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