

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PURDUE PHARMA L.P.

I. PREAMBLE

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

Prior to the Effective Date (as defined below), Purdue established a voluntary compliance program (Corporate Compliance Program), which includes a corporate Compliance Officer and Corporate Compliance Council, a Code of Business Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, and internal review procedures designed, as represented by Purdue, to promote compliance with applicable laws and the promotion of high ethical standards.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Purdue under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which Purdue becomes obligated to make payment to the United States of the Settlement Amount established pursuant to the Settlement Agreement between the United States and Purdue, signed on or about the date of signature of this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

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

1. "Covered Persons" includes:

a. all owners, officers, directors, and employees of Purdue.

Notwithstanding the prior sentence, the term Covered Persons shall not include those owners who: (i) are not involved in the business operations of Purdue Pharma L.P.; and (ii) are owners merely by virtue of their status as beneficiaries of a trust; and

b. all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, or regulatory functions, or research and development activities (except preclinical researchers, clinical investigators, and clinical research organizations) on behalf of Purdue.

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

2. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to the dissemination of promotional or medical/scientific information about Purdue's products, the provision of services relating to Purdue's products, the development of Materials (as defined below), sales, marketing, pricing, or promotion of Purdue's products, research and development (except preclinical researchers, clinical investigators, and clinical research organizations), or to any government contract or regulatory functions (hereafter collectively referred to as "Product Services Related Functions.") To the extent not specified above, Relevant Covered Persons also includes those members of the Office of General Counsel who support Relevant Covered Persons and those individuals from Regulatory Affairs, Corporate Compliance,

Medical Services, Medical Research, Human Resources, Sales Operations, and Training Departments who support Relevant Covered Persons.¹

3. "Materials" shall mean all branded or non-branded, new or revised, non-individualized communications, whether printed or electronic, that are intended for, or have the potential for, external distribution to or consumption by HCPs or consumers. The term Materials shall also mean all new or revised internal training materials whether printed or electronic, concerning Purdue's products or disease states treated by Purdue's products, intended for Relevant Covered Persons involved in sales and marketing of Purdue's products.
4. "Health Care Professionals" ("HCPs") shall mean physicians, nurses, pharmacists, dentists, physician assistants, nurse practitioners, physical therapists, managed care organization representatives, social workers, and students in training programs relating to the above-referenced professions.
5. "Informational Activity" shall mean any program, meeting, or event, including, but not limited to, sponsorship of booths or activities at medical conferences or symposia that involves the promotion of a Purdue product.
6. A "Non-Promotional Educational Activity" shall mean any accredited or non-accredited educational event for HCPs that is financially supported by Purdue, but otherwise independent from the promotional influence of Purdue, and that is not specific to a branded product, such as continuing medical education (CME), medical education, or disease awareness.
7. For the first Reporting Period, the term "Covered Product" as used in Section III.J and Section III of Appendix B (relating to Transactions Reviews), shall mean OxyContin. At least 90 days prior to the start of the second Reporting Period and each subsequent Reporting Period, Purdue shall provide the OIG with a list of products that it currently

¹ If there are future changes in the organizational structure of Purdue relating to the groups and functions enumerated in the preceding sentence, individuals from other groups or functions who provide support to Relevant Covered Persons shall also be considered Relevant Covered Persons.

sells and plans to sell in the upcoming applicable Reporting Period. Purdue shall also provide to the OIG a description of each product and its FDA-approved uses, an explanation of whether the product is or will be actively promoted, and information about the expected relative revenue from the sale of the product. After consulting with Purdue about this information, and prior to the second and each subsequent Reporting Period, the OIG shall, in its discretion identify which and as many Purdue products as it believes appropriate to be "Covered Product(s)" for purposes of Section III.J and Section III of Appendix B for each of the next applicable Reporting Periods, and the OIG shall so notify Purdue.

III. CORPORATE INTEGRITY OBLIGATIONS

Purdue shall establish and maintain a Corporate Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Prior to the Effective Date, Purdue appointed an individual to serve as its Compliance Officer, and Purdue shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Compliance Officer shall be a member of senior management of Purdue, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Purdue, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Purdue as well as for any reporting obligations created under this CIA.

Purdue shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Purdue established a Compliance Committee, called the Corporate Compliance Council. Consistent with the requirements of this Section III.A.2, Purdue shall maintain the Corporate Compliance Council throughout the term of this CIA. The Corporate Compliance Council shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., Office of General Counsel, Human Resources, Corporate Quality, Field Operations, Risk Management and Health Policy, Medical Research, and Regulatory Affairs). The Compliance Officer shall chair the Corporate Compliance Council and the Corporate Compliance Council shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Purdue established a Code of Conduct (known as its "Code of Business Ethics"). To the extent not already accomplished, within 120 days after the Effective Date, Purdue shall distribute the Code of Conduct to all Covered Persons. Purdue shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Purdue's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, and advertise its products in accordance with such requirements;
- b. Purdue's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Purdue's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

- c. the requirement that all of Purdue's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Purdue, suspected violations of any Federal health care program or FDA requirements or of Purdue's own Policies and Procedures as implemented pursuant to Section III.B.2;
- d. the possible consequences to both Purdue and Covered Persons of failure to comply with Federal health care program or FDA requirements and with Purdue's own Policies and Procedures as implemented pursuant to Section III.B.2 and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Purdue's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

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

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

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Purdue shall implement written Policies and Procedures regarding the operation of Purdue's compliance program and its compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. selling, marketing, and promoting Purdue products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b(b);
- c. selling, marketing, promoting, advertising, and disseminating Materials or information about Purdue's products in compliance with all applicable FDA requirements, including requirements relating to the dissemination of information that is fair and accurate², and procedures governing the response to requests for information about non-FDA approved uses (*e.g.*, off-label uses) or about FDA approved product label information including, but not limited to, information concerning the withdrawal, drug tolerance, drug addiction or drug abuse of Purdue's products;
- d. compensation (including salaries and bonuses) for Relevant Covered Persons engaged in promoting and selling Purdue products that are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion or sales of Purdue's products;
- e. the process by which and standards according to which Medical Services and Medical Liaisons provide information about Purdue's products concerning any off-label uses of the products or other product-related information, including, but not limited to, information concerning withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products. These Policies and Procedures shall address the following items:
 - (i) the form and content of information and, if applicable, Materials disseminated by Medical Services and Medical Liaisons; and

² For purposes of this CIA, to the extent that any information or Materials contain statements about the medical or scientific nature of Purdue's products, the term "fair and accurate" shall also mean that such statements are approved or permitted for use in the labeling or supported by substantial evidence or substantial clinical experience.

