CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PFIZER INC

I. PREAMBLE

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

Prior to the Effective Date, Pfizer established a compliance program and initiated certain voluntary compliance measures. In addition, in May 2004, Pfizer entered into a CIA with the OIG in connection with the May 2004 settlement with the United States of a different matter. Pfizer shall continue to fulfill its obligations as required under the 2004 CIA, including the submission of its final Annual Report in September 2009 and responding to any requests for additional information from the OIG in connection with its 2004 CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Pfizer under this CIA shall be five reporting periods, as defined below. The effective date of this CIA shall be the date on which the final signatory executes this document (Effective Date). The first Reporting Period shall be from the Effective Date through December 31, 2010. The second and subsequent Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years.

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

b. all officers and directors of Pfizer;

c. (1) except as carved out below in this Section II.C.1, all employees of Pfizer who are based in the United States, and (2) all employees of Pfizer who are based outside the United States and who have responsibilities relating to Promotional and Product Related Functions; and

d. all contractors, subcontractors, agents, and other persons who perform Promotional and Product Related Functions (as defined below in Section II.C.4) on behalf of Pfizer.

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, 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) officers, employees, contractors, subcontractors, agents, or other personnel of Pfizer Global Manufacturing, Pfizer Animal Health, Pfizer Global Research and Development, or the Biotherapeutics and Bioinnovation Center so long as they do not (i) market, distribute, sell, or promote Government Reimbursed Products or (ii) have responsibilities relating to Promotional and Product Related Functions.

2. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional and Product Related Functions.

3. "Government Reimbursed Products" refers to all Pfizer human pharmaceutical products promoted or sold by Pfizer in the United States that are reimbursed by Federal health care programs.

4. The term "Promotional and Product Related Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; (b) the development, preparation, or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products including those functions relating to material review committees and Pfizer's Medical Information Department; and (c) research, development, and publication related-activities involving Government Reimbursed Products, including postmarketing and other studies, and the authorship, publication and disclosure of study results.

5. 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 supported by Pfizer, including but not limited to, sponsorship of symposia at medical conferences.

6. The term "Third Party Personnel" shall mean personnel of the entities with whom Pfizer has or may in the future (during the term of this CIA) enter into agreements to co-promote a Government Reimbursed Product in the United States or to engage in joint promotional activities in the United States relating to such a product. Pfizer has represented that: (1) Third Party Personnel are employed by entities independent of Pfizer; (2) Pfizer does not control the Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Pfizer 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.7 and V.B.5. Provided that Pfizer complies with the requirements of Sections III.B.2, V.A.7 and V.B.5, Pfizer shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

Pfizer shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

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

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

Pfizer shall report to OIG, in writing, of any change in the identity of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 5 days of such a change.

2. *Compliance Committee.* Prior to the Effective Date, Pfizer established a Compliance Committee, and Pfizer shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments). The Chief Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities under the CIA (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

3. *Audit Committee Compliance Obligations.* Pfizer's Audit 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 Audit Committee shall, at a minimum, be responsible for the following:

a. The Audit Committee shall meet at least quarterly to review and oversee Pfizer's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of the Chief Compliance Officer and other compliance personnel.

b. For each Reporting Period of the CIA, the Audit Committee shall adopt a resolution, signed by each individual member of the Audit Committee, summarizing its review and oversight of Pfizer's compliance program and 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 Audit Committee has made a reasonable inquiry into the operations of Pfizer's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of its Chief Compliance Officer and other compliance personnel. Based on its inquiry, the Audit Committee has concluded that, to the best of its knowledge, Pfizer has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Audit Committee is unable to provide such a conclusion in the resolution, the Audit 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 assure implementation by Pfizer of an effective Compliance Program at Pfizer.

Pfizer shall report to OIG, in writing, any changes in the composition of the Audit Committee, or any actions or changes that would affect the Audit 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 Pfizer employees are specifically expected to monitor and oversee activities within their areas of authority. On an annual basis, the Presidents of Pfizer's Business Units (BUs) and the Finance Director of each BU within World Pharmaceutical Operations (WPO), with the exception of Pfizer's Animal Health Business Unit and the Emerging Markets Business Unit, shall complete a certification indicating that the leadership teams of the respective BU have taken all appropriate steps to ensure compliance, that the leadership team has not directly or indirectly encouraged policy violation, and that controls are operating effectively.

The certification of the BU President and Finance Director shall specifically state that the certifying individual: 1) has reviewed the following: (a) reports from an internal group within Pfizer formed to conduct promotional quality assessments; (b) summary reports of speaker programs, advisory boards, consultant payments, travel and entertainment expenses (c) sales compensation exclusion criteria; and (d) corporate compliance group statistics; and 2) is currently aware of no violations of law, regulation, Pfizer policy, or the CIA requirements; or, 3) in the event that a potential issue has been identified, the certifying individual has referred the potential violations to the Corporate Compliance Group or a member of the Pfizer legal division for further review and follow-up. The certification shall also state that the signatory understands that the certification is being provided to and relied upon by the United States.

As part of the BU President certification process, representatives of marketing/sales, medical, commercial development, strategy and innovation, and US Primary Care regional business unit presidents shall also complete certifications relied upon by the Presidents and the Finance Directors of each respective BU, with the exception of Pfizer's Animal Health Business Unit and the Emerging Markets Business Unit. The individuals referenced in the preceding sentence shall be referred to hereafter as "Certifying Employees."

The certification of each Certifying Employee shall specifically state that the certifying individual: 1) has reviewed the following (as applicable): (a) reports from an internal group within Pfizer formed to conduct promotional quality assessments; (b) summary reports of speaker programs, advisory boards, consultant payments, travel and entertainment expenses (c) sales compensation exclusion criteria; and (d) corporate compliance group statistics; and 2) is currently aware of no violations of law, regulation, Pfizer policy, or the CIA requirements; or, 3) in the event that a potential issue has been identified, the certifying individual has referred the potential violations to the Corporate Compliance Group or a member of the Pfizer legal division for further review and follow-up. The certification shall also state that the signatory understands that the certification is being provided to and relied upon by the United States.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Pfizer developed, implemented, and distributed a written Code of Conduct (known as "The Blue Book") to all Covered Persons. Pfizer currently requires all newly employed Covered Persons to certify in writing or electronically, that they have received, read, understood, and shall abide by Pfizer's Code of Conduct. Pfizer shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons.

The Code of Conduct sets forth and shall continue to set forth, at a minimum, the following:

a. Pfizer's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements;

b. Pfizer's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Pfizer's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

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

d. the possible consequences to both Pfizer and Covered Persons of failure to comply with Federal health care program and FDA requirements and with Pfizer's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.G, and Pfizer'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, the Code of Conduct shall be distributed to each Covered Person. By March 31, 2010, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Pfizer's Code of Conduct. New Covered Persons shall receive the Code of Conduct within 120 days after the Effective Date or within 30 days after becoming a Covered Person, whichever is later, and shall complete the required certification within 30 days after becoming a Covered Person or by March 31, 2010 whichever is later.

