CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ABBOTT LABORATORIES

I. PREAMBLE

Abbott Laboratories (Abbott) 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, Abbott is entering into a Settlement Agreement and a Plea Agreement with the United States. Abbott will also enter into settlement agreements with various States (State Settlement Agreement) and Abbott's agreement to this CIA is a condition precedent to those agreements.

Among other services, Abbott currently markets, promotes and sells human pharmaceutical products that are reimbursed by Federal health care programs in the United States through its U.S. Pharmaceutical Products Group (PPG). Abbott has publicly announced and represented to the OIG that it plans to separate into two, publicly-traded companies: one a diversified medical products company, which may retain the Abbott name (Diversified Company); and the other a research-based human pharmaceuticals company (Pharmaceutical Company), which will not be a subsidiary or corporate affiliate of Abbott. This separation is hereinafter referred to as the "Transaction." Abbott also has represented to the OIG that at the effective date and time of the Transaction (Effective Time), the assets of Abbott's research-based human pharmaceuticals products business will be transferred, conveyed and/or assigned by Abbott to the Pharmaceutical Company and that the Diversified Company shall no longer be involved in the marketing or promotion of research-based human pharmaceutical products in the United States.

Abbott shall keep the OIG apprised of the status of the Transaction until it is completed. Assuming that the Transaction is completed in accordance with the terms described above, Abbott shall include in a contract or agreement with the Pharmaceutical Company relating to the transfer, conveyance or assignment of the assets of the research-based human pharmaceutical products business to the Pharmaceutical Company a provision stating that the Pharmaceutical Company agrees that the terms and obligations of the CIA will become fully binding on the Pharmaceutical Company as of the Effective Time of the Transaction. In the event the Transaction takes place as set forth above, the Pharmaceutical Company will be deemed to be Abbott's successor-in-interest for purposes of this CIA. As of the Effective Time of the Transaction, this CIA shall transfer in its entirety to and be fully binding on the Pharmaceutical Company, which shall assume sole responsibility for the terms and obligations of the CIA. As of the Effective Time, the Pharmaceutical Company's business units and locations and all Covered Persons at each business unit and location shall be subject to the applicable requirements of this CIA; Abbott and the Diversified Company shall no longer be a party to or have any obligations under this CIA.

Prior to the Effective Date of this CIA (as defined below), Abbott established a voluntary compliance program applicable to all officers, managers, and employees of PPG (Compliance Program). The Compliance Program includes a Chief Ethics and Compliance Officer, an Office of Ethics and Compliance, and a U.S. Pharmaceutical Compliance Committee. The Compliance Program also includes a code of conduct, written policies and procedures, educational and training initiatives, a disclosure program, investigation of potential compliance violations, disciplinary procedures, screening measures for ineligible persons, and regular internal auditing procedures.

Abbott shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Abbott may modify its Compliance Program as appropriate, but, at a minimum, Abbott shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Abbott 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 Abbott is obligated to pay the Settlement Amount as set forth in the Settlement Agreement between Abbott and the United States. 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, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Abbott's final Annual Report; or (2) any additional materials submitted by Abbott 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 of Abbott who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading) and all directors of Abbott;

b. all officers and employees of PPG who are engaged in or who have responsibilities relating to any of the Covered Functions (as defined below in Section II.C.7); and

c. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of PPG, including, but not limited to third party vendors who provide services relating to the Covered Functions (e.g., for speaker programs or medical education programs.)

Notwithstanding the above, the term Covered Persons does not include: (1) 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 on behalf of PPG, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year; or (2) employees, contractors, subcontractors, agents or other personnel of Abbott's Animal Health, Diagnostics (including Abbott Diagnostics Division, Abbott Molecular, Abbott Point of Care, STARLIMS, and IBIS), Nutritional Products, and Medical Devices Divisions (including Abbott Vascular, Abbott Diabetes Care, and Abbott Medical Optics), so long as they do not have responsibilities relating to any of the Covered Functions.

2. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to any of the Covered Functions.

3. "Government Reimbursed Products" refers to all Abbott human pharmaceutical products that are marketed or sold by PPG in the United States or pursuant to contracts with the United States that are reimbursed by Federal health care programs.

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

5. The term "Product Related Functions" includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to healthcare professionals (HCPs) and healthcare institutions (HCIs) about Government Reimbursed Products, including those functions relating to any applicable review committees and to PPG's Global Medical Affairs department (GMA) and Global Medical Information department (GMI); (b) contracting with HCPs licensed in the United States to conduct post-marketing clinical trials, investigator-initiated studies, and post-marketing observational studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to government-listed compendia (such as DrugDex or other compendia of information about Government Reimbursed Products.)

6. The term "Managed Healthcare Related Functions" refers to Promotional Functions and Product Related Functions as they relate to interactions between Abbott and: (a) government payors, pharmacy benefit managers (PBMs), or other individuals or entities under contract with or acting on behalf of government payors; and (b) institutional purchasers or providers, long-term care or specialty pharmacies, or other

individuals or entities under contract with or acting on behalf of institutional purchasers or providers and who are in a position to influence the use of Government Reimbursed Products in the institution. Managed Healthcare Related Functions includes functions undertaken by the Integrated Managed Healthcare Group as well as Clinical Executives in the Clinical Evidence and Outcomes group.

7. The term "Covered Functions" refers to "Promotional Functions" and "Product Related Functions" which include "Managed Healthcare Related Functions", as defined above.

8. The term "Third Party Personnel" shall mean personnel who perform Covered Functions who are employees of entities with whom Abbott has entered or may in the future (during the term of this CIA) enter into agreements to promote or co-promote a Government Reimbursed Product in the United States or to engage in joint promotional activities in the United States relating to such a product. Abbott has represented that: (1) Third Party Personnel are employed by entities other than Abbott; (2) Abbott does not control Third Party Personnel; and (2) it would be commercially impractical to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Abbott agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.8 and V.B.5. Provided that Abbott complies with the requirements of Sections III.B.2., V.A.8., and V.B.5, Abbott shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definitions of Covered Persons.

9. The term "Third Party Educational Activity" shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event governed by Federal health care programs and/or FDA requirements and supported by PPG, including but not limited to, sponsorship of symposia at medical conferences.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Responsibilities of Certain Abbott Employees and the Board of Directors.

1. *Compliance Officer.* Prior to the Effective Date, Abbott appointed an individual to serve as its chief compliance officer (known as its Chief Ethics and Compliance Officer or CECO) and Abbott shall maintain a CECO for the term of the CIA. The CECO is, and shall continue to 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 CECO shall be a member of senior management of Abbott, shall report directly to the Chief Executive Officer of Abbott, shall make periodic (at least four times per year) reports regarding compliance matters directly to the Board of Directors of Abbott or a designated Committee of the Board (Board Committee), and shall be authorized to report on such matters to the Board of Directors or Board Committee at any time. Within 90 days after the Effective Date, Abbott shall ensure that the CECO shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The CECO shall be responsible for monitoring the day-to-day compliance activities engaged in by Abbott as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the CECO shall be limited and must not interfere with the CECO's ability to perform the duties outlined in this CIA.

Abbott shall report to OIG, in writing, any change in the identity of the CECO, or any actions or changes that would affect the CECO's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Abbott appointed a compliance committee (known as the U.S. Pharmaceutical Compliance Committee) which, in conjunction with the CECO assists in the implementation and enhancement of the Compliance Program. Abbott shall continue the U.S. Pharmaceutical Compliance Committee during the term of this CIA. The U.S. Pharmaceutical Compliance Committee shall, at a minimum, include the CECO and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as legal, regulatory affairs, sales, marketing, human resources, audit, research and development, and finance. The CECO shall chair the U.S. Pharmaceutical Compliance Committee and the U.S. Pharmaceutical Compliance Committee shall

support the CECO in fulfilling his/her responsibilities with regard to the Compliance Program (e.g., shall assist in the analysis of PPG's risk areas relating to Covered Functions and shall oversee monitoring of internal and external audits and investigations). The U.S. Pharmaceutical Compliance Committee shall meet at least four times per year.