- (ii) the internal review process by Medical Services for information disseminated by Medical Services and Medical Liaisons.

These Policies and Procedures shall also include a requirement that Purdue track and maintain records of what, if any, information or Materials are provided to HCPs by Medical Services or Medical Liaisons.

The Policies and Procedures shall also include a requirement that Purdue develop a database (the Product Inquiries Database) that includes the following items of information for each inquiry received for information about Purdue's products by Medical Services (Inquiry): 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, Request for Medical Information Card *etc.*); 3) name of requesting HCP or other person; 4) nature and topic of Inquiry (including exact language of the Inquiry if made in writing); 5) a determination of the Category and Topic of the Inquiry regarding the product; 6) nature/form of the response from Purdue (including a record of the Materials and/or information, as applicable, provided to the HCP or other person in response to the Inquiry); and 7) if referred by a Purdue sales representative, or if otherwise known, the name or a unique identifier of the Purdue sales representative who called on, or interacted with, the HCP or other person;

f. the process by which and standards according to which Purdue's sales representatives handle and refer requests from HCPs for information about any off-label uses of Purdue's products;

g. the process by which and standards according to which Purdue sales representatives provide Materials³ or respond to requests from HCPs for information about Purdue's products, including information concerning withdrawal, drug tolerance, drug addiction,

³ Purdue has represented that all of the electronic or printed communications disseminated by its sales representatives meet the definition of Materials set forth in Section II.C.3 above and are therefore subject to the Materials review process described in Section III.B.2.m.

or drug abuse of Purdue's products. These Policies and Procedures shall address the following items:

- (i) the form and content of Materials disseminated by sales representatives; and
 - (ii) the internal review process for the Materials and information disseminated by sales representatives.
- h. fee-for-service and all other contractual arrangements (including speaker programs, advisory board programs, focus group programs, research contractual arrangements, and all consultant arrangements) with HCPs. These Policies and Procedures shall be designed to ensure that the arrangements and any associated events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the uses, content, and circumstances of such arrangements and events;
- i. funding or sponsorship of Non-Promotional Educational Activities as defined in Section II.C.6 above. These Policies and Procedures shall be designed to ensure that Purdue's funding and/or sponsorship of Non-Promotional Educational Activities satisfies all applicable Federal health care program and FDA requirements.
- The Policies and Procedures shall require that the Non-Promotional Educational Activity: 1) include the disclosure of Purdue's financial support of the Activity and any financial relationships with faculty, speakers, or organizers at such Activity; 2) have an educational focus; 3) be independent; and 4) be non-promotional in tone/nature;
- j. funding or sponsorship of Informational Activities as defined in Section II.C.5 above. These Policies and Procedures shall be designed to ensure that Purdue's funding or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements;

k. funding of charitable grants or sponsorships in a manner that is designed to ensure that Purdue's funding complies with all applicable Federal health care program requirements and FDA requirements;

l. sponsorship or funding of research activities (including clinical trials, market research, or authorship of articles or other publications) by Purdue in a manner that is designed to ensure that Purdue's funding or sponsorship of such activities complies with all applicable Federal health care program and FDA requirements;

m. development and production of Materials in a manner designed to ensure that the Materials comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall be designed to ensure that the Materials are fair and accurate. The Policies and Procedures shall provide that: 1) all Materials shall be reviewed by at least Medical Services, Regulatory Affairs and the General Counsel's office; 2) the review of all Materials shall be recorded in a Materials Review tracking system; 3) when and if Purdue determines that Materials are not appropriate for continued use (including for promotional purposes) and/or that the statements contained in any Materials are not fair and accurate, Purdue shall take appropriate responsive action. Such responsive action could include a revision and re-issuance of the Materials or information about the Materials, the cessation of the use of the Materials, and/or training of Covered Persons about any changes to the Materials or change in use of the Materials;

n. the process by which sales representatives, appropriate marketing personnel, and personnel in the literature storage warehouse are notified about the discontinuation of the use of any promotional Materials and instructed about the proper disposition of any discontinued Materials. These Policies and Procedures shall provide that: 1) all approved promotional Materials shall be reviewed at least annually in order to determine whether continued use of any such Materials is appropriate for promotional purposes; 2) following such review, sales representatives shall be notified in writing by a member of Senior Sales Management if a decision is made to cease the use

of any particular Materials. Such communication shall include the steps that the representative must take to ensure that use of the affected Materials is discontinued. At a minimum, each such communication will include the timeline for the discontinuation of the use of the affected Materials and instructions for the disposition of the remaining Materials, if any, in the possession of the representative; 3) a member of Senior Sales Management also shall ensure that the Marketing Department immediately informs the literature storage warehouse of the discontinuation decision. Such communication from the Marketing Department shall include instructions for the disposition of any affected promotional Materials that are currently in stock in the literature storage warehouse; and

o. employee discipline for violations of Purdue's Policies and Procedures, including those policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Purdue shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, Purdue shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Purdue's:

a. CIA requirements;

- b. Purdue's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues); and
- c. in general, the proper methods of promoting, marketing, selling, and disseminating information about Purdue's products in accordance with Federal health care program and FDA requirements.

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

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above. This Specific Training shall explain:

- a. all Federal health care program requirements relevant to the proper methods for selling, marketing, promoting, and providing information (including pricing information) about Purdue's products, including, but not limited to, the requirements of the Federal anti-kickback statute; the Civil Monetary Penalties Law; the civil False Claims Act; and the Medicaid Drug Rebate statute;
- b. all applicable FDA requirements relevant to promotion, marketing, research, and dissemination of medical or scientific information about Purdue's products including but not limited to, the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations and written directives;
- c. the personal obligation of each Relevant Covered Person involved in Product Services Related Functions to comply with all applicable legal requirements;

d. the legal sanctions for violations of the Federal health care program requirements or FDA requirements relating to Product Services Related Functions; and

e. examples of proper and improper practices relating to Product Services Related Functions.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Purdue employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

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

3. *Supplemental Instruction and Training to Field Sales Force.* If Purdue learns that the statements contained in any Materials or other information used by Purdue in detailing HCPs (e.g., journal articles) are not fair and accurate, Purdue shall evaluate and implement appropriate corrective action, and instruct its sales representatives accordingly within 30 days after learning of this information. If the FDA-approved label or package insert for any Purdue product is changed during a Reporting Period, Purdue shall provide training to its sales representatives about the change within 30 days after the change is implemented. This Supplemental Training shall be in addition to the General and Specific Training requirements set forth above.

4. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

5. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of their training, including the applicable Federal health care program and FDA requirements.

6. *Update of Training.* Purdue shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program and FDA requirements, any issues discovered during internal audits or the Reviews required under Section III.D, and any other relevant information.

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

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Reviewers.* Within 120 days after the Effective Date, Purdue shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform a Promotional and Product Services Engagement. Each IRO engaged by Purdue shall have expertise in Federal health care program and FDA requirements. Each IRO shall assess, along with Purdue, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Frequency of IRO Reviews.* The Promotional and Product Services Engagement shall consist of two components – a systems review (the Promotional and Product Services Systems Review) and a transactions review (Promotional and Product Services Transactions Review), as described more fully in Appendix B to this CIA, which is incorporated by reference.

If there are no material changes in Purdue's systems, processes, policies, and practices relating to Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the second and fourth Reporting Periods. As set forth in Appendix B, if Purdue materially changes its systems, processes, policies, and practices relating to Product Services Related Functions, then the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the second and fourth Reporting Periods.

The Promotional and Product Services Transactions Review shall be performed annually. For the first Reporting Period, the Transactions Review shall cover the last two quarters of the Reporting Period. Thereafter each subsequent Transactions Review shall cover a complete Reporting Period. The IRO(s) shall perform all components of each of these annual Reviews.

c. Retention of Records. The IRO and Purdue shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Purdue) related to the reviews.

2. *IRO Review Reports.* The IRO shall prepare a report based upon each Promotional and Product Services Transaction Review and Promotional and Product Services Systems Review performed. Information to be included in each Report is described in Appendix B.

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

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

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Purdue a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Reviews and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Prior to the Effective Date, Purdue established a Disclosure Program (*i.e.*, the Purdue Ethics and Compliance Hotline) that includes a mechanism (*e.g.*, a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Purdue's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirements believed by the individual to be a potential violation of criminal, civil, or administrative law. Purdue shall maintain this Disclosure Program throughout the term of this CIA. Purdue shall appropriately publicize the existence of the disclosure mechanism (*e.g.*, via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be

conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Purdue shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).
- c. “Screened Persons” include prospective and current officers, directors, and employees of Purdue. Screened Persons also include

those prospective and current contractors and agents of Purdue who are Covered Persons. Screened Persons also include those prospective and current owners of Purdue who: (i) are Covered Persons; (ii) have more than a 5% ownership interest in Purdue; or (iii) received more than 5% of the distribution from the trust referenced in Section II.C.1.a in the year preceding the screening.

2. *Screening Requirements.* Purdue shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Purdue shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

b. Purdue shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Purdue shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Purdue to refrain (if applicable) from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Purdue understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Purdue may be liable for overpayments (if applicable) and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Purdue meets the requirements of Section III.F.

Purdue represents that in February 2007 it screened all Purdue employees against the Exclusion Lists. Such screening shall satisfy Purdue's obligations as set forth in Section III.F.2.b with regard to its employees for purposes of the first Reporting Period. For purposes of the annual screening requirements set forth in Section III.F.2.b as applicable to Purdue employees in the second and subsequent Reporting Periods, Purdue shall screen its employees by February of each subsequent year.

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

4. *Pending Charges and Proposed Exclusions.* If Purdue has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, Purdue shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at headquarters, Purdue shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Purdue conducted or brought by a governmental entity or its agents involving an allegation that Purdue has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Purdue shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting of Reportable Events.

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

- i. anything that involves a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or any FDA requirements relating to the labeling

or promotion of products for which penalties or exclusion may be authorized; or

ii. the filing of a bankruptcy petition by Purdue.

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

2. Reporting of Reportable Events. If Purdue determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Purdue shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

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

ii. a description of Purdue's actions taken to correct the Reportable Event; and

iii. any further steps Purdue plans to take to address the Reportable Event and prevent it from recurring.

iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program and/or FDA authorities implicated.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication from Purdue to the FDA that substantively discusses Purdue's or a Covered Person's unlawful or improper promotion of Purdue's products or the misbranding of Purdue products, Purdue shall provide a copy of the report, correspondence, or communication to the OIG. Purdue shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Monitoring and Review of Requests for Information from Medical Services.

Purdue's Policies and Procedures address the selling, marketing, promoting, and dissemination of Materials and information about Purdue's products in compliance with all applicable Federal health care program and FDA requirements and the procedures governing the response to requests for information about non-FDA approved uses (e.g., off-label uses) or about the FDA approved product label information including, but not limited to, withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products.

These Policies and Procedures address how requests for information about off-label uses of Purdue's products are to be handled. Purdue's policies provide, among other things, that Covered Persons may not directly or indirectly solicit, encourage, or promote any Purdue product for off-label uses. Purdue's policy permits only Medical Services, either alone or in conjunction with Medical Liaisons, to answer questions and provide information and, if applicable, Materials about off-label uses of Purdue's products.

Purdue shall document and record all inquiries that Medical Services receives from HCPs regarding its products in the Product Inquiries Database. Medical Services shall not supply information in response to a request for information (including requests concerning withdrawal, drug tolerance, drug addiction, drug abuse, or off-label uses of Purdue's products) unless the request is recorded in the Product Inquiries Database.

1. *Product Inquiries Database and Focus Inquiry Report.*

Medical Services personnel shall record in the Product Inquiries Database the information identified in Section III.B.2.e above for each Inquiry. Medical Services assigns each Inquiry into one of 11 pre-established Categories (e.g., Comparative Claims, Adverse Events, etc.) Each Inquiry is also sub-classified by Topic (e.g., Withdrawal, Tolerance, etc.) All Inquiries that are generated by, or in connection with, an interaction between a Purdue sales representative and an HCP (e.g., through a call made by a sales representative from an HCP's office, through a Medical Information Request Form, or through an Inquiry in which the HCP identifies the sales representative involved) shall be known as "Sales Force Related Inquiries."

