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.