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

2. *Third Party Personnel.* Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Pfizer shall send a letter to each entity employing Third Party Personnel. The letter shall outline Pfizer'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 Pfizer's Compliance Program. Pfizer 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 Pfizer's Code of Conduct and a description of Pfizer's Compliance Program available to its Third Party Personnel; or (b) represent to Pfizer that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures*. Prior to the Effective Date, Pfizer implemented written Policies and Procedures regarding the operation of the Compliance Program and Pfizer's compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within 120 days after the Effective Date, Pfizer shall ensure that the Policies and Procedures address or shall continue to address:

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

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

c. appropriate ways to conduct Promotional and Product Related Functions in compliance with all applicable FDA requirements;

d. the materials and information that may be distributed by Pfizer sales representatives about Pfizer's Government Reimbursed Products and the manner in which Pfizer sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Pfizer's Government Reimbursed Products. These Policies and Procedures shall require that sales representatives refer all requests for information about non-FDA approved ("off-label") uses of Pfizer's Government Reimbursed Products to Pfizer's Medical Information Department (USMI). These policies also shall require that distribution of reprints of medical journal articles by sales representatives must be consistent with applicable FDA guidance and other relevant requirements;

e. the materials and information that may be distributed by USMI and the mechanisms through, and manner in which, USMI receives and responds to requests for information submitted by sales representatives about off-label uses of Pfizer's Government Reimbursed Products; the form and content of information disseminated by Pfizer in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that USMI develop a database(s) to track all requests for information about Pfizer's products to USMI. This database shall be referred to as the "USMI Database." The USMI Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Pfizer's products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI) 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 Pfizer (including a record of the materials provided to the HCP or HCI in response to the request); 6) the name of the Pfizer representative who requested the Inquiry on behalf of the HCP or HCI, as applicable; and 7) the name of the Pfizer representative who called on or interacted with the HCP or HCI, if known.

The Policies and Procedures shall continue to include a process whereby an alert is triggered when certain systematic thresholds of sales representative facilitated medical information requests (which are subject to reduction for compliance and other purposes) are exceeded (e.g., when more than a specified number of facilitated medical information inquiries associated with a particular sales representative within a specified time period or when indicia of potentially improper conduct exist). As of the Effective Date and as described in Section III.L below, Pfizer is implementing an electronic tablet system to be used by certain of its sales representatives in detailing activities. The electronic tablets and Pfizer's centralized supporting infrastructure shall be referred to as the "Tablet PC System." Pfizer shall continue the

QA Alert process described above until it has rolled out the Tablet PC System to all relevant sales representatives.[1] During the term of this CIA, Pfizer's Policies and Procedures also shall continue the process whereby when USMI provides materials to an HCP or HCI in response to an Inquiry, Pfizer ask that the HCP or HCI notify Pfizer if the HCP or HCI did not request the information, and Pfizer shall investigate all such notifications from HCPs or HCIs;

f. systems, processes, policies, and procedures relating to the manner and circumstances under which medical personnel (such as Medical Science Liaisons) 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 Pfizer's Government Reimbursed Products;

g. systems, processes, policies, and procedures relating to the development, implementation, and review of call plans for field sales representatives who promote Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Pfizer 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 Pfizer modify the call plans as necessary in a manner designed to ensure that Pfizer is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

1 To the extent that certain groups of sales representatives do not receive the Tablet PC System, Pfizer shall continue the QA Alert system, or an equivalent alert system, for those sales representatives during the term of the CIA.

h. systems, processes, policies, and procedures relating to the development, implementation, and review of plans for the distribution of samples of Pfizer's Government Reimbursed Products (Sample Distribution Plans), including specific consideration of methods to centralize the distribution of samples. 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 Pfizer. The Policies and Procedures shall also require that Pfizer modify the Sample Distribution Plans as necessary to ensure that Pfizer is promoting its 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, preceptorships, mentorships, ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

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

k. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.5 above. These Policies and Procedures shall be designed to ensure that Pfizer's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: 1) Pfizer disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection 5 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 Pfizer's financial support of the Third Party Educational Activity and any financial relationships that Pfizer might have with faculty, speakers, or organizers at such Activity; 3) any faculty, speakers, or organizers at the Third Party Educational Activity disclose any financial relationship with Pfizer; 4) the Third Party Educational Activity have an educational focus; 5) the content, organization, and operation of the Third Party Educational Activity be independent of Pfizer control; 6) Pfizer support only Third Party Educational Activity that is non-promotional; and 7) Pfizer support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Educational Activity that is fair, balanced, accurate and not misleading;

l. review of all promotional and other written materials and information intended to be disseminated outside Pfizer 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 Pfizer's review and approval process and are elevated when appropriate. 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 address requirements regarding the review of promotional materials by relevant Review Committees of the BUs prior to the distribution or use of such materials and shall require that all material deviations from the standard Review Committee policy shall be documented and referred to the Compliance Department for appropriate follow-up;

m. sponsorship, funding of, and disclosures relating to research and development-related activities (including clinical trials, market

research or authorship of articles and other publications). These Policies and Procedures shall be designed to ensure that Pfizer's funding, sponsorship, and disclosure complies with all applicable Federal health care program and/or FDA requirements;

n. compensation (including through salaries, bonuses, and contests) for Relevant Covered Persons who are sales representatives. These Policies and Procedures shall: 1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Government Reimbursed Products; 2) include mechanisms designed to exclude or factor from incentive compensation sales that may be attributable to the off-label use of Pfizer products; and 3) include a requirement that incentive compensation for Government Reimbursed Products identified as having elevated risk in the risk assessment process explained below in Section III.D shall be reviewed and adjusted to minimize the risk of improper promotion; and

o. disciplinary policies and procedures for violations of Pfizer'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 relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education.

Pfizer represents that it provides training to its employees on a regular basis concerning a variety of topics. The training covered by this CIA need not be separate and

distinct from the regular training provided by Pfizer, but instead may be integrated fully into such regular training so long as the training covers the areas specified below.

1. *General Training.* By March 31, 2010, Pfizer shall provide at least one hour of General Training to each Covered Person. This General Training, at a minimum, shall explain:

a. CIA requirements; and

b. Pfizer's Compliance Program, including the Code of Conduct. This training shall include updates about Pfizer's conformance with the requirements of its Compliance Program (e.g., including explanations of instances in which Covered Persons satisfied the requirements of the program, general statistical information about disciplinary actions taken against Covered Persons for violations of Pfizer's policies, and general explanations about the types of violations that occurred.)

In addition, by December 31, 2009, Pfizer shall notify all Covered Persons in writing or in electronic format of the fact that Pfizer entered a CIA and shall provide them with an explanation of Pfizer's requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or by January 31, 2010, 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.* By March 31, 2010, each Relevant Covered Person engaged in Promotional and Product Related Functions shall receive at least three hours of Specific Training applicable to their specific job functions in addition to the General Training required above. This Specific Training shall include a discussion of:

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

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

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

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

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

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

New Relevant Covered Persons shall receive the applicable training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or by March 31, 2010, whichever is later.

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

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

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, Pfizer trainers, and/or outside consultant trainers selected by Pfizer.