All Sales Force Related Inquiries that relate to information about withdrawal, drug tolerance, drug addiction, drug abuse, or any off-label uses of Purdue's products are

categorized into one of three Categories (Comparative Claims, Dosing and Administration, and Therapeutic Uses) or one of four Topics (Withdrawal, Addiction, Tolerance, or Abuse) contained in other Categories. For purposes of the first Reporting Period, Sales Force Related Inquiries for the Covered Product from the Comparative Claims, Dosing and Administration, and Therapeutic Uses Categories and the Withdrawal, Addiction, Tolerance or Abuse Topics from other Categories shall be referred to collectively as the "Focus Inquiries." At least 90 days prior to the beginning of the second Reporting Period and each subsequent Reporting Period, Purdue shall identify and provide information to the OIG about the Categories and Topics to be used by Medical Services in classifying Inquiries in the Product Inquiries Database for the upcoming Reporting Period. Prior to the start of the second Reporting Period and every Reporting Period thereafter, the OIG will consult with Purdue about the Categories and Topics information provided. After such consultation and in its discretion, the OIG may change or expand the list of Categories and Topics containing Inquiries that shall be considered Focus Inquiries and the OIG shall so notify Purdue. The Covered Product(s) identified pursuant to Section II.C.7 for Reporting Periods subsequent to the first Reporting Period shall be the basis for the Focus Inquiries for the applicable Reporting Period.

On a quarterly basis, Medical Services shall submit a report to the Compliance Officer that lists all the Focus Inquiries (Focus Inquiry Report). The Focus Inquiry Report shall include the information outlined in Section III.B.2.e for each Inquiry.

2. Compliance Officer Review and Analysis.

a. On at least a semi-annual basis, the Compliance Officer (or his/her designee) shall review a random selection of 75 Focus Inquiries listed on the Focus Inquiry Report to identify situations in which the Compliance Officer believes a sales representative may have made improper statements about any Purdue product(s), including those improper statements related to withdrawal, drug tolerance, drug addiction, drug abuse, or off-label uses of the product(s) (including situations in which it appears that the Inquiries for such information may have been prompted by the sales force personnel (*i.e.*, may not have been unsolicited)) (Suspect Inquiries). In conducting this review, the Compliance Officer (or his/her designee) shall prepare a Focus Inquiry Monitoring Form (or any successor form) for each Suspect Inquiry;

b. For each Suspect Inquiry, the Compliance Officer (or his/her designee) shall conduct an additional compliance review (Additional Compliance Review) that includes the following: 1) investigatory steps; 2) specific findings based on the Additional Compliance Review; and 3) all appropriate follow up action, including appropriate discipline of the Purdue sales representative and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H above, if applicable. All of the Compliance Officer's factual findings from the Additional Compliance Review shall be recorded on the related Focus Inquiry Monitoring Form. In addition, the Focus Inquiry Monitoring Form shall include a general description of the process by which the Compliance Officer conducted his/her monitoring and review activities, including, but not limited to, the types of records reviewed and the identities of individuals interviewed.

The Compliance Officer shall provide a report on the results of the reviews described in these Sections III.J.2.a-b on at least a semi-annual basis to the Corporate Compliance Council. Purdue shall make all Focus Inquiry Monitoring Forms available to the OIG upon request; and

c. On at least an annual basis, the Compliance Officer shall review Medical Services' Policies and Procedures relating to the handling of Focus Inquiries and provide a report on the results of such Policies and Procedures review to the Corporate Compliance Council.

K. Purdue's Promotion Monitoring Program.

Purdue has implemented a formalized process through which Purdue's District Managers evaluate and monitor sales representative interactions with HCPs (Promotion Monitoring Program). Through the Promotion Monitoring Program, each sales representative is evaluated by Purdue's District Managers annually through direct observations of the interactions between the sales representatives and HCPs. The District Managers record their observations (including numerical evaluations, narrative descriptions of observations, and developmental recommendations) in either a Field Contact Report or in a New Representative Development Program Form (for those sales representatives in their first year of employment by Purdue) (collectively, "Promotion Monitoring Program Forms.")

Purdue shall continue this Promotion Monitoring Program during the term of this CIA as outlined below. Specifically, Purdue District Managers shall directly observe

during ride-alongs at least five full days of the interactions between each sales representative and HCPs during each Reporting Period (or a *pro rata* portion thereof, if the sales representative is employed for less than the full Reporting Period.) Purdue's District Managers shall conduct the observations at their discretion throughout the Reporting Period (rather than during a single timeframe during the Reporting Period). The Promotion Monitoring Program Forms shall include: 1) the identity of the sales representative and the District Manager; 2) the date of the detailing sessions with the HCPs; 3) the Purdue products discussed during the detailing sessions; 4) observations about the interaction between the sales representative and each HCP visited; 5) an identification and description of any potential improper statements about any Purdue product(s), including those improper statements relating to withdrawal, drug tolerance, drug addiction, drug abuse, or off-label uses of the product(s); and 6) developmental recommendations for the sales representative.

If the District Manager observes any potentially improper statements about any Purdue product(s), including those improper statements relating to withdrawal, drug tolerance, drug addiction, drug abuse, or off-label uses of any product, he or she shall bring the matter to the attention of the Compliance Officer and provide copies of the Promotion Monitoring Program Forms to the Corporate Compliance Department. This indication of potentially improper statements may be made through the use of a rating of "1" (meaning not fully compliant) on the Promotion Monitoring Program Form (or an analogous indication on any successor rating system.) Such a rating on the Promotion Monitoring Program Form indicates a potential compliance issue.

If the Compliance Officer receives any Promotion Monitoring Program Forms relating to instances in which a sales representative may have made improper statements about any Purdue products, including those improper statements relating to withdrawal, drug tolerance, drug addiction, drug abuse, or off-label uses of the products, the Compliance Officer (or a designee) shall perform an additional review. This review shall be known as the "Compliance Detailing Review". If, as a result of the Compliance Detailing Review, Purdue determines that there was improper promotion of the product, Purdue shall: 1) make specific findings based on the Compliance Detailing Review; and 2) undertake all appropriate follow up action, including appropriate discipline of the Purdue sales representative and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H above, if applicable.

Purdue shall make all Promotion Monitoring Program Forms available to the OIG upon request.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Purdue changes locations or sells, closes, purchases, or establishes a new business unit or location, Purdue shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider or supplier number, and any corresponding contractor's name and address that issued each Federal health care program provider or supplier number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Purdue shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Corporate Compliance Council required by Section III.A;
3. a copy of Purdue's Code of Conduct required by Section III.B.1;
4. a copy of all Policies and Procedures required by Section III.B.2;
5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
6. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

7. a description of the Disclosure Program required by Section III.E;
8. the following information regarding the IRO(s):
 - a. identity, address, and phone number;
 - b. a copy of the engagement letter;
 - c. a summary and description of any and all current and prior engagements and agreements between Purdue and the IRO;
 - d. the proposed start and completion dates of each Review;
9. a certification from the IRO regarding its professional independence and objectivity with respect to Purdue;
10. a description of the process by which Purdue fulfills the requirements of Section III.F regarding Ineligible Persons;
11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and the actions taken in response to the screening and removal obligations set forth in Section III.F;
12. a list of all of Purdue's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal healthcare program provider or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Purdue currently submits claims (if applicable);

13. a description of Purdue's corporate structure, its lines of business, and its United States subsidiaries that are engaged in the manufacturing, marketing, promotion, selling, or distribution of health care products; and

14. the certifications required by Section V.C.