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

3. *Board of Directors Compliance Obligations*. The Abbott Board of Directors (Board) or an authorized subcommittee thereof (Board Committee) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board or Board Committee shall, at a minimum, be responsible for the following:

a. The Board or Board Committee shall meet at least four times per year to review and oversee Abbott's Compliance Program as it relates to the Covered Functions undertaken by PPG, which includes receiving updates about the activities of the CECO, the U.S. Pharmaceutical Compliance Committee, and the Compliance Program. The Board or Board Committee shall also receive updates about adoption and implementation of 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, and shall evaluate the effectiveness of the Compliance Program.

b. For each Reporting Period of the CIA, the Board or Board Committee shall adopt a resolution, signed by each individual member of the Board or Board Committee, summarizing its review and oversight of PPG's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors (or authorized subcommittee thereof) has made a reasonable inquiry into the operations of Abbott's Compliance Program as it relates to the Covered Functions undertaken by PPG during the preceding twelve-month period, which included receiving updates and reports by the CECO and/or a representative from the U.S. Pharmaceutical Compliance Committee about the effectiveness of the Compliance

Program and the activities of the CECO and the U.S. Pharmaceutical Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Abbott has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board or Board Committee is unable to provide such a conclusion in the resolution, the Board or Board Committee shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Abbott.

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

4. *Management Accountability and Certifications*: In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Abbott officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that their applicable business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Executive Vice President, Pharmaceutical Products Group; Senior Vice President, Proprietary Pharmaceutical Products, Global Commercial Operations; Senior Vice President, Pharmaceuticals Research and Development; Senior Vice President, Global Strategic Marketing and Services, Pharmaceutical Products Group; Vice President, Regulatory Affairs; Vice President, Proprietary Pharmaceuticals United States; Vice President, Pharmaceuticals, Manufacturing and Supply, and, to the extent that a PPG business unit performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other PPG executives, vice-presidents, or leader/heads of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit.

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

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the

_____ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Abbott policies, and I have taken steps to promote such compliance. In the event that I have identified potential issues of noncompliance with these requirements, I have referred all such issues consistent with Abbott processes for reporting potential misconduct for further review and follow up. Apart from those referred issues, I am not currently aware in [insert department name] of any violations of applicable Federal health care program requirements, FDA requirements, or the obligations of the CIA. I understand that this certification is being provided to and relied upon by the United States."

Abbott has represented that the position of Executive Vice President, PPG, will cease to exist as of the Effective Time of the Transaction. Following the Transaction, a copy of the certification from the CEO of the Pharmaceutical Company as required by Section 14 of the Plea Agreement shall be submitted to the OIG pursuant to this Section III.A.4 in lieu of the certification from the Executive Vice President, PPG. After the Effective Time of the Transaction and through the remaining term of the CIA, Abbott shall continue to submit to the OIG certifications from the individuals occupying the other positions outlined above in accordance with the requirements of this Section III.A.4.

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

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Abbott developed, implemented, and distributed a written or electronic code of conduct to all Covered Persons who are Abbott employees. This code is known as Abbott's Code of Business Conduct. Abbott makes, and shall continue to make, adherence to the Code of Business Conduct an element in evaluating the performance of all employees who are Covered Persons. Abbott's Code of Business Conduct includes, or within 120 days after the Effective Date, shall be revised to address or include the following:

a. Abbott's commitment to full compliance with all Federal health care program requirements and FDA requirements, including its

commitment to comply with all requirements relating to the Covered Functions;

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

c. Abbott's requirement that all of its Covered Persons shall be expected to report to the CECO, or other appropriate individual designated by Abbott, suspected violations of any Federal health care program requirements, FDA requirements, or of Abbott's own Policies and Procedures;

d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and Abbott's Policies and Procedures; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and Abbott'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 Abbott's Code of Business Conduct. New Covered Persons shall receive the Code of Business 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.

Abbott shall periodically review the Code of Business Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Business 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 Business Conduct within 30 days after the distribution of the revised Code of Business Conduct.

2. *Third Party Personnel.* Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Abbott shall send a letter to each entity employing Third Party Personnel. The letter shall outline Abbott's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Abbott's Compliance Program. Abbott shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Abbott's Code of Conduct and a description of Abbott's Compliance Program available to its Third Party Personnel; or (b) represent to Abbott that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* To the extent not already accomplished, Abbott shall implement written policies and procedures regarding the operation of the Compliance Program and compliance with Federal health care program and FDA requirements (Policies and Procedures). At a minimum, the Policies and Procedures must address the following with respect to Covered Functions and/or Government Reimbursed Products:

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

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

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

d. the materials and information that may be distributed by Abbott sales representatives about Government Reimbursed Products and the manner in which sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products. These Policies and Procedures shall require that Abbott sales representatives not prompt requests for information about non-FDA approved ("off-label") uses of Government Reimbursed Products but that, if HCPs make such inquiries, all such requests shall be referred to GMI;

e. the materials and information that may be distributed by GMI and the mechanisms through, and manner in which, GMI receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Abbott's Government Reimbursed Products that have been submitted or referred by a sales representative; the form and content of information disseminated by GMI in response to such requests; and the internal review process for the information disseminated. The Policies and Procedures shall require responses to such requests (often called "medical information letters") to be accurate and unbiased.

The Policies and Procedures shall include a requirement that GMI develop a database ("Inquiries Database") to track all requests for information about Government Reimbursed Products. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about PPG's products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting HCP, health care institution (HCI), or other individual or entity in accordance with applicable privacy laws; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Abbott (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the Abbott representative who called on or interacted with the HCP, customer, or HCI, if known;

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

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

h. the development, implementation, and review of plans for the distribution of samples of Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive such samples from Abbott. The Policies and Procedures shall also require that Abbott modify the Sample Distribution Plans as necessary to ensure that Abbott is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;

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

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

k. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that PPG's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

l. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.9 above. These Policies and Procedures shall be designed to ensure that PPG's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require CME grant-making decisions to be approved by Abbott's financial or other organizations separate from sales and marketing and that financial support shall be provided only to programs that foster increased understanding of scientific, clinical or healthcare issues.

The Policies and Procedures shall require that: 1) Abbott disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection III.B.3.1.4 below, any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose Abbott's financial support of the Third Party Educational Activity and to require faculty, speakers, or organizers at such Activity to disclose any financial relationship with Abbott; 3) the Third Party Educational Activity have an educational focus; 4) the content, organization, and operation of the Third Party Educational Activity (including the faculty, educational methods, materials, and venue) be independent of Abbott's control; 5) Abbott support only Third Party Educational Activity that is non-promotional in tone/nature; and 6) Abbott's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

m. review of promotional materials and information about Government Reimbursed Products intended to be disseminated outside Abbott by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during the review and approval process and are elevated when appropriate. Abbott currently uses a process for the review and approval of all promotional pieces directed to HCPs or customers that have product claims or disease awareness educational information. Abbott shall continue to use the current process or a substantively equivalent process during the term of the CIA. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: 1) applicable review committees review all promotional materials prior to the distribution or use of such materials; and 2) deviations from the standard review committee practices and protocols (including

timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

n. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Procedures shall be designed to ensure that Abbott's funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;

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

p. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (e.g., any changes based on Abbott's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The Policies and Procedures shall include a requirement that Abbott conduct an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by PPG to any Compendia. Abbott U.S. compliance personnel shall be involved in this review;

q. sponsorship of post-marketing clinical trials, investigator-initiated studies (IISs) (sometimes also called investigator-

sponsored studies or (ISSs)), and post-marketing observational studies (collectively "Research") by PPG, including the decision to provide financial or other support for such Research; the manner in which Research support is provided; and support for the publication of information about the Research, including the publication of information about the Research outcomes and results; and uses made of publications relating to Research;

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

s. disciplinary policies and procedures for violations of Abbott's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

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

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

C. Training and Education.

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

a. CIA requirements; and

b. Compliance Program (including the Code of Business Conduct).

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*. Abbott shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training shall be known as Specific Training.

Within 120 days after the Effective Date, each Relevant Covered Person engaged in Promotional Functions or Product Related Functions shall receive at least three hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

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

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

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

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

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

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

Within 120 days after the Effective Date, each Relevant Covered Person engaged in Managed Healthcare Related Functions shall receive at least three hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

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

h. Abbott's systems and processes applicable to Managed Healthcare Related Functions;

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

j. the personal obligation of each individual involved in Managed Healthcare Related Functions to ensure that all information provided or reported to Government Payors (or to PBMs or other individuals or entities under contract with or acting on behalf of the payors) or to institutional payors is complete, accurate and not misleading;

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

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

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

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. *Board Member Training.* Within 120 days after the Effective Time, Abbott shall provide simultaneously to each member of the Board of Directors three hours of training covering the topics set forth in Section III.C.1 above and addressing the responsibilities of board members and corporate governance.