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

6. *Computer-based Training.* Pfizer may provide the training required under this CIA through appropriate computer-based training approaches. If Pfizer 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 Covered Persons receiving such training. In addition, if Pfizer 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 Plan Process. Pfizer represents that, prior to the Effective Date, it implemented a standardized process to allow Pfizer legal and other personnel to assess and identify risks associated with many Government Reimbursed Products. This process is referred to as the Risk Assessment and Mitigation Planning (or RAMP™) tool and is described in more detail in Appendix C. For purposes of the CIA, this tool shall be referred to as "RAMP". RAMP involves a semi-annual identification and evaluation of risks associated with Government Reimbursed Products that focuses on assessing risks, including those in the areas of: safety/product liability, advertising and promotion issues (including the risk of off-label promotion), and healthcare law and compliance. Based on the outcomes of the risk assessment, Pfizer legal and other personnel centrally develop and implement a unique plan for each product designed to mitigate or reduce the identified risks. Pfizer shall perform the RAMP process throughout the term of the CIA for all those Government Reimbursed Products that have field force support.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Pfizer shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews required by this CIA to assist Pfizer in assessing and evaluating its Promotional and Product Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Pfizer shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Pfizer, 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.

The IRO(s) shall conduct reviews that assess Pfizer's systems, processes, policies, procedures, and practices relating to Promotional and Product Related Functions (collectively, "IRO Reviews").

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components - a systems review and a transactions review. The IRO systems review shall assess Pfizer's systems, processes, policies, and procedures relating to Promotional and Product Related Functions. If there are no material changes in Pfizer's relevant systems, processes, policies, and procedures, the IRO systems review shall be performed for the periods covering calendar year 2010 and the fourth Reporting Period. If Pfizer 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 calendar year 2010 and the fourth Reporting Period.

The Promotional and Product Services Transactions Review shall be performed annually and shall cover calendar year 2010 and each of the subsequent four Reporting Periods. The IRO(s) shall perform all components of each annual transaction review. As set forth more fully in Appendix B, the IRO transactions review shall include pre-specified components. In addition, each transactions review shall also include a review of up to three additional areas or practices of Pfizer identified by the OIG in its discretion (hereafter "Additional Items".)

For purposes of identifying the Additional Items to be included in the IRO transactions review for a particular Reporting Period, the OIG will consult with Pfizer and may consider internal audit work conducted by Pfizer, Pfizer's Government Reimbursed Product portfolio, the nature and scope of Pfizer's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Section III.B of Appendix B, Pfizer may propose to the OIG that its internal audit(s) be 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 Pfizer's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify Pfizer of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Pfizer 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 Pfizer shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Pfizer) related to the reviews.

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each Review performed (IRO Review Report). The information and content to be included in the IRO Review Report is described in Appendix B, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO Review 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). Pfizer 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 Pfizer's final Annual Report shall be initiated no later than one year after Pfizer's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Pfizer 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, Pfizer may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Pfizer 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 Review issues with Pfizer 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 Pfizer a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review and that it has concluded that it is, in fact, independent and objective.

F. Review of Risk Assessment and Mitigation Plan Process.

1. *General Description.*

a. *Engagement of Outside Reviewer.* Within 120 days after the Effective Date, Pfizer shall engage an entity (hereinafter "Outside Reviewer") with expertise in the pharmaceutical industry, FDA legal and other requirements (including FDA requirements relating to promotion and labeling of products), and applicable Federal health care program requirements. The Outside Reviewer shall conduct reviews that assess Pfizer's systems, processes, policies, procedures,

and practices relating to the Promotion Category of RAMP and its implementation (RAMP Review).[2]

The applicable requirements relating to the Outside Reviewer are outlined in Appendix A to this CIA. The Outside Reviewer shall assess, along with Pfizer, 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 Review.* As set forth more fully in Appendix C, the RAMP Reviews shall consist of two components - a systems review and a transactions review. The RAMP Systems Review shall assess Pfizer's systems, processes, policies, and procedures relating to the Promotion Category of RAMP. If there are no material changes in Pfizer's relevant systems, processes, policies, and procedures, the RAMP Systems Review shall be performed for the periods covering calendar year 2010 and the fourth Reporting Period. If Pfizer materially changes its relevant systems, processes, policies, and procedures, the Outside Reviewer shall perform a RAMP 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.

The RAMP Transactions Review shall be performed annually and shall cover the second, third, fourth, and fifth Reporting Periods. The Outside Reviewer shall perform all components of each annual RAMP Transaction Review.

c. *Retention of Records.* The Outside Reviewer shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports related to the RAMP Review.

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2 In the event of material changes to RAMP during the term of the CIA, including to the items covered in the Promotion Category of RAMP, Pfizer shall consult with the OIG about the change. The OIG may require that the scope of the RAMP Review include categories in addition to, or instead of, the Promotion Category.

2. *RAMP Report.* The Outside Reviewer shall prepare a report based upon each RAMP Review performed (RAMP Review Report). The information and content to be included in the RAMP Review Report is described in Appendix C, which is incorporated by reference.

3. *Independence and Objectivity Certification.* The Outside Reviewer shall include in its RAMP Review Report a certification or sworn affidavit that it has evaluated its professional independence and objectivity with regard to the RAMP Review and that it has concluded that it is, in fact, independent and objective.

G. Disclosure Program. Pfizer currently has a disclosure program that Pfizer represents is designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and Pfizer's policies (the "Disclosure Program"). During the term of the CIA, Pfizer shall maintain a Disclosure Program that includes a mechanism (a toll-free compliance telephone line and/or on-line electronic reporting) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Pfizer's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Pfizer shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

The Chief Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in

response to the internal reviews. The disclosure log shall be made available to OIG upon request.

H. 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.* Pfizer shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

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

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

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

3. *Removal Requirement.* If Pfizer has actual notice that a Covered Person has become an Ineligible Person, Pfizer shall remove such Covered Person from responsibility for, or involvement with, Pfizer'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 Pfizer 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, Pfizer shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

I. Notification of Government Investigation or Legal Proceedings. Within 30 days after discovery by Pfizer, Pfizer shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that Pfizer 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. Pfizer shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

J. Reportable Events.

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

a. a matter that a reasonable person would consider a probable violation 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;

c. an FDA Warning Letter issued to Pfizer or any Pfizer subsidiary relating to the promotion of any Government Reimbursed Product; or

d. the filing of a bankruptcy petition by Pfizer.

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

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

a. a complete description of the Reportable Event, including: (i) how the incident or practice arose and continued; (ii) the causes of the incident or practice, if known, (e.g., intentional conduct, lack of internal controls, etc.); (iii) the time frame during which the incident or practice took place; (iv) the business units and Government

Reimbursed Products involved or impacted; (v) the Covered Persons who participated in the incident or practice; (vi) whether any managers or other supervisory personnel were aware of the incident or practice; and (vii) the legal and Federal health care program and/or FDA authorities implicated;

b. a description of Pfizer's internal investigation of the Reportable Event, including: (i) how the incident or practice was identified and the origin of the information that led to its discovery; and (ii) the chronology of the investigative steps taken in connection with Pfizer's internal investigation into the Reportable Event, including the number and job category (e.g., sales representative) of individuals interviewed; and a description of the files, documents, and records reviewed; and

c. a description of Pfizer's actions taken to correct the Reportable Event and any further steps Pfizer plans to take to address the Reportable Event and prevent it from recurring, in including a description of any disciplinary action taken.

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

e. If the Reportable Event involves the issuance of a Warning Letter to Pfizer or a Pfizer subsidiary, the report to the OIG shall consist of a copy of the Warning Letter and a copy of any written response to the Warning Letter submitted to the FDA by Pfizer or the applicable Pfizer subsidiary.

f. Pfizer shall not be required to report as a Reportable Event any matter previously disclosed under Section III.I.

K. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Pfizer and the FDA that materially discusses Pfizer's or a Covered Person's actual or potential unlawful or improper promotion of Pfizer's products (including any improper dissemination of

information about off-label indications), Pfizer shall provide a copy of the report, correspondence, or communication to the OIG. Pfizer shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

L. Field Force Monitoring and Review Efforts. To the extent not already accomplished, within 120 days after the Effective Date, Pfizer shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor field sales representatives' interactions with HCPs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of field sales representatives' interactions with HCPs and to identify potential off-label promotional activities. As described in more detail below, the FFMP shall include: 1) a Speaker Monitoring Program; 2) direct field observations (Observations) of field sales representatives; and 3) the monitoring and review of other records relating to field sales representatives' interactions with HCPs (Records Reviews).

In addition, during the term of the CIA Pfizer shall maintain a program through which it provides legal and compliance support to field sales representatives, including through the placement of attorneys directly in the field. Among other responsibilities, such regional attorneys shall be responsible for the review, approval, and monitoring of field sales force activities and the education of the field sales force.

Throughout the term of this CIA, Pfizer shall also maintain a centralized, electronic system to be used by field sales representatives in connection with the detailing of HCPs (detailing system). The detailing system shall include controls designed to ensure compliance with Federal health care program and FDA requirements and shall permit the tracking of detail-related activities, including the submission of Inquiries (as defined above in Section III.B.3.e) and the distribution of samples of Government Reimbursed Products to HCPs. The detailing system shall include a centralized mechanism through which sales representatives shall submit Inquiries to Pfizer's Medical Information Department, including a requirement that the requesting HCP sign the Inquiry prior to submission. With regard to the distribution of samples, the detailing system and its controls shall identify which HCPs are eligible to receive what type of sample based upon whether the HCP is likely to prescribe the product for a use consistent with the FDA-approved label for the product. The detailing system described herein shall be the exclusive manner through which sales representatives must initiate and submit

Inquiries from HCPs to Pfizer's Medical Information Department and/or track samples of Government Reimbursed Products provided to HCPs.

Pfizer began implementing the Tablet PC System prior to the Effective Date as referenced above in Section III.B.3.e. Pfizer represents that the Tablet PC System does, or with one exception[3], will include the controls relating to the submission of Inquiries and the distribution of samples that are outlined in the preceding paragraph. Therefore, Pfizer agrees to maintain the Tablet PC System, or another system including these controls, for the term of this CIA. Pfizer represents that it shall fully distribute the Tablet PCs to sales representatives in the Primary Care, Oncology, Established Products and Specialty Business Units who are detailing HCPs, facilitating Inquiries, and distributing samples no later than June 30, 2010. For any sales representatives who do not perform all three of these detail-related activities and do not receive a Tablet PC, Pfizer shall implement and/or maintain controls relating to the detailing of HCPs, the submission of Inquiries, and the distribution of samples by such personnel that are designed to permit the tracking of such activities and to ensure compliance with Federal health care program and FDA requirements.

Speaker Program Activities. Prior to the Effective Date, with regard to speaker programs, Pfizer required 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 regarding the use of Pfizer approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses.) Pfizer shall continue such requirements during the term of the CIA. Pfizer shall ensure that all speaker programs continue to be initiated and tracked through a centralized, electronic system that includes controls designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements. Pfizer shall ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by Pfizer. Pfizer shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, Pfizer shall use its centralized system to handle all logistics and spending associated with speaker programs, including the tracking and review of the

3 To the extent that the Tablet PC System does not initially include a control that identifies which HCPs are eligible to receive what type of sample based on their likely prescribing habits, within 120 days after the Effective Date the Tablet PC System shall include a certification step requiring the field sales representative to make an affirmative statement indicating that, to the best of his or her knowledge, the samples are being provided to an HCP who is an appropriate recipient of the sample consistent with the FDA-approved label for the product.

aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. Pfizer shall require certifications by sales representatives or other Pfizer personnel that a speaker program complied with Pfizer requirements, or in the event of non-compliance, Pfizer shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, Pfizer shall institute a Speaker Monitoring Program under which Pfizer personnel or outside personnel acting on behalf of Pfizer shall attend 200 speaker programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a random 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 Pfizer sales representative activities during the program to assess whether the programs were conducted in a manner consistent with Pfizer's Policies and Procedures. Results from the Speaker Program Audits shall be compiled and reported to Pfizer headquarters for review and remediation as appropriate. Potential violations of Pfizer's Policies and Procedures shall be reported to the Compliance Department for appropriate follow-up activity. Pfizer 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.

Observations. As a component of the FFMP, Pfizer field-based attorneys or other compliance/legal personnel shall conduct observations of field sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with Pfizer's Policies and Procedures. These observations shall be full day ride-alongs with field 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, judgmentally selected by Pfizer compliance personnel, include a review of each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, Pfizer compliance/legal personnel shall prepare a report which includes:

1) the identity of the sales representative;
2) the identity of the Pfizer compliance professional or other Pfizer employee;

3) the date and duration of the Observation;
4) the product(s) promoted during the Observation;
5) an overall assessment of compliance with Pfizer policy; and
6) the identification of any potential off-label promotional activity by the field sales representative.

Pfizer compliance/legal personnel shall conduct at least 60 Observations during each Reporting Period.

Records Reviews. As a component of the FFMP, Pfizer shall also review various types of records to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. For each Reporting Period, Pfizer shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products for which elevated risk levels were identified through the risk assessment process in the RAMP tool. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.

These Records Reviews shall be conducted via a multi-disciplinary monitoring team (including the promotional quality assessment team discussed above) and shall include the monitoring and review of: 1) records and systems associated with field sales representatives' interactions with HCPs and HCIs relating to promotional speaker program activities, starters, travel and entertainment, payments to HCPs, and requests for medical information; 2) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of representatives interactions with HCPs and HCIs[4]; 3) field sales representative call notes; 4) field sales representatives' e-mails and other electronic records; and 5) recorded results of the Observations of field sales force representatives, coaching guides, and district manager notes (as applicable).

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 field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. Results from the Speaker Program Audits, Observations, and Records Review shall be compiled and reported to the Chief Compliance Officer for review and remediation as appropriate. Potential violations

4 With regard to message recall studies or other similar studies, Pfizer shall review studies for those products for which a heightened risk level was identified through the risk assessment process in the RAMP tool on a semi-annual basis. This review shall consist of a trend and/or signal detection analysis designed to identify potential risk signals.

related to improper promotion of a Government Reimbursed Product or potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Department for appropriate follow-up activity.

In the event that a compliance issue, including but not limited to a potential off-label promotion or noncompliance with Pfizer's legal requirements, compliance program requirements or Policies and Procedures, is identified during any Speaker Program Audit, Observation, or Records Review, Pfizer shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.J above, as applicable. Any compliance issues identified during a Speaker Program Audit, Observation and/or report from Records Review and any corrective action shall be recorded in the files of the compliance department.

Pfizer 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, Pfizer 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 Pfizer took as a result of such determinations. Pfizer shall make the Observation reports for all other Observations available to the OIG upon request.