B. Annual Reports. Purdue shall submit to OIG annually a report with respect to the status of, and findings regarding, Purdue's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Corporate Compliance Council described in Section III.A;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (*e.g.*, change in applicable legal requirements) and copies of any compliance-related Policies and Procedures;

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

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

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

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

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

5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letters (if applicable);

6. Purdue's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

7. a summary and description of any and all current and prior engagements and agreements between Purdue and the IRO, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence and objectivity with respect to Purdue;

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

10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs or to FDA requirements;

11. any changes to the process by which Purdue fulfills the requirements of Section III.F regarding Ineligible Persons;

12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Purdue in response to the screening and removal obligations set forth in Section III.F;

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

14. a summary describing any ongoing communication with the FDA required to have been reported pursuant to Section III.I. The summary shall include a description of the matter, and the status of such matter;

15. a description of all changes to the most recently provided list of Purdue's

locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal healthcare program provider or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Purdue currently submits claims (if applicable);

16. a description of all internal audits relating to the Product Services Related Functions completed in the Reporting Period. For each audit completed, the description shall include the dates the audit was conducted, the functional area audited, the subject of the audit, the scope of the audit, the quantity and classification of findings made during the audit, the number of corrective and/or preventative actions that address the findings, and the percentage of corrective and/or preventative actions completed as of the last day of the Reporting Period. Upon request, individual audit findings and related corrective and/or preventative actions shall be made available to the OIG; and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Purdue is in compliance with all of the requirements of this CIA;

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

3. Purdue has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

4. All of Purdue's: (a) Policies and Procedures as referenced in Section III.B.2

above; (b) templates for the standardized contracts and other similar documents; (c) training materials used for purposes of Section III.C, above; and (d) Materials have been reviewed by competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable Federal health care program or FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

5. Purdue has complied with its obligations under Sections III.B.2.m-n to review Materials during the Reporting Period and has taken appropriate responsive action if the Materials are determined not to be fair and accurate. Documentation and information supporting this certification shall be available to OIG upon request.

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

Purdue: Bert I Weinstein
Vice President, Corporate Compliance
Purdue Pharma L.P.
One Stamford Forum
Stamford, CT 06901-3431
Telephone: 203.588.8288
Facsimile: 203.588.6269

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Purdue's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Purdue's locations for the purpose of verifying and evaluating: (a) Purdue's compliance with the terms of this CIA; and (b) Purdue's compliance with the requirements of the Federal health care programs in which it participates and with FDA requirements. The documentation described above shall be made available by Purdue to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Purdue's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Purdue shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Purdue's employees may elect to be interviewed with or without a representative of Purdue present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

Purdue is expected to fully and timely comply with all of its CIA obligations.

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

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

- a. a Compliance Officer;
- b. a Corporate Compliance Council;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements;
- h. notification of Government investigations or legal proceedings;

i. notification of communications with the FDA (as required by Section III.I.);

j. the monitoring and review of requests for information from Medical Services; and

k. the Field Sales Force Promotion Monitoring Program.

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

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

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Purdue fails to submit any Review Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day Purdue fails to comply with Section VII. (This Stipulated Penalty shall begin to accrue on the date Purdue fails to comply.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Purdue as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Purdue fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Purdue, stating the specific grounds for its determination that Purdue has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Purdue shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Purdue receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

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

C. Payment of Stipulated Penalties.

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

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

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in

Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Purdue has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

- a. a failure by Purdue to report a Reportable Event and take corrective action, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D.

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

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

- a. Purdue is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Purdue has begun to take action to cure the material breach; (ii)

Purdue is pursuing such action with due diligence; and (iii) Purdue has provided to OIG a reasonable timetable for curing the material breach.

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

E. Dispute Resolution

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

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Purdue was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Purdue shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an

adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Purdue to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Purdue requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

- a. whether Purdue was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Purdue had begun to take action to cure the material breach within that period; (ii) Purdue has pursued and is pursuing such action with due diligence; and (iii) Purdue provided to OIG within that period a reasonable timetable for curing the material breach and Purdue has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Purdue, only after a DAB decision in favor of OIG. Purdue's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Purdue upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Purdue may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Purdue shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Purdue, Purdue shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above

shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, Purdue and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Purdue;

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

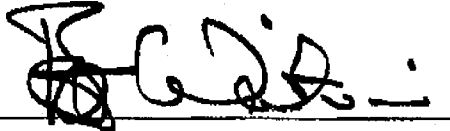
C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. OIG may agree to a suspension of Purdue's obligations under the CIA in the event of Purdue's cessation of participation in Federal health care programs. If Purdue withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, Purdue shall notify OIG at least 30 days in advance of Purdue's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Purdue signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

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

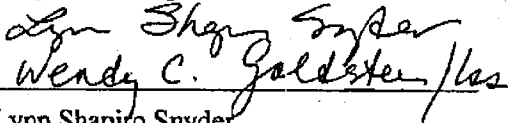
ON BEHALF OF PURDUE PHARMA L.P.



Bert I Weinstein, Vice President
Corporate Compliance

5/7/07

DATE



Lynn Shapiro Snyder
Wendy C. Goldstein
Counsel for Purdue Pharma L.P.

5/7/07

DATE



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



Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

5/8/07

DATE

APPENDIX A INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

Purdue shall engage an IRO 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/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Purdue if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Purdue may continue to engage the IRO.

If Purdue 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, Purdue shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Purdue if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Purdue may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Promotional and Product Services Engagement who have expertise in the Federal health care program and FDA requirements applicable to sales, marketing, research, and promotion of pharmaceutical products. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Purdue products are reimbursed;

2. assign individuals to design and select the Promotional and Product Services Engagement samples who are knowledgeable about the 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 Promotional and Product Services Engagement in accordance with the specific requirements of the CIA, including Appendix B to the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in Promotional and Product Services Engagement;
3. respond to all OIG inquires in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. IRO Independence/Objectivity.