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

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

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

6. *Update of Training.* Abbott shall review its training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews or the Risk Process Reviews and any other relevant information.

7. *Computer-based Training.* Abbott may provide the training required under this CIA through appropriate computer-based training approaches. If Abbott 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 Abbott chooses to provide computer-based General or Specific Training, all applicable requirements to provide a number of "hours" of training in this Section III.C may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

D. Risk Assessment and Mitigation Process. Abbott has represented that prior to the Effective Date, Abbott implemented certain standardized risk assessment and mitigation standards, processes, and practices for Government Reimbursed Products, including in the areas of sales, marketing, and promotion (including the risk of off-label promotion) and product safety. These processes are described in more detail in Appendix B and shall be referred to as Abbott's Risk Assessment and Mitigation Processes (Risk Assessment and Mitigation Processes). These Risk Assessment and Mitigation Processes consist of the development and maintenance of standardized and centrally managed regulatory history documents for currently promoted Government Reimbursed Products and the following centralized, cross-functional review processes: PPD Material Review Board; PPD Management Review; and PPG Safety Review Board and Safety Council meetings. Based on the outcomes of these Risk Assessment and Mitigation Processes, PPG develops and implements actions designed to mitigate any identified risks, Abbott shall maintain these or equivalent standards, processes, and practices throughout the term of the CIA.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Abbott shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (or firms) (hereinafter "Independent Review Organization(s)" or "IRO(s)"), to perform reviews to assist Abbott in assessing and evaluating its Covered Functions. More specifically, the IRO(s) shall conduct reviews that assess Abbott's systems, processes, policies, procedures, and practices relating to the Covered Functions (including Research and publication activities associated with such Research) (defined below in Section III.L.2 and Section III.L.3, and collectively referred to as "Research and Publication Activities"), and Risk Assessment and Mitigation Processes (IRO Reviews).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by Abbott shall have expertise in applicable Federal health care program and FDA requirements relating to the Covered Functions as may be appropriate to the Review for which

the IRO is retained, including expertise in the pharmaceutical industry with respect to Research and Publication Activities and FDA requirements relating to marketing and promotion of products. Each IRO shall assess, along with Abbott, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

b. *Frequency and Brief Description of Reviews.*

(i) System, Transaction, and Additional Items Reviews. As set forth more fully in Appendix B, the IRO reviews shall consist of two components: Systems Reviews and Transactions Reviews relating to the Covered Functions. The Systems Reviews shall assess Abbott's systems, processes, policies, and procedures relating to the Covered Functions and Risk Assessment and Mitigation Processes. If there are no material changes in Abbott's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Abbott materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

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

In addition, each Transactions Review shall also include a review of up to three additional areas or practices of Abbott identified by the OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Abbott and may consider internal audit work conducted by Abbott, the Government Reimbursed Product portfolio, the nature and scope

of PPG's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

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

The OIG shall notify Abbott of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Abbott shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

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

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

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

Prior to initiating a Validation Review, OIG shall notify Abbott 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, Abbott may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. Abbott agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Abbott 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 Abbott a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

F. Disclosure Program.

Prior to the Effective Date, Abbott established a Disclosure Program that includes a mechanism (the toll free Ethics and Compliance Helpline) to enable individuals to disclose, to the CECO or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Abbott's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Abbott publicizes, and shall continue to appropriately publicize, the existence of the Disclosure Program and the Ethics and Compliance Helpline (e.g., via periodic e-mails to employees, by posting the information in prominent common areas, or through references in the Code of Business Conduct and during training.)

The Disclosure Program shall emphasize a nonretribution, non-retaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the CECO (or designee) shall gather all relevant information from the disclosing individual. The CECO (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information 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, Abbott shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

Abbott shall maintain, a disclosure log, which includes 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 for PPG shall be made available to OIG upon request.

G. Ineligible Persons.

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

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

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

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

b. "Exclusion Lists" include:

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

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

2. *Screening Requirements.* Abbott shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. as part of the hiring or contracting process, Abbott shall require all prospective and current Covered Persons to disclose whether they are Ineligible Persons and shall screen potential Covered Persons against the Exclusion Lists prior to engaging their services.

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

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

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

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

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

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Abbott shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Abbott conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that Abbott 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. Abbott 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.

I. Reportable Events.

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

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

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

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

d. the filing of a bankruptcy petition by Abbott.

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

2. *Reporting of Reportable Events.* If Abbott determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Abbott shall notify OIG,

in writing, within 30 days after making the determination that the Reportable Event exists.

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

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

b. a description of Abbott's actions taken to correct the Reportable Event; and

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

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

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

K. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its PPG sales representatives' interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs and HCIs and to identify

potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: 1) a Speaker Monitoring Program; 2) direct field observations (Observations) of sales representatives; and 3) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to PPG's speaker programs, Abbott shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use Abbott approved materials and may not directly or indirectly promote the product for off-label uses.) Abbott shall maintain centralized electronic system(s) through which all such speaker programs are administered. These system(s) shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by Abbott. Abbott shall maintain a comprehensive list of speaker program attendees through its centralized system(s). In addition, Abbott shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with such speaker programs conducted during each Reporting Period. Abbott shall require certified evaluations by sales representatives or other Abbott personnel regarding whether a speaker program complied with Abbott requirements, and in the event of non-compliance, Abbott shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, Abbott shall institute a Speaker Monitoring Program under which Abbott compliance or other appropriately trained personnel who are independent from the functional area being monitored shall attend speaker programs during each Reporting Period and conduct live audits of 150 such programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Abbott representative activities during the program to assess whether the programs were conducted in a manner consistent with Abbott's Policies and Procedures. Abbott shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Abbott U.S. compliance personnel (or other appropriately trained Abbott personnel who are independent from the functional area being monitored) shall conduct observations of U.S. sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with Abbott's Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by Abbott U.S. compliance personnel or other appropriately trained Abbott personnel who are independent from the monitored functional area both on a risk-based targeting approach and on a sampling approach, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, Abbott U.S. compliance personnel (or other appropriately trained Abbott personnel who are independent from the monitored functional area) shall prepare a report which includes:

1) the identity of the sales representative;
2) the identity of the monitoring personnel;
3) the date and duration of the Observation;
4) the product(s) promoted during the Observation;
5) an overall assessment of compliance with Abbott policy; and
6) the identification of any potential off-label promotional activity or other improper conduct by the sales representative.

Abbott U.S. compliance personnel (or other appropriately trained Abbott personnel who are independent from the monitored functional area) shall conduct at least 50 Observations during each Reporting Period.

3. *Records Reviews.* As a component of the FFMP, Abbott shall also review various types of records to assess PPG sales representatives' interactions with HCPs and HCIs in order to identify potential or actual compliance violations. For each Reporting Period, Abbott shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products and a sampling of the representatives promoting those products in every separate region of the United States. The OIG shall have the discretion to identify up to three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about Abbott's products provided by Abbott, upon request by the

OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, Abbott shall select the three products to be reviewed.

These Records Reviews shall include the monitoring and review of: 1) records and systems relating to such sales representatives' interactions with HCPs and HCIs (including records from any available electronic detailing system(s) for the particular sales representative, sales communications from managers, sample distribution records, and expense reports); 2) requests for, or inquiries relating to, medical information about Government Reimbursed Products; 3) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales representatives' interactions with HCPs and HCIs; 4) sales representatives' call notes; 5) sales representatives' e-mails and other electronic records; and 6) recorded results of the Observations of sales representatives and applicable notes or information from the sales representatives' managers.

4. *Reporting and Follow-up.* Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate. In the event that a potential violation of Abbott's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, Abbott shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable. Any compliance issues identified during a Speaker Program Audit, Observation and/or Records Review and any corrective action shall be recorded in the files of the U.S. Compliance Department.

Abbott shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Abbott also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Abbott took as a result of such determinations. Abbott shall make the Observation reports for all other Observations available to the OIG upon request.

L. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 120 days after the Effective Date Abbott shall develop and implement a monitoring program for the following types of activities: 1) consultant arrangement activities; 2) research-related activities; 3) publication activities; and 4) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that Abbott engages U.S.-based HCPs or HCIs for services that relate to Promotional Functions or to Product Related Functions other than for speaker programs, research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. Abbott shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Abbott.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall establish a process to develop annual budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year period. The Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. Abbott's U.S. compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable Abbott Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented

in the needs assessment form and shall be subject to review and approval by Abbott U.S. compliance personnel.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Abbott received the work product generated by the Consultant.