M. Headquarters Monitoring Activities. Pfizer shall develop a monitoring program for the following types of activities that are initiated, budgeted, and handled from Pfizer headquarters: 1) consulting arrangements, 2) publication activities, and 3) medical education grants and health care related charitable contributions submitted by MEG (described below).

1. *Consulting Arrangement Activities.* To the extent that Pfizer engages HCPs for services other than for speaker programs (e.g., as a member of an advisory board or to attend consultant meetings) that relate to Promotional and Product Related Functions, such HCPs shall be referred to herein as Consultants. Pfizer shall require all Consultants to enter written agreements describing the scope of work to be performed, the consultant 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 Pfizer. Prior to the retention of Consultants, Pfizer shall ensure that a business rationale form has been completed to

justify the retention of the consultant. The business rationale form shall include an identification of the business need for the information to be provided by the Consultant and provide specific details about the consulting arrangement (including, for example, information about the numbers and qualifications of the HCPs 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).

To the extent not already accomplished, within 120 days after the Effective Date, Pfizer shall establish a process to develop an annual Consultant budgeting plan that relates to the annual brand operating plans and that identifies the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on Consultant-related activities. Personnel from Pfizer's legal department shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan. Within 120 days after the Effective Date, Pfizer shall also establish a process for the review by personnel from Pfizer's legal department of all business rationale forms associated with the retention of any Consultant prior to the retention of the Consultant. The purpose of this legal review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and that Consultant arrangements are consistent with the applicable approved Consultant budgeting plan. Any deviations from the Consultant budgeting plans shall be documented in the business rational form (or elsewhere, as appropriate) and shall be considered as part of the legal review. To the extent not already accomplished, within 120 days after the Effective Date, Pfizer shall amend its policies to require the collection, assessment, and retention of work product generated by Consultants.

Within 120 days after the Effective Date, Pfizer shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of at least 50 consultant programs with HCPs during each Reporting Period. Of the Consultant Program Audits, at least 35 of the audits shall pertain to non-advisory board programs, and 15 shall pertain to advisory board programs. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a random sampling approach. Personnel conducting the Consultant Program Audits shall review business rationale forms, consultant contracts, and materials relating to the program or work of the Consultant (including a verification that the work product resulting from any Consultant-related program or event or otherwise generated by the Consultant is consistent with the stated business need set forth on the business rationale

form or elsewhere), in order to assess whether the programs and arrangements were conducted in a manner consistent with Pfizer's Policies and Procedures. Results from the Consultant Program Audits shall be compiled and reported to Pfizer headquarters for review and remediation as appropriate. Potential violations of Pfizer's Policies and Procedures shall be reported to the Compliance Department for appropriate follow-up activity.

2. *Publication Activities.* To the extent that Pfizer engages 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. Pfizer 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 Pfizer. To the extent not already accomplished, within 120 days after the Effective Date, Pfizer shall establish a needs assessment process for Publication Activities. Needs assessments shall be completed and approved by Pfizer's Legal department prior to Pfizer's engagement of an HCP or HCI to conduct Publication Activities. The needs assessment shall provide specific details about the 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.)

Within 120 days after the Effective Date, Pfizer shall establish a Publication Monitoring Program through which it shall conduct audits of at least 30 Publication Activities during each Reporting Period. The Publication Monitoring Program shall select Publication Activities for review both on a risk-based targeting approach and on a random sampling approach. Personnel conducting the Publication Monitoring Program shall review needs assessment documents, contracts, and materials relating to the Publication Activities (including work product resulting from the Publication Activities), in order to assess whether the activities were conducted in a manner consistent with Pfizer's Policies and Procedures. Results from the Publication Monitoring Program shall be compiled and reported to Pfizer headquarters for review and remediation as appropriate. Potential violations of Pfizer's Policies and Procedures shall be reported to the Compliance Department for appropriate follow-up activity.

3. *Medical Education Group Activities.* Pfizer represents that it has established a Medical Education Group (MEG) within its Chief Medical Office as the exclusive mechanism through which requestors may seek or be awarded grants for

continuing medical education activities. In addition, the MEG group also reviews and awards certain charitable contributions to a healthcare related charitable organization in which the contribution's purpose is: (1) related to patient disease state education; (2) to provide health screening; or (3) to improve patient access to treatment (i.e., affordability of care).

Pfizer represents that its sales and marketing departments have no involvement in, or influence over, the review and approval of medical education grants or healthcare related charitable contribution requests. Grant requests and the types of charitable contribution requests referenced in the preceding paragraph shall be submitted through an on-line process and requests shall be processed in accordance with standardized criteria developed by MEG. Pfizer shall continue the medical education grant and charitable contribution 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 system subsequent to the Effective Date.

To the extent not already accomplished, within 120 days after the Effective Date, Pfizer shall establish a Grant Monitoring Program through which it shall conduct audits for each Reporting Period of at least 60 medical education grant and charitable contribution requests that have been processed through MEG. The Grant Monitoring Program shall include audits of at least 50 medical education grant requests and at least 10 charitable contribution requests. The Grant Monitoring Program shall select grants and charitable contributions for review both on a risk-based targeting approach and on a random sampling approach. Personnel conducting the Grant Monitoring Program shall review grant and charitable contribution requests, documents relating to the MEG team's review of the requests, and documents and materials relating to the grants, charitable contributions and any events or activities funded through the grants or contributions in order to assess whether the activities were conducted in a manner consistent with Pfizer's Policies and Procedures. Results from the Grant Monitoring Program shall be compiled and reported to Pfizer headquarters for review and remediation as appropriate. Potential violations of Pfizer's Policies and Procedures shall be reported to the Compliance Department for appropriate follow-up activity.

4. *Follow Up Reviews and Reporting.* In the event that a potential violation of Pfizer's legal requirements, Policies and Procedures, or compliance requirements are identified, including but not limited to potential off-label promotion during any Consultant Monitoring Program, Publication Monitoring Program, or Grant Monitoring Program (collectively, "Headquarters Monitoring Activities"), Pfizer shall

investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable. Any compliance issues identified during any Headquarters Monitoring Activities referenced above and any corrective action shall be recorded in the files of the Compliance Department.

Pfizer shall include a summary of the results of the Consultant Monitoring Program, Publication Monitoring Program, and Grant Monitoring Program as part of each Annual Report. As part of each Annual Report, for any instance not previously reported as a Reportable Event under Section III.J of this CIA, Pfizer also shall provide the OIG with a detailed description of any instance identified through Headquarters Monitoring Activities in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Pfizer's requirements or Policies and Procedures, and a description of the action(s) that Pfizer took as a result of such determinations. Pfizer shall make the documents relating to Headquarters Monitoring Activities available to the OIG upon request.

N. Notice to Health Care Providers and Entities. Within 120 days after the Effective Date, Pfizer shall send, by first class mail, postage prepaid and return receipt requested, a notice containing the language set forth below to all HCPs and HCIs that Pfizer currently details. This notice shall be dated and shall be signed by Pfizer's Chief Executive Officer. The body of the letter shall state the following:

> As you may be aware, Pfizer Inc recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion of certain of its products.
>
> This letter provides you with additional information about the settlement, explains Pfizer's commitments going forward, and provides you with access to information about those commitments. In general terms, the Government alleged that Pfizer unlawfully promoted drugs (Bextra, Geodon, Lyrica, and Zyvox) for certain uses not approved by the Food & Drug Administration (FDA). To resolve these matters, a subsidiary of Pfizer pled guilty to a felony* criminal violation of the Federal Food, Drug & Cosmetic Act and Pfizer agreed to pay more than $2.3 billion to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[Pfizer shall**

* As of January 29, 2010, the word "misdemeanor" was replaced with the word "felony" to correct a factual error regarding the criminal plea.

include a link to the USAO, OCL, and Pfizer websites in the letter.]