The IRO must perform the Promotional and Product Services Engagement in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Purdue.

E. IRO Removal/Termination.

1. *Provider.* If Purdue terminates its IRO during the course of the engagement, Purdue must submit a notice explaining its reasons to OIG no later than 30 days after termination. Purdue must engage a new IRO in accordance with Paragraph A of this Appendix.

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 Purdue to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Purdue to engage a new IRO, OIG shall notify Purdue 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, Purdue may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Purdue shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any

differences regarding the IRO with Purdue prior to requiring Purdue to terminate the IRO. However, the final determination as to whether or not to require Purdue to engage a new IRO shall be made at the sole discretion of OIG.

**Appendix B to CIA for Purdue Pharma L.P.
Promotional and Product Services Engagement**

I. IRO Engagement, General Description

As specified more fully below, Purdue shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist Purdue in assessing and evaluating certain of its systems, processes, policies, and procedures related to Product Services Related Functions as defined in Section II.C.2 of the CIA (Promotional and Product Services Engagement). The Promotional and Product Services Engagement shall consist of two components - a systems review (the Promotional and Product Services Systems Review) and a transactions review (the Promotional and Product Services Transactions Review), as described more fully below. Purdue may engage, at its discretion, a single entity to perform both components of the Promotional and Product Services Engagement, provided that the entity has the necessary expertise and capabilities to perform both.

The Promotional and Product Services Systems Review shall be a review of Purdue's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Product Services Related Functions as set forth in Section II.A below. If there are no material changes in Purdue's applicable systems, processes, policies, and procedures during the term of the CIA, the IRO shall perform the Promotional and Product Services Systems Review for the second and fourth Reporting Periods. If Purdue materially changes its systems, processes, policies, and procedures relating to Product Services Related Functions (other than any such material changes that occur during the second and fourth Reporting Periods), the IRO shall perform an additional Promotional and Product Services Systems Review covering the Reporting Period in which such changes were made in addition to conducting the Review for the second and fourth 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 practices previously reported did not materially change; and 3) a review of any systems, processes, policies, and practices that materially changed.

The Promotional and Product Services Transactions Review shall include reviews of a sample of Inquiries reflected in the Product Inquiries Database relating to the Covered Product(s) and a sample of the Promotion Monitoring Program Forms relating to the Covered Product(s) as set forth in Section III.A below. The IRO shall perform the Promotional and Product Services Transactions Review on an annual basis and, except for the Transactions Review for the first Reporting Period, each IRO review shall cover a single complete Reporting Period. As of the Effective Date of this CIA, Purdue represents that it is in the process of modifying certain systems, processes, and policies

associated with the Product Inquiries Database and with the Promotion Monitoring Program. Purdue further represents that these modifications will be substantially completed by the end of the second quarter of the first Reporting Period. Therefore, for the first Transactions Review only, the Review shall cover the last two quarters of the first Reporting Period rather than covering the complete Reporting Period. Thereafter, each subsequent Transactions Review shall cover a complete Reporting Period.

II. Promotional and Product Services Systems Review

A. General Business Policies and Practices for Review

For at least the second and fourth Reporting Periods, the IRO shall review Purdue's systems, processes, policies, and procedures associated with the following activities, systems, and policies (Reviewed Policies and Practices):

- 1) Purdue's systems, policies, processes, and procedures applicable to the development of Materials (as defined in Section II.C.3 of the CIA), the Materials Review process, and the process by which Materials are discontinued from use and notification of the discontinuation is provided to all applicable personnel, including sales representatives and marketing personnel;
- 2) Purdue's systems, policies, processes, and procedures applicable to the manner in which Purdue sales representatives respond to requests or inquiries relating to information about non-FDA approved uses (*e.g.* off-label uses) of Purdue's products. This review shall include the manner in which sales representatives refer such requests and inquiries to Medical Services;
- 3) Purdue's systems, policies, processes, and procedures applicable to the manner in which Purdue sales representatives provide Materials, including Materials concerning FDA approved product label information regarding withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products or respond to requests from HCPs for information about Purdue's products;
- 4) Purdue's systems, policies, processes, and procedures applicable to the manner in which Medical Services and Medical Liaisons provide information about Purdue's products concerning any off-label uses of the products or other product-related information, including, but not limited to, information related to withdrawal, drug tolerance, drug addiction, or drug abuse of Purdue's products. This review shall include a review of:

- a. the form and content of information and, if applicable, Materials, disseminated by Medical Services and Medical Liaisons in response to Inquiries and the means by which Purdue tracks and records what information or, if applicable, Materials are provided to HCPs;
 - b. Purdue's internal review and development process for the information disseminated by Medical Services and Medical Liaisons in response to inquiries for information about Purdue products;
 - c. Purdue's systems, processes, and procedures to track Medical Services information and/or Materials, as applicable, requests and responses to such requests;
 - d. the manner in which Medical Services and Medical Liaisons, as applicable, collect and document information in the Product Inquiries Database;
 - e. the process through which Medical Services produces the Product Inquiries Reports provided to the Corporate Compliance Department; and
 - f. the internal review of Product Inquiry Reports and related processes, procedures, and the resolution of any issues identified;
- 5) Purdue's policies and procedures applicable to the manner and circumstances in which Medical Services personnel and Medical Liaisons participate in promotional activities with HCPs (either alone or with members of the sales force) and the role of the Medical Services personnel and Medical Liaisons in such activities;
- 6) Purdue's systems, policies, and procedures relating to funding or sponsorship of any Non-Promotional Educational Activity or Informational Activity. This review shall include a review of the following items, as applicable:
- a. the processes and procedures used to approve the funding (including justification of the amount thereof) or sponsorship of the Non-Promotional Educational Activity or Informational Activity;
 - b. whether and in what manner Purdue tracks or monitors the prescribing habits of the use of Purdue products by individuals or entities receiving the funding or sponsorship of the Non-Promotional Educational Activity or Informational Activity, if any; and
 - c. the budget funding source within Purdue (*e.g.*, department or division) from which funds are allocated for the Non-Promotional Educational Activity or Informational Activity.