Within 120 days after the Effective Date, Abbott shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 50 Consultant arrangements with HCPs. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. Abbott U.S. compliance personnel (or other appropriately trained Abbott personnel who are independent from the monitored functional area) shall conduct Consultant Program Audits by reviewing needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Abbott's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate.

2. *Research-Related Activities.* To the extent that PPG engages U.S.-based HCPs or HCIs to conduct post-marketing clinical trials or post-marketing observational studies relating to Government Reimbursed Products, such HCPs and HCIs shall be referred to collectively as "Researchers". Abbott has represented that its policies and procedures require that PPG sales and marketing personnel may not direct Research, as defined in Section.III.B.3.q of this CIA, and may not control or unduly influence the decision to select a Researcher or site. Abbott has further represented that it requires Research funded or controlled by PPG to be approved by its medical and/or scientific organizations. Abbott has also represented that such Research and any resulting publications are intended to foster increased understanding of scientific, clinical or healthcare issues. Finally, Abbott has represented that it will not approve Research purely for the purpose of developing an article or reprint for PPG sales representative use. Abbott shall maintain these or equivalent standards, processes and practices, throughout the term of the CIA.

Abbott shall require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid, and compliance obligations for the Researchers. Researchers shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Abbott.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall establish an annual budgeting plan for Researchers that identifies the business or scientific need for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. Abbott U.S. compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with Abbott Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Abbott U.S. compliance personnel.

To the extent that PPG provides financial or other support to U.S.-based HCPs or HCIs for IIS/ISS regarding Government Reimbursed Products, such HCPs and HCIs shall be referred to as "Investigators." Abbott has represented that its policies and procedures require that PPG sales and marketing personnel may not direct IIS/ISS and may not control or unduly influence the approval of IIS/ISS proposals. Abbott has further represented that PPG standards shall require all Investigators to enter into a written agreement describing the scope of the work to be performed, including any publications related to the research, any fees to be paid, and the compliance obligations of the

Investigators. Investigators shall be paid according to a centrally managed pre-set rate structure that is determined based on a fair market value analysis conducted by Abbott.

To the extent not already accomplished, within 120 days of the Effective Date, Abbott shall establish a process for the review and approval of such IIS/ISSs. The process shall require consideration of the business and scientific need for research by the potential Investigators, as well as review of specific details regarding the research arrangements (including, for example, information regarding the proposed research to be done and the type of work to be generated).

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall amend its policies and procedures in a manner designed to ensure that each Researcher and/or Investigator performed the work for which that individual was engaged.

Within 120 days after the Effective Date, Abbott shall establish a Researcher and Investigator Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher and Investigator Program Audits) of at least 30 Researcher arrangements and 15 Investigator arrangements with HCPs or HCIs. The Researcher and Investigator Monitoring Program shall review Researcher and Investigator arrangements both on a risk-based targeting approach and on a sampling approach. Abbott U.S. compliance personnel (or other appropriately trained Abbott personnel who are independent from the functional area being monitored) shall conduct the Researcher and Investigator Program Audits by reviewing needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were supported by Abbott and performed by the Researchers and Investigators in a manner consistent with Abbott's Policies and Procedures. Results from the Researcher and Investigator Program Audits, including identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate.

3. *Publication Activities.* To the extent that Abbott engages U.S.-based HCPs or HCIs to produce articles or other publications relating to Government Reimbursed Products (collectively "Publication Activities") such HCPs or HCIs shall be referred to as Authors. Abbott has represented that its standards and processes for the development and submission of scientific publications involving Government Reimbursed Products (including results from post-marketing clinical trials or post-marketing observational studies conducted with Researchers) require review and approval by PPG's medical,

scientific and/or regulatory affairs organizations prior to Abbott submission and incorporate ICMJE criteria for identifying Authors, including the requirements that the Author provide substantial contributions to the publication and provide final review of the content to be published. Abbott further requires that Authors disclose financial or other support provided by Abbott. Abbott shall maintain these or equivalent standards, processes and practices throughout the term of the CIA, and further shall require that scientific publications be published in a timely manner and present scientific information in a balanced way that does not exclude or inappropriately downplay negative safety or health information.

Abbott shall require all Authors to enter written agreements describing the scope of work to be performed, the fees to be paid in connection with the Publication Activities, and compliance obligations of the Authors. Authors shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Abbott.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various Publication Activities (Publications Plans). Each Publications Plan shall also identify the budgeted amounts to be spent on Publication Activities. Abbott's U.S. compliance personnel shall be involved in the review and approval of such annual Publications Plans, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities and related events are used for legitimate purposes in accordance with Abbott Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall establish a needs assessment process for Publication Activities. This process shall ensure that a needs assessment has been completed prior to the retention of an Author for a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work.) Any deviations from the Publications Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Abbott U.S. compliance personnel.

Within 120 days after the Effective Date, Abbott shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at

least 30 Publication Activities. The Publication Monitoring Program shall select publications for review both on a risk-based targeting approach and on a sampling approach. Abbott U.S. compliance personnel conducting the Publication Monitoring Program (or other appropriately trained Abbott personnel who are independent from the functional area being monitored) shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to assess whether the activities were conducted in a manner consistent with Abbott's Policies and Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate.

4. *Medical Education Grant Activities.* Abbott represents that it has established a Grants Management System within the finance organization of its U.S. Proprietary Pharmaceuticals Division (PPD), which is the exclusive mechanism through which requestors may seek or be awarded grants for independent medical education activities supported by PPD. PPG represents that its sales and marketing departments have no involvement in, or influence over, the review and approval of medical education grants in the United States. Grant requests shall be submitted to a grant management department(s) in the PPG finance organization(s) (or another organization that is separate from sales and marketing) and all such requests shall be processed in accordance with standardized criteria developed by the grant management department(s). Abbott shall continue the medical education grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new process or system subsequent to the Effective Date.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 medical education grants in the United States. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. Abbott U.S. compliance personnel (or other appropriately trained Abbott personnel who are independent from the monitored functional area) shall conduct Grants Monitoring by reviewing proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant office's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with Abbott's Policies and Procedures. Results from the Grant Monitoring Program, including the identification of

potential violations of policies, shall be compiled and reported to the U.S. Compliance Department for review and follow-up as appropriate.

5. *Follow Up Reviews and Reporting.* In the event that a potential violation of Abbott's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, is identified during any aspect of the Non-Promotional Monitoring Program, Abbott shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the U.S. Compliance Department.

Abbott shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, Abbott also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Abbott's requirements or Policies and Procedures, and a description of the action(s) that Abbott took as a result of such determinations. Abbott shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

M. Notice to Health Care Providers and Entities. Within 90 days after the Effective Date, Abbott shall send, by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth below to all HCPs and HCIs that PPG currently details. This notice shall be dated and shall be signed by Abbott's Vice President, Proprietary Pharmaceuticals, United States. The body of the letter shall state the following:

> As you may be aware, Abbott recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion and use of one of its products. This letter provides you with additional information about the settlement, explains Abbott's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that Abbott unlawfully promoted Depakote for uses not approved by the Food & Drug Administration (FDA) and that Abbott engaged in other improper conduct relating to Depakote. To resolve these matters, Abbott pled guilty to a misdemeanor criminal violation of the Federal Food, Drug & Cosmetic Act (FDCA) and agreed to pay a criminal fine and forfeiture amounts of $700 million. In addition, the Government alleged that Abbott violated the False Claims Act and Abbott entered into a civil settlement to resolve these allegations pursuant to which Abbott agreed to pay $800 million to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[Abbott shall include a link to the USAO, OCL, and Abbott websites in the letter.]**

As part of the federal settlement, Abbott also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at http://oig.hhs.gov/fraud/cia/index.html. Under this agreement, Abbott agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Abbott's representatives to Abbott's Compliance Department or the Food & Drug Administration (FDA).

Please call Abbott at **XXXX** or **visit us at [insert name of web link]** if you have questions about the settlement referenced above or to report any instances in which you believe that an Abbott representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by an Abbott Representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to **XXXXX.**

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

As part of the Implementation Report and each Annual Report, Abbott shall provide to the OIG a summary of the calls and messages received.

