J&J and J&J Pharmaceutical Affiliates to identify the Covered Executive.

(ii) **Recoupment Committee**. The Recoupment Determination shall be made by a committee of senior executives representing the Compliance, Legal, Internal Controls, Finance and Human Resources groups (Recoupment Committee). The Recoupment Committee may also include members of other functional areas or business groups, as it deems necessary. A Covered Executive shall not participate in the Recoupment Committee while that individual is subject to a Recoupment Determination. If a Recoupment Determination involves an Executive Officer of J&J, a Recoupment Determination for such individual shall be subject to approval by the Board of Directors (or appropriate committee thereof) of J&J. For purposes of this section, "Executive Officer" means any member of the Executive Committee of J&J, the Corporate Controller, and such other executives of J&J subject to the reporting requirements of Section 16 of the Securities Exchange Act of 1934, as amended, as may be determined by the Company's Board of Directors.

(iii) **Recoupment Determination Process**. J&J or a J&J Pharmaceutical Affiliate shall initiate the Recoupment Determination process within 30 days after discovery by J&J or the J&J Pharmaceutical Affiliate, or notification pursuant to Paragraph C(i), of a potential Triggering Event.

As part of the Recoupment Determination process, the Recoupment Committee or appropriate Delegate (as defined below) shall: i) undertake an appropriate and substantive review or investigation of the facts and circumstances associated with the Triggering Event or any written notifications about potential Triggering Events received pursuant to Paragraph C(i) above; ii) make written findings regarding the facts and circumstances associated with the Triggering Event and any written notifications about potential Triggering Events received pursuant to Paragraph C(i) above; and iii) set forth in writing its determinations (and the rationale for such determinations) about: 1) whether a Triggering Event occurred; 2) the extent of bonus monies or Equity Awards (collectively "performance pay") that will be subject to forfeiture and/or repayment by the Covered Executive, if any; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of performance pay from the Covered Executive; and 4) the timetables under which J&J and the applicable J&J Pharmaceutical Affiliate will implement the forfeiture and/or attempt to recoup the performance pay. For purposes of this Paragraph, a "Delegate" shall refer to the J&J or J&J Pharmaceutical Affiliate

personnel to whom the Recoupment Committee has delegated one or more of its required tasks in furtherance of the Executive Financial Recoupment Program.

(D) Reporting. The Recoupment Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of J&J about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph C(i)(2) above; ii) a description of any Recoupment Determinations where a Triggering Event occurred during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the means for collecting any recoupment and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Affirmative Recoupment Determinations that were not fully completed in prior years. In addition, the Recoupment Committee shall provide similar annual reports to the Board(s) of Directors of any J&J Pharmaceutical Affiliate that employs/employed a Covered Executive that is the subject of a Triggering Event.

The Recoupment Committee shall also provide annual reports to the OIG about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph C(i)(2) above; ii) a summary description of any Recoupment Determinations where a Triggering Event occurred during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the method for collecting any recoupment, and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Affirmative Recoupment Determinations that were not fully completed in prior years. J&J shall provide OIG with additional information regarding any Recoupment Determination where a Triggering Event has occurred upon OIG's request.

J&J and J&J Pharmaceutical Affiliates commit, to the extent permitted by controlling law, to maintaining all of the forfeiture and recoupment commitments set forth in Paragraphs A-D above for at least the duration of the CIA, absent agreement otherwise with the OIG.