In addition, with respect to Non-Promotional Educational Activities, this review shall include a review of the following items:

- d. the criteria used to determine whether and under what circumstances the funding or sponsorship of the Non-Promotional Educational Activity would be provided;
- e. the processes and criteria used to select recipients of the funding or sponsorships of the Non-Promotional Educational Activity, including the role played by sales representatives in the processes (if any), and the circumstances under which there may be exceptions to the processes;
- f. Purdue's Policies and Procedures related to circumstances under which the recipient or the recipient's agent is required to disclose Purdue's funding or sponsorship of the Non-Promotional Educational Activity and any financial relationship Purdue may have with the recipients; and
- g. Purdue's Policies and Procedures relating to the independence of any of the Non-Promotional Educational Activity programs funded;

Further, with respect to Informational Activities, this review shall include a review of the following items:

- h. Purdue's Policies and Procedures relating to the content and promotional nature of any Informational Activity programs sponsored by Purdue;
- 7) Purdue's systems, policies, and procedures relating to its Promotion Monitoring Program. This review shall include a review of the following items:
- a. the processes and procedures used in connection with the Promotion Monitoring Program;
 - b. the frequency and duration of monitoring activities under the Promotion Monitoring Program;
 - c. the identification of Purdue personnel responsible for the monitoring of activities in connection with the Promotion Monitoring Program and their role with regard to the Program; and
 - d. the performance criteria against which the sales representatives are evaluated in connection with the Promotion Monitoring Program;
- 8) Purdue's policies, processes, and procedures relating to the disciplinary actions that Purdue may impose in the event a Covered Person violates a Purdue policy or procedure; and
- 9) Purdue's systems, policies, processes, and procedures for compensating (including with salaries and bonuses) Relevant Covered Persons engaged in promoting or

selling Purdue products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance.

B. Promotional and Product Services Review Report

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

- 1) a description of the documentation (including Policies and Procedures) reviewed and any personnel interviewed;
- 2) a detailed description of Purdue's systems, policies, processes, and practices with regard to the items identified in Sections II.A.1-9 above, including a general description of Purdue's control and accountability systems (*e.g.*, documentation and approval requirements, tracking mechanisms, *etc.*) and written Policies and Procedures relating to the Reviewed Policies and Practices;
- 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.1-9 above are made known or disseminated within Purdue;
- 4) a detailed description of any system used to track and respond to Inquiries about Purdue's products that are handled by Medical Services;
- 5) a description of Purdue's systems, policies, and procedures used to track the review and approval of Materials relating to Purdue products through the Materials Review process, the systems, policies, and procedures used to disseminate approved Materials to sales or marketing personnel, and the systems, policies and procedures to implement the discontinuation of use of any Materials;
- 6) a general description of the disciplinary measures that Purdue has established for failure to comply with its systems, processes, policies and procedures relating to the Reviewed Policies and Practices;
- 7) a detailed description of Purdue's compensation system (including salaries and bonuses) for Relevant Covered Persons engaged in the promotion and sales of Purdue products, including a description of the bases upon which compensation is determined and the extent to which compensation is based

on product performance. To the extent that Purdue may establish compensation differently for individual products, the IRO shall report separately on each type of compensation arrangement;

- 8) findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and practices associated with the Reviewed Policies and Practices, if any; and
- 9) recommendations to improve any of the systems, policies, processes, or practices associated with the Reviewed Policies and Practices, if any.

III. Promotional and Product Services Transactions Review

The IRO shall conduct a Promotional and Product Services Transactions Review for each of the Reporting Periods. As described below, the Transactions Review shall include reviews of a sample of Inquiries reflected in the Medical Services Product Inquiries Database (or "Database") and a sample of the Promotion Monitoring Program Forms resulting from the Promotion Monitoring Program.

A. Promotional and Product Services Transactions Review

1. Review of Sales Force Related Inquiries Made to Medical Services.

As set forth in Section III.B.2 of the CIA, Purdue has established Policies and Procedures that address the process by which and standards according to which Medical Services personnel and Medical Liaisons respond to Inquiries from HCPs about Purdue products.

a. Internal Review of Product Inquiry Database.

Purdue shall document and record all Inquiries received by Medical Services in the Product Inquiries Database. The information to be included in the Product Inquiries database is set forth in Section III.B.2.e. Medical Services assigns each inquiry into Categories and Topics. Section III.J.1 of the CIA defines Focus Inquiries. All Inquiries that are generated by or in connection with an interaction between a sales representative and an HCP (e.g., through a call made by a sales representative from an HCP's office, through a Medical Information Request Form, or through an Inquiry in which the HCP identifies the sales representative involved) shall be known as "Sales Force Related Inquiries." For purposes of each Reporting Period, the OIG shall identify the Categories and Topics of Sales Force Related Inquiries that shall constitute the Focus Inquiries for the period.

As set forth in Section III.J of the CIA, Purdue undertakes several internal steps with regard to Focus Inquiries. The Corporate Compliance Officer reviews a sample of the Focus Inquiries referenced in Focus Inquiry Reports on a semi-annual basis. The Compliance Officer identifies those Focus Inquiries relating to situations in which improper promotion of the Purdue products may have occurred. Focus Inquiries for which the Compliance Officer determines that improper promotion may have occurred shall be known as "Suspect Inquiries." Additional Compliance Reviews are conducted for Suspect Inquiries, and the requirements of the Additional Compliance Reviews are set forth in Section III.J.2.b.

b. *IRO Review of Focus Inquiries.*

As part of the Promotional and Product Services Transactions Review, the IRO shall evaluate Purdue's processes relating to its Product Inquiries Database, the assignment of the Inquiries into Categories and Topics, and Additional Compliance Reviews. Specifically, for each Reporting Period, the IRO shall select a random sample of 15 Sales Force Related non-Focus Inquiries relating to the Covered Product(s), and a random sample of 60 Focus Inquiries relating to the Covered Product(s). Of the Focus Inquiries, the IRO shall select 40 of the Focus Inquiries that were Suspect Inquiries and 20 that were not Suspect Inquiries.

For each Inquiry reviewed, the IRO shall determine:

1. whether each item of information identified in Section III.B.2.e of the CIA is included in the Product Inquiries Database for each Inquiry reviewed by the IRO;
2. for each Sales Force Related non-Focus Inquiry reviewed by the IRO, whether the non-Focus Inquiry was categorized in accordance with Purdue's Policies and Procedures;
3. for each Suspect Inquiry for which the Compliance Officer conducted an Additional Compliance Review: (i) the basis for suspecting that improper promotion may have occurred; (ii) the steps undertaken as part of the Additional Compliance Review; (iii) the findings of the Compliance Officer as a result of the Additional Compliance Review; and (iv) any follow-up actions taken by Purdue based on the Compliance Officer's findings;

4. for each non-Suspect Focus Inquiry, the basis for identifying the Inquiry as non-Suspect and whether Purdue followed its policies in identifying the Inquiry as a non-Suspect Focus Inquiry; and
5. for each Inquiry reviewed by the IRO that was also reviewed by the Compliance Officer, whether the conclusions reached by the IRO and the Compliance Officer were consistent and, if not, the reasons for the discrepancies.