N. Reporting of Physician Payments.

1. *Reporting of Payment Information.* Quarterly Reporting: On or before January 1, 2013, Abbott shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.N.2) directly or indirectly from PPG during the third quarter of 2012 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, Abbott shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

Annual Reporting: On or before March 31, 2013, and 90 days after the end of each subsequent calendar year, Abbott shall post on its website a report of the cumulative value of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from PPG and reported in accordance with the preceding paragraph during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

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

2. *Definitions and Miscellaneous Provisions.*

(i) Abbott shall continue to make each annual listing and the most recent quarterly listing of Payments as described above in Section III.N available on its website during the term of the CIA. Abbott shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all

applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.N affects the responsibility of Abbott to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

(ii) For purposes of Section III.N.1, "Payments" is defined to include all "payments or transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Abbott would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by Abbott or by a vendor retained by Abbott to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

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

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

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

O. Other Transparency/Disclosure Initiatives.

Abbott represents that it posts, at least annually, information on its company website regarding educational grants and charitable donations to U.S medical and other health care professional organizations, patient organizations, academic institutions,

hospitals, medical education companies and other scientific associations in amounts of more than $200. The information posted on the company website includes: (1) definitions for the types of grants and donations posted; (2) list of recipients in alphabetical order; and (3) payment amount and purpose. Abbott shall continue to post (and provide updates to) the above-described information about PPG-supported educational grants and charitable donations throughout the term of this CIA. Abbott shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of such educational grants and charitable donations or posting of the above-referenced information relating to such funding.

Abbott represents that it requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Abbott that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. Abbott shall continue this requirement throughout the term of this CIA. Abbott represents that within 120 days after the Effective Date, Abbott shall, if necessary, amend its policies relating to Consultants to explicitly state that Abbott requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Abbott that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 150 days following the Effective Date, Abbott shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. Abbott shall continue these disclosure requirements throughout the term of this CIA.

Abbott represents that it expects all Authors of scientific publications to fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Abbott and to disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Abbott further represents that it expects all Authors to fully comply with all other applicable disclosure obligations that may be externally imposed on them based on their affiliation with any publication, HCI, medical committee, or other medical or scientific organization, including scientific journals. Within 120 days after the Effective Date, Abbott, if necessary, shall amend its policies relating to Authors to explicitly state Abbott's requirement about full disclosure by Authors consistent with

the requirements of any publication, HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts with Authors and in any new contracts with Authors entered into after 150 days following the Effective Date, Abbott shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with Abbott, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall register all clinical studies and report results of such clinical studies on the National Institutes of Health (NIH) sponsored website (www.clinicaltrials.gov) in compliance with all current federal requirements. Abbott shall continue to comply with Federal health care program requirements, or other applicable requirements relating to the registration and results reporting of clinical studies throughout the term of this CIA. In addition, if there is a change in Federal health care program requirements, FDA requirements, NIH requirements, or other applicable requirements relating to registration and results reporting of clinical study information, Abbott shall fully comply with such requirements. Abbott also represents that its standards, processes and practices require that Abbott notify appropriate regulatory authorities, ethics committees and investigators of the discontinuation of clinical studies, and that Abbott shall maintain these or equivalent standards, processes and practices regarding discontinuation of clinical studies throughout the term of the CIA.

To the extent not already accomplished, within 120 days after the Effective Date, Abbott shall post or make available information on its company website about postmarketing commitments (PMCs) as defined by the FDA for Government Reimbursed Products. The Abbott website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing Abbott studies, and information about the nature and status of FDA post-marketing commitments. Abbott shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Abbott changes locations or closes a business unit or location related to or engaged

in any of the Covered Functions, Abbott shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

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

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

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Abbott 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 CECO required by Section III.A, and a summary of other noncompliance job responsibilities the CECO may have;

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

3. the names of the members of the Board of Directors or Board Committee referenced in Section III.A.3;

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

5. a copy of Abbott's Code of Business Conduct required by Section III.B.1;

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

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

8. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing co-promotions and other applicable agreements with the party employing the Third Party Personnel; and (b) a description of the entities' response to Abbott's letter;

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

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

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

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

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

Abbott and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Abbott;

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

12. a description of the process by which Abbott fulfills the requirements of Section III.G regarding Ineligible Persons;

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

14. a certification from the CECO that, if required under Section III.N and to the best of his/her knowledge, information regarding Payments has been posted on Abbott's website as required by Section III.N;

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

16. a description of Abbott's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. Abbott shall submit to OIG annually a report with respect to the status of, and findings regarding, Abbott'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 CECO and any change in the membership of the U.S. Pharmaceutical Compliance Committee, the Board of Directors or Board Committee, or the group of Certifying Employees described in Sections III.A.2-4;

2. a copy of the resolution by the Board or Board Committee required by Section III.A.3;

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

4. 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 requirements);

5. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing co-promotions and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' response to Abbott's letter;

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

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

   b. the number of Covered Persons required to complete the General and Specific Training, percentage of individuals who completed the training, and an explanation of any exceptions.

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

7. a complete copy of all reports prepared pursuant to Sections III.E, along with a copy of the IRO's engagement letters;

8. Abbott's response to the reports prepared pursuant to the reviews outlined in Sections III.E, along with corrective action plan(s) related to any issues raised by the reports;

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

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

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

12. any changes to the process by which Abbott fulfills the requirements of Section III.G regarding Ineligible Persons;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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 of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

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

16. a summary of the FFMP and the results of the FFMP required by Section III.K, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Abbott took as a result of such determinations;

17. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.L, including detailed description of any identified instances in which it was determined that the activities violated Abbott's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Abbott took as a result of such determinations;

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

19. a description of all changes to the most recently provided list of Abbott's locations (including addresses) as required by Section V.A.15; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

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

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 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.

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

2. Chief Ethics and Compliance Officer: In each Implementation Report and Annual Report, Abbott shall include the following individual certification by the CECO:

1. to the best of his or her knowledge, except as otherwise described in the report, Abbott is in compliance with 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. Abbott's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, to the best of his or her knowledge, Abbott's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Abbott have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by Abbott and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent regulatory, medical and/or 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

4. Abbott's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.g) and, for each product the call plans were found to be consistent with Abbott's policy objectives as referenced above in Section III.B.3.g.

D. Designation of Information. Abbott 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. Abbott 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

Abbott: Robert Funck
Chief Ethics and Compliance Officer
Abbott Laboratories
Dept. 036X, Bldg. AP6C-1
100 Abbott Park Road
Abbott Part, IL 60064
Telephone: 847.937.1231
Facsimile: 847.938.1957

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Abbott 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 Abbott'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. Abbott shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Abbott's employees may elect to be interviewed with or without a representative of Abbott present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

Abbott 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, Abbott 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 Abbott fails to establish and implement any of the following obligations as described in Section III:

a. a Chief Ethics and Compliance Officer;

b. a U.S. Pharmaceutical Compliance Committee;

c. the Board of Directors or Board Committee compliance obligations, including the resolution from the Board or Board Committee;

d. a written Code of Business Conduct;

e. written Policies and Procedures;

f. the training of Covered Persons, Relevant Covered Persons, and Board Members;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements;

i. notification of Government investigations or legal proceedings;

j. reporting of Reportable Events;

k. notification of written communications with FDA as required by Section III.J;

l. a program for FFMP as required by Section III.K;

m. a program for Non-Promotional Monitoring Program as required by Section III.L;

n. notification to HCPs and HCIs as required by Section III.M; and

o. posting of any Payments as required by Section III.N.