As part of the federal settlement, Pfizer 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, Pfizer 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 Pfizer's representatives to Pfizer's Compliance Department or the FDA.

Please call or email Pfizer at **1-800-TBD** or **[Pfizer shall insert website address in the letter]** if you have questions about the settlement referenced above or to report any instances in which you believe that a Pfizer representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any such instances to the FDA's Division of Drug Marketing, Advertising, and Communications at 301-796-1200. You should direct medical questions or concerns about the products to **[insert name and telephone number for contact line]**.

We appreciate your time and attention. Pfizer is dedicated to ensuring that it brings you the scientific and medical information you need to make well-informed decisions about whether Pfizer products are right for your patients.

The Chief Compliance Officer (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 disclosure log shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Pfizer shall provide to the OIG a summary of the calls and messages received.

O. Reporting of Physician Payments.

On or before March 31, 2010, Pfizer 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 (as defined below) who or which received Payments (as defined

below) directly or indirectly from Pfizer between July 1, 2009 and December 31, 2009 and the aggregate value of such Payments.

After the initial posting, Pfizer shall post annual listings on March 31, 2011 and March 31 of each of the three successive Reporting Period years. The annual listing on March 31, 2011 and thereafter shall include cumulative information about Payments made by Pfizer during each of the respective prior calendar years.

In addition, beginning on June 1, 2011, Pfizer shall include on its website a listing of all U.S. based physicians and Related Entities who or which received Payments from Pfizer during the first calendar quarter of 2011. Thereafter, 60 days after the end of each subsequent calendar quarter, Pfizer shall also post on its website a listing of updated information about all Payments provided during the preceding quarter(s) in each calendar year. The quarterly and annual reports shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.O shall include a complete list of all individual physicians, and/or Related Entities to whom or to which Pfizer directly or indirectly made Payments in the preceding calendar year for 2010 and after June 1, 2011 for the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or the name of the Related Entity. The Payment amounts in the lists shall be reported in $10,000 increments (e.g., $0 - $10,000; $10,001- $20,000; etc.) or in the actual amount paid, provided, however, that the Payment amounts shall be listed in the same way (incrementally or in actual amounts) for all physicians and/or Related Entities on the listing For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician or Related Entity has provided to Pfizer for contact purposes; and (iv) the aggregate value of the Payment(s) in the preceding quarter(s) 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.

Pfizer shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website at least throughout the term of this CIA. Pfizer shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and records related to all applicable Payments and to the annual and quarterly listings of Payments. Nothing in this Section III.O affects the responsibility of Pfizer 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 Entities.

If the proposed Physician Payments Sunshine Act of 2009 or similar legislation is enacted, the OIG shall determine whether the purposes of this Section III.O are reasonably satisfied by Pfizer's compliance with such legislation. In such case, and in its sole discretion, the OIG may agree to modify or terminate provisions of Section III.O as appropriate.

For purposes of this Section III.O, the term "Payments" is defined to include all payments or transfers of value (whether in cash or in kind) made to physicians including all payments (including, for example, honoraria payments, other payments, and reimbursement for lodging, travel and other expenses) made in connection with physicians serving as speakers, participating in speaker training, or serving as Consultants or Authors; payments or compensation for services rendered; grants; fees; payments relating to research; payments relating to education; and payment or reimbursement for food, entertainment, gifts, trips or travel, product(s)/item(s) provided for less than fair market value, or other economic benefit paid or transferred. The term also 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 Pfizer would otherwise report a Payment if made directly to the physician. The term "Payments" includes any Payments made, directly or indirectly, by Pfizer to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

The term "Payments" does not include: i) samples of drug products that meet the definition set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other pricing terms. Only for purposes of the reporting of Payments on March 31, 2010, the term "Payments" does not include: i) individual Payments of less than $25 per instance, or ii) aggregate Payments in a year to a physician or Related Entity of less than $500. Beginning with the March 31, 2011 report and all reports thereafter, individual Payments under $25 per instance and aggregate Payments of less than $500 shall be included in the Payment amounts listed in the applicable report.

For purposes of this Section III.O, 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. The term "physician" as used herein does not include bona-fide employees of Pfizer or its subsidiaries.

Pfizer's posting of Payment information shall be subject to any applicable confidentiality provisions contained in clinical research agreements that were entered with a U.S.-based physician prior to July 1, 2009. Pfizer agrees that it shall not include any such confidentiality provisions in any new or renewed clinical research agreements entered after the Effective Date of the CIA that require any Payment (as defined in this Section III.O) to a U.S.-based physician.

P. Other Transparency/Disclosure Initiatives.

Pfizer represents that it does not provide funding to companies the business of which is developing and conducting medical education programs (also known as medical education communication companies). Pfizer does provide funding to healthcare organizations that also provide continuing medical education, incidental to their healthcare mission. As described above in Section III.M, all requests for medical education grants shall be made through Pfizer's MEG process. In addition, MEG also reviews and approves certain charitable contributions to a healthcare related charitable organization in which the contribution's purpose is: (1) related to patient disease state education; (2) to provide health screening; or (3) to improve patient access to treatment (i.e., affordability of care) and these contributions shall be made through Pfizer's MEG process. Pfizer represents that it conditions the provision of CME grants and health care related charitable contributions on the recipients' consent to public disclosure of the grant or charitable contribution. Pfizer represents that on a quarterly basis it posts on its company website: 1) the recipient organization's name: 2) a brief description of the program for which the grant or charitable contribution was requested; and 3) the amount of the grant or charitable contribution. Pfizer shall continue to post (and provide quarterly updates to) the above-described information about continuing medical education grants and charitable contributions handled through MEG on its website throughout the term of this CIA. Pfizer shall notify the OIG in writing at least 60 days prior to any change in its policy regarding the funding of medical education grants and charitable contributions handled through MEG or the posting of information.

Pfizer represents that it expects all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Pfizer that may be externally imposed on the Consultants based on their affiliation with any HCI, medical committee (including formulary or P&T committees or committees associated with the development of treatment protocols or standards), or other medical or scientific organization. Within 120 days after the Effective Date, Pfizer shall amend its policies relating to Consultants to explicitly state Pfizer's expectation about full disclosure by Consultants consistent with

the requirements of any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 120 days following the Effective Date, Pfizer shall include an explicit requirement that the Consultants fully comply with applicable disclosure requirements and disclose their relationship with Pfizer as required pursuant to their affiliation with any HCI, medical committee, or other medical or scientific organization.

Pfizer represents that it expects all Authors of biomedical manuscripts to fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Pfizer. Pfizer 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 biomedical journals. Within 120 days after the Effective Date, Pfizer shall amend its policies relating to Authors to explicitly state Pfizer's expectation about full disclosure by Authors consistent with the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts with Authors and in any new contracts with Authors entered into after 120 days following the Effective Date, Pfizer shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, their relationship with Pfizer, 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.