2. Review of Purdue's Promotion Monitoring Program.

As outlined in Section III.K of the CIA, Purdue has implemented a formalized process through which Purdue's District Managers evaluate and monitor sales representative interactions with HCPs (Promotion Monitoring Program). The District Managers record their observations on Promotion Monitoring Program Forms and provide copies of the forms to the Corporate Compliance Department for all situations in which the District Manager observes any sales representatives making potentially improper statements about any Purdue product(s). This indication of potentially improper statements may be made through the use of a rating of "1" (meaning not fully compliant) on the Promotion Monitoring Program Form (or an analogous indication on any successor rating system). Such a rating on the Promotion Monitoring Program Form indicates a potential compliance issue.

As set forth in Section III.K, if the Compliance Officer receives any Promotion Monitoring Program Forms indicating that a sales representative may have made improper statements about any Purdue product(s) (e.g., a rating of "1" was indicated on the Promotion Monitoring Program Form), the Compliance Officer (or a designee) shall perform an additional review known as the "Compliance Detailing Review". Section III.K sets forth the requirements relating to the Compliance Detailing Review.

As part of each Promotional and Product Services Transactions Review, the IRO shall review a sample of the Promotion Monitoring Program Forms completed as part of Purdue's Promotion Monitoring Program and that relate to the Covered Product(s). Purdue shall provide to the IRO a list of employees (or unique employee identification numbers) and information about whether a Compliance Detailing Review was conducted with regard to each employee. The IRO shall randomly select 40 employees from the list for whom a Compliance Detailing Review was conducted and 10 employees for whom no Compliance Detailing Review was conducted. For each selected employee, Purdue shall provide the IRO with a list of all the Promotion Monitoring Program Forms

completed for the employee during the Reporting Period under review, and the IRO shall randomly select one Form for each employee.

For each Promotion Monitoring Program Form, the IRO shall determine whether:

- a. each item of information identified in Section III.K of the CIA is included in each Promotion Monitoring Program Form reviewed;
- b. a Compliance Detailing Review was conducted for each Program Monitoring Program Form containing an indication that a sales representative may have made improper statements about any Covered Product(s) (e.g., a rating of "1" was indicated on the Promotion Monitoring Program Form); and
- c. for each instance in which a Compliance Detailing Review was conducted: (i) the basis for suspecting that improper promotion may have occurred; (ii) the steps taken as part of the Compliance Detailing Review; (iii) the findings that resulted from the Compliance Detailing Review; and (iv) the follow-up action take as a result of the Compliance Detailing Review.

B. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a Report based on its Promotional and Product Services Transactions Review. Each Report shall include the following:

1. Elements to Be Included:

- a. Promotional and Product Services Transactions Review Objectives: A clear statement of the objectives intended to be achieved by the Review;
- b. Engagement Protocol: A detailed narrative description of the procedures performed and a description of the universe of Inquiries from which samples were selected; and
- c. Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Promotional and Product Services Transactions Review.

2. Results to Be Included:

The following results shall be included in each Promotional and Product Services Transactions Review Report:

- a. a description of each type of sample unit reviewed, including the number of each type of sample reviewed (*i.e.*, Covered Product related Inquiries or Promotion Monitoring Program Forms) and an identification of the types of documents and information reviewed in association with each Inquiry and Promotion Monitoring Program Form;
- b. for each Covered Product Inquiry sample unit, a summary of the information contained in the Product Inquiries Database about the Inquiry;
- c. for each Inquiry sample unit reviewed, the IRO's findings and supporting rationale as to whether each item of information required by Section III.B.2.e of the CIA is included in the Product Inquiries Database;
- d. for each Sales Force Related non-Focus Inquiry reviewed, whether the Inquiry was categorized in accordance with Purdue's Policies and Procedures;
- e. for each Suspect Inquiry for which the Compliance Officer conducted an Additional Compliance Review, a summary of; (i) the basis for suspecting that improper promotion may have occurred; (ii) the steps undertaken as part of the Additional Compliance Review; (iii) the findings of the Compliance Officer as a result of the Additional Compliance Review; and (iv) any follow-up actions taken by Purdue as a result of the Compliance Officer's findings;
- f. for each non-Suspect Focus Inquiry, a description of the rationale for identifying the Inquiry as non-Suspect, and a determination of whether Purdue followed its policies in identifying the Inquiry as a non-Suspect Focus Inquiry;
- g. for each Inquiry reviewed by the IRO that was also reviewed by the Compliance Officer, a description of whether the conclusions reached by the IRO and the Compliance Officer were consistent and, if not, the reasons for the discrepancies;

- h. for each Promotion Monitoring Program Form, a summary of the information contained in the form;
- i. for each Promotion Monitoring Program Form, the IRO's findings and supporting rationale as to whether each item of information required by Section III.K of the CIA is included in the Promotion Monitoring Program Form. For any item listed in Section III.K that is not included on the form, an explanation of the reason for the omission;
- j. a determination of whether a Compliance Detailing Review was conducted in connection with each Promotion Monitoring Program Form containing an indication that a Purdue sales representative may have made improper statements about any Covered Product(s) (e.g., a rating of "1" was indicated on the Promotion Monitoring Program Form);
- k. for each Promotion Monitoring Program Form for which a Compliance Detailing Review was completed, a summary of: (i) the basis for suspecting that improper promotion may have occurred; (ii) the steps taken as part of the Compliance Detailing Review; (iii) the findings that resulted from the Compliance Detailing Review; and (iv) the follow-up action taken as a result of the findings of the Compliance Detailing Review;
- l. the IRO's findings and supporting rationale regarding any weaknesses in Purdue's systems, processes, policies, and practices relating to the Product Inquiries Database system and Focus Inquiry Reports, if any;
- m. the IRO's findings and supporting rationale regarding any weaknesses in Purdue's systems, processes, policies, and practices relating to the Promotion Monitoring Program, if any;
- n. the IRO's recommendations for improvement in Purdue's systems, processes, policies, and practices relating to the Product Inquiries Database and Focus Inquiry Reports, if any; and
- o. the IRO's recommendations for improvement in Purdue's systems, processes, policies, and practices relating to the Promotion Monitoring Program, if any.