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 Abbott fails to engage and use an IRO as required in Section III.E 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 Abbott fails to submit the Implementation Report or any 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 Abbott fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Abbott 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 Abbott fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Abbott stating the specific grounds for its determination that Abbott has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Abbott shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Abbott 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. Abbott 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 Abbott 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 Abbott 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 Abbott 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 Abbott of: (a) Abbott'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, Abbott 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 Abbott elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Abbott cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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

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

D. Exclusion for Material Breach of this CIA.

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

a. a repeated or flagrant violation of the obligations under this CIA,

including, but not limited to, the obligations addressed in Section X.A;

b. a failure by Abbott to report a Reportable Event and take corrective action as required in Section III.I;

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

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

e. a failure of the Board or Board Committee to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Abbott constitutes an independent basis for Abbott's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Abbott has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Abbott of: (a) Abbott'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*. Abbott 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. Abbott 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) Abbott has begun to take action to cure the material breach; (ii) Abbott is pursuing such action with due diligence; and (iii) Abbott has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, Abbott fails to satisfy the requirements of Section X.D.3, OIG may exclude Abbott from participation in the Federal health care programs. OIG shall notify Abbott in writing of its determination to exclude Abbott (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 Abbott'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, Abbott 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 Abbott 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, Abbott 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 Abbott was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Abbott 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 Abbott to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Abbott 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 Abbott 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) Abbott had begun to take action to cure the material breach within that period; (ii) Abbott has pursued and is pursuing such action with due diligence; and (iii) Abbott provided to OIG within that period a reasonable timetable for curing the material breach and Abbott 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 Abbott, only after a DAB decision in favor of OIG. Abbott's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Abbott 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 Abbott 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. Abbott 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 Abbott, Abbott 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

Abbott and OIG agree as follows:

A. Except as provided in clause F below, this CIA shall be binding on the successors, assigns, and transferees of Abbott;

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

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

D. The undersigned Abbott 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.

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

F. If, in connection with the Transaction, Abbott causes the Pharmaceutical Company to expressly agree to be bound by all of the terms and conditions of, and to assume all the obligations of Abbott under, this CIA, then the Transaction shall automatically, and without any further action by Abbott, the Diversified Company, the Pharmaceutical Company, the OIG, the United States or any instrumentality thereof, effect a novation of this CIA as of the Effective Time of the Transaction, with the Pharmaceutical Company becoming the party to and replacing Abbott in all respects under this CIA, whereupon the Pharmaceutical Company shall be fully responsible for complying with the CIA, and neither Abbott nor the Diversified Company shall have any obligation or liability under this CIA whatsoever.

ON BEHALF OF ABBOTT LABORATORIES

Robert E Funck

5/4/12

ROBERT E. FUNCK
Vice President, Chief Ethics and
Compliance Officer
Abbott Laboratories

DATE

5/4/12

ETHAN M. POSNER, ESQ.
Covington & Burling
Counsel for Abbott Laboratories

DATE

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

5/6/12

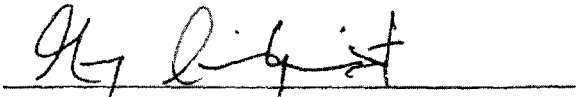
GREGORY E. DEMSKE
Chief Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

DATE

5/7/12

MARY E. RIORDAN
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE



5/7/12

GREGORY LINDQUIST
Associate Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

Appendix A to Corporate Integrity Agreement

Independent Review Organization

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

A. IRO Engagement.

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

If Abbott 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, Abbott shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Abbott at the request of OIG, whichever is later, OIG will notify Abbott if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Abbott may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and have expertise in applicable Federal health care program and FDA requirements that relate to the Covered IRO Functions, including expertise relating to research regarding pharmaceutical products , publication activities associated with such research, and marketing and promotional activities associated with pharmaceutical products. The assigned individuals shall be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care programs under which Abbott products are reimbursed;

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

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

C. IRO Responsibilities.

The IRO shall:

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

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

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

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

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

D. Independence and Objectivity.

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

E. IRO Removal/Termination.

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

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Abbott to engage a new

IRO in accordance with Paragraph A of this Appendix. Abbott must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Abbott to engage a new IRO, OIG shall notify Abbott 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, Abbott may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Abbott prior to requiring Abbott to terminate the IRO. However, the final determination as to whether or not to require Abbott to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B TO CIA FOR ABBOTT LABORATORIES

INDEPENDENT REVIEW ORGANIZATION REVIEWS

I. Covered Functions Review, General Description

As specified more fully below, Abbott shall retain an Independent Review Organization (IRO) to perform reviews (IRO Reviews) to assist Abbott in assessing and evaluating its systems, processes, policies, procedures, and practices related to certain of Abbott's Promotional Functions and Product Related Functions, including Managed Healthcare Related Functions, as well as Abbott's Risk Assessment and Mitigation Processes (collectively "Covered IRO Functions"). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Abbott may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Abbott's systems, processes, policies, and procedures relating to the Covered IRO Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Abbott materially changes its systems, processes, policies, and procedures relating to the Covered IRO Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first 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 procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Review

A. Description of Reviewed Policies and Procedures

The Covered IRO Functions Systems Review shall be a review of Abbott's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain of the Covered IRO Functions. Where practical, Abbott personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems

Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Abbott in accordance with the preceding sentence.

Specifically, the IRO shall review Abbott's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Abbott's systems, processes, policies, and procedures applicable to the manner in which Abbott representatives (including sales representatives, marketing personnel, personnel from the Integrated Managed Healthcare group, and/or GMA departments) handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.,* off-label) uses of Government Reimbursed Products) and the dissemination of materials relating to the uses of these products. This review shall include:

a) the manner in which Abbott sales representatives handle requests for information about off-label uses of Government Reimbursed Products (*e.g.*, by referring all such requests to GMI personnel at Abbott);

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

c) the form and content of information and materials related to Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs"), and health care institutions (HCIs), payors, and formulary decision-makers by Abbott;

d) Abbott's systems, processes, policies, and procedures (including the Inquiries Database) to track requests for information about off-label uses of products and responses to those requests;

e) the manner in which Abbott collects and supports information reported in any systems used to track and respond to requests for product information, including its Inquiries Database;

f) the processes and procedures by which GMI, the Office of Ethics and Compliance, or other appropriate individuals within Abbott identify situations in which it appears that off-label or other improper promotion may have occurred; and

g) Abbott's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion.

2) Abbott's systems, processes, policies, and procedures applicable to the manner and circumstances under which its GMA personnel (including any medical science liaisons, clinical executives, or analogous personnel) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of the medical personnel at such meetings or events;

3) Abbott's systems, processes, policies, and procedures relating to Abbott's internal review of promotional materials related to Government Reimbursed Products disseminated to HCPs, HCIs and government payors and individuals or entities acting on behalf of HCPs or HCIs;

4) Abbott's systems, policies, processes and procedures relating to incentive compensation for Relevant Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Abbott establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

5) Abbott's systems, processes, policies, and procedures relating to the development and review of call plans (as defined in Section III.B.3.g of the

CIA) for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

6) Abbott's systems, processes, policies, and procedures relating to Sample Distribution Plans (as defined in Section III.B.3.h of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Abbott (including, separately, from Abbott sales representatives and other Abbott personnel or components). It shall also include a review of whether samples of Products are distributed by Abbott through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

7) Abbott's systems (including any centralized electronic systems), processes, policies, and procedures relating to PPG speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

8) Abbott's systems, processes, policies, and procedures relating to non-speaker related consultant or other fee-for-service arrangements PPG entered into with HCPs or HCIs as defined in Section III.L.1 of the CIA) and all events and expenses relating to such engagements and arrangements;

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

10) Abbott's systems, processes, policies, and procedures relating to the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product ("Compendia"). This includes any initial submission of information to any Compendia and the submission of any

additional, updated, supplemental, or changed information, (e.g., any changes based on Abbott's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia). The review shall also assess Abbott's processes relating to its annual review of all arrangements, processing fees, or other payments or financial support (if any) provided to any Compendia;

11) Abbott's systems, processes, policies, and procedures relating to sponsorship of Research, as defined in Section III.B.3.q and Section III.L.2 of the CIA, and to Publication Activities as defined in Section III.L.3 of the CIA including the decision to provide financial or other support for such research; the manner in which support is provided for such research; and publication activities associated with research, including the publication of information about the trial outcomes;

12) Abbott's systems, processes, policies and procedures relating to authorship of any articles or other publications about Government Reimbursed Products or therapeutic areas or disease states that may be treated with Government Reimbursed Products, as defined in Section III.B.3.r and Section III.L.3 of the CIA, including, but not limited to, the disclosure of any and all relationships between the author and Abbott, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

13) Abbott's systems, policies, processes, and procedures applicable to the manner and circumstances under which PPG personnel (including sales representatives, medical science liaisons, or analogous personnel) participate in meetings with government payors, pharmacy benefit managers (PBMs), or other individuals or entities under contract with or acting on behalf of government payors (collectively, "Government payors") regarding Government Reimbursed Products and the role of the Abbott personnel at such meetings;

14) the form and content of information and materials disseminated by Abbott to Government payors and Abbott's systems, policies, processes, and procedures relating to Abbott's internal review and approval of

information and materials related to Government Reimbursed Products disseminated to Government payors by Abbott; and