Pfizer represents that it registers every Pfizer-sponsored[5] clinical Phase I-IV interventional study in patients on the National Institutes of Health (NIH) sponsored website (www.clinicaltrials.gov). Pfizer represents that it discloses the summary of results of all studies registered on the above-referenced NIH website in an industry-sponsored results database, including result summaries for interventional studies in patients involving products that do not receive regulatory approval, and that it posts the basic results for studies of FDA approved products (or of products that are subsequently approved by the FDA) that are completed after September 27, 2007 on the NIH website. Pfizer shall continue to post clinical study information as described above on the NIH website throughout the term of this CIA. In addition, if there is a change in Federal health care program requirements, FDA requirements, or other applicable requirements

5 Studies sponsored by Pfizer are studies relating to products for which Pfizer holds the Investigational New Drug (IND) Application or other regulatory authorization for the study.

relating to the reporting of clinical study information, Pfizer shall fully comply with such requirements.

Pfizer represents that it posts information on its company website about post-marketing commitments (PMCs). More specifically, the Pfizer website (www.pfizer.com/pmc) provides study descriptions and status of FDA post-marketing commitments, current due dates, total listed Pfizer PMCs, and general information about the PMC process. Pfizer shall continue to post the above-described information about PMCs on its website 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, Pfizer changes locations or closes a business unit or location related to Promotional and Product Related Functions, Pfizer 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, Pfizer purchases or establishes a new business unit or location related to Promotional and Product Related Functions, Pfizer shall notify OIG no later than the date that Pfizer publicly discloses the purchase or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (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. In the event that Pfizer purchases or merges with an entity that will result in the addition of a significant number of new Covered Persons, Pfizer shall consult with OIG regarding a plan and timeline for implementing the CIA requirements with respect to those new Covered Persons.

C. Sale of Unit or Location. In the event that, after the Effective Date, Pfizer proposes to sell any or all of its business units or locations related to Promotional and Product Related Functions that are subject to this CIA, Pfizer shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed by Pfizer. 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, Pfizer 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 Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;

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

3. the names of the members of the Audit Committee referenced in Section III.A.3;

4. the names and positions of the BU leadership and other certifying employees required by Section III.A.4;

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

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

7. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Pfizer's letter;

8. a copy or 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);

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 Covered Persons required to be trained, percentage of Covered Persons 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) a summary and description of any and all current and prior engagements and agreements between Pfizer and the IRO;

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

12. the following information regarding the Outside Reviewer: (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements or agreements between Pfizer and the Outside Reviewer, if applicable;

13. a certification from the Outside Reviewer regarding its professional independence and objectivity with respect to Pfizer;

14. a description of the Disclosure Program required by Section III.G;

15. a description of the process by which Pfizer fulfills the requirements of Section III.H regarding Ineligible Persons;

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

17. a certification by the Chief Compliance Officer that the notice required by Section III.N was mailed to each HCP and HCI, the number of HCPs and HCIs that received a copy of the notice, a sample copy of the notice (i.e., the number of return receipts received) required by Section III.N, and a summary of the calls or messages received in response to the notice;

18. a certification from the Chief Compliance Officer that, to the best of his/her knowledge, information regarding Payments has been posted on Pfizer's website as required by Section III.O;

19. a list of all of Pfizer's U.S. locations (including locations and mailing addresses, but excluding offices operated out of individuals' residences); the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

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

21. the certifications required by Section V.C.

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

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer and any change in the membership of the Compliance Committee, the Audit Committee , or the group of BU leadership and other certifying employees described in Sections III.A.2-4;

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

3. 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);

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

5. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Pfizer'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 initial and annual training, the percentage of Covered Persons who actually completed the initial and annual 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 Section III.E;

8. Pfizer's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

9. a summary and description of any and all current and prior engagements and agreements between Pfizer 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 Pfizer;

11. a complete copy of all reports prepared pursuant to Section III.F;

12. Pfizer's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.F;

13. a summary and description of any and all current and prior engagements and agreements between Pfizer and the Outside Reviewer, if different from what was submitted as part of the Implementation Report;

14. a certification from the Outside Reviewer regarding its professional independence and objectivity with respect to Pfizer;

15. a summary of the disclosures in the disclosure log required by Section III.G that relate to the Government Reimbursed Products or to Federal health care programs;

16. any changes to the process by which Pfizer fulfills the requirements of Section III.H regarding Ineligible Persons;

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

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

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

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

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

22. a summary of the Headquarters Monitoring Activities and the results of the Headquarters Monitoring Activities described in Section III.M (i.e., Consultant Monitoring Program, Publication Monitoring Program, and the Grant Monitoring Program), including detailed description of any identified instances not previously reported as a Reportable Event under Section III.J of this CIA in which it was determined that the activities violated Pfizer's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Pfizer took as a result of such determinations;

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

24. reporting on the initiatives described in Section III.P;

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

26. a list of all actively promoted Government Reimbursed Products that identifies (a) the Pfizer Business Unit responsible for each product and (b) whether or not the product was subject to the RAMP process during the preceding Reporting Period; and

27. 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. The following certifications shall be included in the Implementation Report and Annual Reports:

1. Certifying Employees: In each Annual Report, Pfizer shall include the certifications of the BU leadership and other certifying employees as required by Section III.A.4;

2. Chief Compliance Officer: In the Implementation Report and Annual

Reports, Pfizer shall include the following individual certification by the Chief Compliance Officer:

a. 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;

b. to the best of his or her knowledge, except as otherwise described in the applicable report, Pfizer is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA;

c. Pfizer'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/or legal personnel working at their direction and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Pfizer's promotional materials or medical information containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Pfizer that contain promotional claims or medical information about a Government Reimbursed Product have been reviewed by regulatory, medical, and/or legal personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns are properly addressed and are elevated when appropriate, 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 personnel. 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

d. Pfizer'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 Pfizer's policy objectives as referenced above in Section III.B.3.g.

D. Designation of Information. Pfizer 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. Pfizer 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

Pfizer: Chief Compliance Officer
Pfizer Inc
235 East 42nd Street (150/5/22)
New York, NY 10017
Telephone: 212.733.0752
Facsimile: 212.464.7736

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, Pfizer 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 Pfizer's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Pfizer's locations for the purpose of verifying and evaluating: (a) Pfizer's compliance with the terms of this CIA; and (b) Pfizer'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 Pfizer 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 Pfizer'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. Pfizer shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Pfizer's employees may elect to be interviewed with or without a representative of Pfizer present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

Pfizer is expected to fully and timely comply with all of its CIA obligations. The breach and default remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against Pfizer under applicable legal authorities or under any applicable settlement agreement or consent decree between the State and Pfizer.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Pfizer 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 Pfizer fails to establish, implement, or accomplish any of the following obligations as described in Section III:

a. a Chief Compliance Officer;

b. a Compliance Committee;

c. the resolution from the Audit Committee;

d. a written Code of Conduct;

e. written Policies and Procedures;

f. the training of Covered Persons and Relevant Covered Persons;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements;

i. notification of Government investigations or legal proceedings;

j. notification of written communications with FDA as required by Section III.K;

k. a program for FFMP as required by Section III.L;

l. a program for Headquarters Monitoring Activities as required by Section III.M;

m. notification to HCPs and HCIs as required by Section III.N;

n. posting of any Payments as required by Section III.O;

o. the reporting of any Reportable Event.