15) Abbott's systems, processes, policies and procedures relating to Risk Assessment and Mitigation Processes, as defined in Section III.D of the CIA. This shall include a review of the processes for developing, maintaining and using the regulatory history documents for Government Reimbursed Products, and the processes and standards relating to the conduct of the PPD Material Review Board, PPD Management Review, PPG Safety Review Board and PPG Safety Council meetings. This review shall include:

a) a review of the systems, standards, and processes for developing, maintaining and using the regulatory history documents and a review of the type of information included in regulatory history documents to assess whether those systems, standards, and processes are resulting in documents that contain the appropriate information to assist in the identification of potential promotional risks associated with the product;

b) a review of the functional areas of the Abbott organization that participate in the PPD Review Board, PPD Management Review, PPG Safety Review Board, and PPG Safety Council meetings and the information considered during each respective type of meeting to assess whether each type of cross-functional board or group is provided the appropriate responsibilities and sources of information to identify potential risks associated with Government Reimbursed Products and Abbott activities relating to such products;

c) a review of the systems, standards, and processes used by the PPD Review Board, PPD Management Review, PPG Safety Review Board, and PPG Safety Council to generate follow-up action items for identified risks associated with Government Reimbursed Products and Abbott activities relating to such products to assess how follow-up or action items are generated for identified risks and whether additional follow-up or action items would be appropriate; and

d) a review of the systems, standards, and processes used by the PPD Review Board, PPD Management Review, PPG Safety Review Board, and PPG Safety Council to track and manage follow-up or action items to assess whether all such items are appropriately tracked and implemented or resolved, including identifying individuals responsible for the follow-up or action item.

B. IRO Systems Review Report

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

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

2) a detailed description of Abbott's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-15 above, including a general description of Abbott's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-15 above are made known or disseminated within Abbott;

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

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

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

III. IRO Transaction Review

As described more fully below in Sections III.A-F, the Transactions Review shall include: (1) a review of Abbott's call plans and Abbott's call plan review process; (2) a review of Sampling Events as defined below in Section III.B; (3) a review of records relating to a sample of the Payments that are reported by Abbott pursuant to Section III.N of the CIA; (4) a review of records relating to Abbott's Risk Assessment and Mitigation Processes; (5) a review of Research and Publications Activities as set forth below in Section III.D; and (6) a review of up to three additional items identified by the OIG in accordance with Section III.E.1.b of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews.

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A. IRO Review of Abbott's Call Plans and Call Plan Review Process

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

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

The IRO shall note any instances in which it appears that the sampled HCPs or HCIs on a particular call plan are inconsistent with Abbott's criteria relating to the call plan and/or Abbott's Policies and Procedures. The IRO shall also note any instances in which it appears that Abbott failed to follow its criteria or Policies and Procedures.

B. IRO Review of the Distribution of Samples of Abbott Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. Abbott shall provide the IRO with: i) a list of Government Reimbursed Products for which Abbott distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) information about Abbott's policies and procedures relating to the distribution of samples of each type of product, including Abbott's Sample Distribution Plan showing which types of samples may be distributed by sales representatives to HCPs and HCIs of particular medical specialties or types of clinical practices. Abbott shall also provide the IRO with information about the reviews of Sample Distribution Plans that Abbott conducted during the Reporting Period as set forth in Section III.B.3.h of the CIA and any modifications to the distribution plans made as a result of Abbott's reviews.

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

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

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA and whether the sample was distributed by an Abbott representative in a manner consistent with Abbott's sample distribution policy for the product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by an Abbott representative other than a sales representative, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a Abbott sales representative, conversation with a representative

of Abbott's GMI department, independent research or knowledge of the HCP or HCI, etc.).

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

C. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

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

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

2. Selection of Sample for Review

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

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

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

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

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

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

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

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

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

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

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

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

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

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

D. IRO Review of Risk Assessment and Mitigation Processes

As described briefly in Section III.D of the CIA, Abbott implemented certain standardized risk assessment and mitigation standards, processes, and practices that are collectively known as the "Risk Assessment and Mitigation Processes". Abbott's Risk Assessment and Mitigation Processes include:

1) regulatory history documents developed by Regulatory Affairs and used by Regulatory Affairs, Medical, Marketing and/or Legal functions to identify and mitigate potential promotional risks associated with actively promoted Government Reimbursed Products. These documents contain the relevant regulatory history relating to advertising and promotion of the Government Reimbursed Product, including agency feedback, product labeling history, and FDA enforcement activity (if any) with respect to the product and/or the product class;

2) activities of the PPD Material Review Board, which conducts cross-functional reviews (by Medical, Regulatory Affairs, Marketing Operations, Commercial and Quality Assurance) of certain promotional and non-promotional materials;

3) activities of the PPD Management Review Board, which is a management level forum that reviews the outcomes of PPD Material Review Board meetings and identifies additional action items as appropriate and includes members from Quality and Regulatory. Responsibilities include review of contact from relevant government agencies;

4) activities of the PPG Safety Review Board, which oversees cross-functional activities related to PPG products and monitors operational performance relevant to drug safety. Members include senior representatives from Pharmacovigilance, Clinical Development and Regulatory Affairs; and

5) activities of the PPG Safety Council, which provides PPG management oversight, governance, and review of significant safety issues involving PPG products. Members include senior management of Research & Development, Regulatory Affairs and Legal Regulatory & Compliance.

Regulatory Affairs and/or Quality are represented in all of the above-referenced review teams. Based on the outcomes of these Risk Assessment and Mitigation

Processes, PPG develops and implements actions designed to mitigate any identified risks. Abbott shall maintain these or equivalent standards, processes, and practices throughout the term of the CIA.

The IRO shall conduct annual reviews and assessments of Abbott's Risk Assessment and Mitigation Processes. In connection with the IRO review, Abbott shall provide the IRO with a list of Government Reimbursed Products promoted by Abbott during the Reporting Period and a list of PPD Material Review Board, PPD Management Review, PPG Safety Review Board and PPG Safety Council meetings that occurred during the Reporting Period. At least 120 days prior to the end of the Reporting Period, Abbott shall provide to OIG a list of Government Reimbursed Products promoted by Abbott. OIG shall have the option to select and notify Abbott (no later than 90 days prior to the end of the Reporting Period) of three Government Reimbursed Products to be reviewed by the IRO in connection with the review of the Risk Assessment and Mitigation Process. If OIG does not identify products for review, the IRO shall select the products to be reviewed.

For each Reporting Period, the IRO will review the following records with respect to each of the following elements of the Risk Assessment and Mitigation Processes:

1) Regulatory history documents: with respect to three (3) currently promoted Government Reimbursed Products and a sample of ten (10) promotional materials related to each product that were approved during the Reporting Period and which are currently in use, the IRO will review whether: (a) there is an approved regulatory history document; (b) the regulatory history document has been reviewed by Regulatory Affairs at least annually to ensure it is complete and current; (c) required training on the regulatory history documents has been provided to Covered Persons responsible for creating, reviewing and/or approving proposed promotional materials related to Government Reimbursed Products; and (d) for the selected promotional materials, there is documentation showing that the regulatory history documents were used as required by existing policies and procedures.

2) PPD Material Review Board: the IRO will review whether: (a) meetings of the PPD Material Review Board took place as per policies and procedures; (b) agendas and meeting minutes were prepared and retained; (c) materials or other documentation were presented at or reviewed in the

meeting(s); and (d) follow up or action items were identified and, if so, were acted upon and/or resolved.

3) PPD Management Review: the IRO will review whether: (a) meetings of the PPD Management Review Committee took place as per policies and procedures; (b) agendas and meeting minutes were prepared and retained; (c) materials or other documentation were presented at or reviewed in the meeting(s); and (d) follow up or action items were identified and, if so, acted upon and/or resolved.

4) PPG Safety Review Board: the IRO will review whether: (a) meetings occurred as specified in the applicable policies and procedures; (b) required core members attended the meetings; (c) agendas, materials or other documentation were presented at or reviewed in the meeting(s) as per policies and procedures; (d) meeting minutes were timely published to members as per policies and procedures; (e) decisions were documented and communicated to Safety Review Board Members as per policies and procedures; (f) Issue Management Teams were formed as per procedures and, if so, whether the Team's progress was monitored; and (g) follow up or action items were identified and, if so, were acted upon and/or resolved.

5) PPG Safety Council: the IRO will review any topics referred to the Safety Council during the review period and determine whether: (a) a meeting was scheduled as per policies and procedures; (b) appropriate representatives from the key functional areas per the applicable policy (which does not include sales or marketing) attended the meeting; (c) agendas, materials or other documentation were presented at or reviewed in the meeting; (d) meeting minutes were timely published to members as required; (e) follow up or action items were identified and, if so, were documented, acted upon and/or resolved.

E. IRO Review of Research and Publications Activities

The IRO shall conduct a review and assessment of Abbott's Research and Publications Activities as described in Section III.L of the CIA.

Review of Research Activities: Abbott shall provide the IRO with a list of Research activities (as defined in Section III.B.3.q of the CIA) that occurred during the Reporting Period, and the IRO shall select a sample of 15 such activities, which sample includes a

review of each type of Research (*i.e.*, post-marketing clinical trials, investigator-initiated studies (IIS), and post-marketing observational studies.) The IRO shall review samples of each type of Research in proportion to the relative numbers of each type of Research that occurred during the reporting period. Abbott shall provide the IRO with documents relating to the Research Activities sufficient for the IRO to conduct the reviews outlined below.

For each sampled Research activity, the IRO will review whether: (i) the activity was approved consistent with Abbott's standards, policies, procedures and processes, including obtaining required medical, scientific and/or regulatory approvals to confirm the activity was reviewed to determine there is a legitimate, scientific need or merit for the activity; (ii) there is an executed written agreement with the Researcher that meets the requirements of Abbott's standards, policies and procedures; and (iii) the Research was initiated, directed and/or funded by Abbott's Global Pharmaceutical Research and Development organization pursuant to Abbott's policies.

In addition, if PPG discontinues any PPG clinical study for a Government Reimbursed Product during a Reporting Period for safety-related reasons pursuant to Abbott's policies, Abbott shall provide the IRO with copies of notifications that Abbott provided to regulatory authorities, ethics committees, and investigators about the discontinuation of the studies. The IRO shall review the notifications to determine whether Abbott notified regulatory authorities, ethics committees, and investigators in accordance with applicable Abbott standards, policies, procedures, and processes.

Review of Publication Activities: Abbott shall provide the IRO with a list of Publication Activities (as defined in Section III.L.3 of the CIA) that occurred during the Reporting Period, and the IRO shall select a sample of 20 Publication Activities for review. More specifically, the IRO shall review Publication Activities associated with 10 abstracts and 10 manuscripts. Abbott shall provide the IRO with copies of the Publications and documents relating to the Publication Activities sufficient for the IRO to conduct the review outlined below.

The IRO will review the selected Publication Activities to test whether the Publication Activity was consistent with Abbott's standards, policies, procedures and processes, including those that require: i) review and approval by PPG's medical, scientific and/or regulatory affairs organizations prior to Abbott submission to verify the content presents scientific information in a balanced way that does not exclude or inappropriately downplay negative safety or health information; ii) incorporation of ICMJE criteria for identifying Authors; iii) disclosure of financial or other support provided by Abbott; iv)

acknowledgement of other contributors; v) disclosure of potential conflicts of interest; vi) access to data; and vii) avoidance of redundant publications (unless permitted by a journal/congress or otherwise of scientific value).

F. IRO Review of Additional Items

As set forth in Section III.E.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). No later than 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Abbott of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Abbott shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Abbott's systems, processes, policies, and procedures based on its review of each Additional Item).

Abbott may propose to the OIG that its internal audit(s) and/or reviews conducted as part of the Field Force Monitoring Program described in Section III.K of the CIA or the Monitoring of Non-Promotional Activities Program described in Section III.L of the CIA be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Abbott's internal audit work and monitoring activities to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Abbott's planned internal audit work and monitoring activities, the results of the Transactions Review(s) during prior Reporting Period(s), and Abbott's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Abbott's request to permit its internal audit work or monitoring activities to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Abbott shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of Abbott's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an

instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Abbott in its internal audits.

G. Transactions Review Report

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

1) General Elements to Be Included in Report

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

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

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

2) Results to be Included in Report

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

(Relating to the Call Plan Reviews)

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

b) for each Government Reimbursed Product which was promoted during the Reporting Period: i) a description of the criteria used by Abbott in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) a description of the review

conducted by Abbott of the call plans and an indication of whether Abbott reviewed the call plans as required by Section III.B.3.g of the CIA; iii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with Abbott's criteria relating to the call plan and/or Abbott's Policies and Procedures; and iv) a description of all instances in which it appears that Abbott failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;

c) the findings and supporting rationale regarding any weaknesses in Abbott's systems, processes, policies, procedures, and practices relating to Abbott's call plans or the review of the call plans, if any;

d) recommendations, if any, for changes in Abbott's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans or the review of the call plans;

(Relating to the Sampling Event Reviews)

e) for each Government Reimbursed Product distributed during the Reporting Period: i) a description of Sample Distribution Plan (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by Abbott in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that Abbott failed to follow its Sample Distribution Plan for

the Government Reimbursed Product(s) provided during the Sampling Event;

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

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

(Relating to the Physician Payment Listing Reviews)

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

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

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

sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;

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

(Relating to the Review of Risk Assessment Mitigation Processes)

l) a list of Government Reimbursed Products promoted by Abbott during the Reporting Period; an identification of the three Government Reimbursed Products for which regulatory history documents and associated promotional materials were reviewed by the IRO for the reporting period; and a description of the promotional materials that were reviewed for each of the three Government Reimbursed Products;

m) a list of the PPD Material Review Board, PPD Management Review, PPG Safety Review Board and PPG Safety Council meetings that occurred during the Reporting Period; a description of the types of materials that were reviewed in connection with the meetings for each board or group; a description of the types of risks that may have been identified during the meetings; and a description of the types of follow-up or action items that may have been reviewed and/or identified during the meetings;

n) for each set of PPD Material Review Board, PPD Management Review, PPG Safety Review Board and PPG Safety Council meetings for which follow-up or action items were identified as a way to address identified risks, whether the follow-up or action items were completed and/or addressed;

o) for each set of regulatory history documents reviewed (including associated promotional materials) and each set of PPD Material Review Board, PPD Management Review, PPG Safety Review Board and PPG Safety Council meetings

reviewed, an identification and description of all instances in which required activity was not completed in accordance with applicable Abbott standards, policies, procedures and processes (including an explanation of the way in which the activity failed to meet Abbott standards, policies, procedures, and processes);

p) for each set of regulatory history documents reviewed (including associated promotional materials) and each set of PPD Material Review Board, PPD Management Review, PPG Safety Review Board and PPG Safety Council meetings reviewed, the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in Abbott's systems, processes, policies, procedures, and practices relating to the Risk Assessment and Mitigation Processes, if any;

q) recommendations, if any, for changes in Abbott's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the Risk Assessment and Mitigation Processes;

(Relating to the Review of Research and Publication Activities)

r) a description of each Research Activity reviewed, including an identification of the types of documents and information reviewed in connection with each sampled Research Activity and an assessment of whether the reviewed Research Activity and/or related documentation was completed in accordance with applicable Abbott standards, policies, procedures and processes;

s) for each discontinued clinical study reviewed by the IRO (if any), a description of the discontinued study; and an assessment of whether Abbott notified all regulatory authorities, ethics committees, and investigators about the discontinuation in accordance with Abbott's standards, processes and practices;

t) a description of each Publication Activity reviewed, including an identification of the types of documents and information reviewed in connection with each sampled Publication

Activity and an assessment of whether the reviewed Publication Activity and/or related documentation was completed in accordance with applicable Abbott standards, policies, procedures and processes;

u) for each Research and Publication Activity reviewed, an identification and description of all instances in which required activity and/or documentation was not completed in accordance with applicable Abbott standards, policies, procedures and processes (including an explanation of the way in which the reviewed Research or Publication Activity failed to meet Abbott standards, policies, procedures, and processes);

v) the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in Abbott's systems, processes, policies, procedures, and practices relating to Abbott's Research and Publications Activities, if any;

x) recommendations, if any, for changes in Abbott's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Research and Publications Activities.

(Relating to the Review of Additional Items)

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

z) for each Additional Item reviewed, the IRO's findings based on its review;

aa) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Abbott's systems, processes, policies, procedures, and practices relating to the Additional Item, if any;

bb) for each Additional Item reviewed, recommendations, if any, for changes in Abbott's systems, processes, policies, and

procedures that would correct or address any weaknesses or deficiencies uncovered during the review.