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 Pfizer fails to engage an IRO, as required in Section III.E and Appendices A and B, or the Outside Reviewer required by Section III.F and Appendices A and C.

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

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Pfizer fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.E and Appendices A and B or the Outside Reviewer Report required by Section III.F and Appendices A and C.

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

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Pfizer 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 Pfizer fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Pfizer,

stating the specific grounds for its determination that Pfizer has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Pfizer shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Pfizer 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. Pfizer 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 Pfizer 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 Pfizer 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 Pfizer 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 Pfizer of: (a) Pfizer'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, Pfizer 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 Pfizer elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Pfizer 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.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Pfizer has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

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

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

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

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

Pfizer and OIG agree as follows:

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

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 Pfizer 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; and

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.

ON BEHALF OF PFIZER INC

/Douglas M. Lankler/

8/31/09
Date

Douglas M. Lankler
Senior Vice President
and Chief Compliance Officer
Pfizer Inc

/Brien T. O'Connor/

8/31/09
Date

Brien T. O'Connor
Ropes & Gray LLP
Counsel for Pfizer Inc

/John S. Rah/

8/31/2009
Date

John S. Rah
Morgan, Lewis & Bockius LLP
Counsel for Pfizer Inc

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

/Gregory E. Demske/

8/31/09

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

DATE

Appendix A to Corporate Integrity Agreement

Independent Review Organization and Outside Reviewer

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

A. IRO Engagement.

Pfizer shall engage an IRO that possesses the qualifications set forth in Paragraph C, below, to perform the responsibilities in Paragraph E, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph G. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Pfizer if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Pfizer may continue to engage the IRO.

If Pfizer 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, Pfizer 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 written notice of the identity of the selected IRO, OIG will notify Pfizer if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Pfizer may continue to engage the IRO.

B. Outside Reviewer Engagement.

Pfizer shall engage an IRO that possesses the qualifications set forth in Paragraph D, below, to perform the responsibilities in Paragraph F, below. The Outside Reviewer shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph G. Within 30 days after OIG receives written notice of the identity of the selected Outside Reviewer, OIG will notify Pfizer if the Outside Reviewer is unacceptable. Absent notification from OIG that the Outside Reviewer is unacceptable, Pfizer may continue to engage the Outside Reviewer.

If Pfizer engages a new Outside Reviewer during the term of the CIA, this Outside Reviewer shall also meet the requirements of this Appendix. If a new Outside Reviewer is engaged, Pfizer shall submit the information identified in Section V.A.12 of the CIA to OIG within 30 days of engagement of the Outside Reviewer. Within 30 days after OIG receives written notice of the identity of the selected Outside Reviewer, OIG will notify Pfizer if the Outside Reviewer is unacceptable. Absent notification from OIG that the Outside Reviewer is unacceptable, Pfizer may continue to engage the Outside Reviewer.

C. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Review who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care programs under which Pfizer products are reimbursed;

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

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

D. Outside Reviewer Qualifications.

The Outside Reviewer shall:

1. assign individuals to conduct the RAMP Review who have expertise in the pharmaceutical industry, FDA legal and other requirements (including FDA requirements relating to promotion and labeling of products), and applicable Federal health care program requirements. The assigned individuals also shall be experienced in risk identification and mitigation in relation to product marketing and promotion; and

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

E. IRO Responsibilities.

The IRO shall:

1. perform each component of the 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 inquires in a prompt, objective, and factual manner; and

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

F. Outside Reviewer Responsibilities.

The Outside Reviewer shall:

1. perform each RAMP 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 RAMP 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 inquires in a prompt, objective, and factual manner; and

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

G. Independence and Objectivity.

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

The Outside Reviewer must perform the RAMP Review in an independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the Outside Reviewer and Pfizer.

H. IRO Removal/Termination.

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

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

Prior to requiring Pfizer to engage a new IRO, OIG shall notify Pfizer 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, Pfizer may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Pfizer shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Pfizer prior to requiring Pfizer to terminate the IRO. However, the final determination as to whether or not to require Pfizer to engage a new IRO shall be made at the sole discretion of OIG.

I. Outside Reviewer Removal/Termination.

1. *Pfizer Termination of Outside Reviewer*. If Pfizer terminates its Outside Reviewer during the course of the engagement, Pfizer must submit a notice explaining its reasons to OIG no later than 30 days after termination. Pfizer must engage a new Outside Reviewer in accordance with Paragraph B of this Appendix.

2. *OIG Removal of Outside Reviewer*. In the event OIG has reason to believe that the Outside Reviewer does not possess the qualifications described in Paragraph D, is not independent and/or objective as set forth in Paragraph G, or has failed to carry out its responsibilities as described in Paragraph F, OIG may, at its sole discretion, require Pfizer to engage a new Outside Reviewer in accordance with Paragraph B of this Appendix.

Prior to requiring Pfizer to engage a new Outside Reviewer, OIG shall notify Pfizer 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, Pfizer may request a meeting with OIG to discuss any aspect of the Outside Reviewer's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Pfizer shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the Outside Reviewer with Pfizer prior to requiring Pfizer to terminate the Outside Reviewer. However, the final determination as to whether or not to require Pfizer to engage a new Outside Reviewer shall be made at the sole discretion of OIG.

Appendix B to Corporate Integrity Agreement

Promotional and Product Related Review

I. Promotional and Product Related Review, General Description

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

If there are no material changes in Pfizer's systems, processes, policies, and procedures relating to Promotional and Product Related Functions, the IRO shall perform the Promotional and Product Systems Review for the first and fourth Reporting Periods. If Pfizer materially changes its systems, processes, policies, and procedures relating to Promotional and Product Related Functions, the IRO shall perform a Promotional and Product 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 Promotional and Product Transactions Review for each Reporting Period of the CIA.

II. Promotional and Product Systems Review

A. Description of Reviewed Policies and Procedures. The Promotional and Product Systems Review shall be a review of Pfizer's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional and Product Related Functions. Where practical, Pfizer 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 Pfizer pursuant to the preceding sentence.

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

1. Pfizer's systems, policies, processes, and procedures applicable to the manner in which Pfizer sales representatives handle and submit requests or inquiries to Pfizer's Medical Information Department (USMI) relating to information about the uses of Pfizer's Government Reimbursed Products (including non-FDA-approved (i.e., off-label) uses) and the dissemination of materials relating to off-label uses of Pfizer's Government Reimbursed Products. This review shall include:

a. the manner in which Pfizer sales representatives handle and submit requests for information about off-label uses of Pfizer's Government Reimbursed Products to USMI;
b. the manner in which USMI personnel, handle and respond to requests submitted by sales representatives for information about off-label uses of Pfizer's 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 Pfizer's Government Reimbursed Products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions (HCIs) by Pfizer;
d. Pfizer's systems, processes, and procedures (including the USMI Database) used to track requests for information submitted by sales representatives to USMI about off-label uses of Pfizer's Government Reimbursed Products and responses to those requests;
e. the manner in which Pfizer collects and supports information reported in any systems used to track and respond to requests for product information, including the USMI Database;
f. the processes and procedures by which USMI and Pfizer's Compliance Department or their designees monitor and identify situations in which it appears that improper off-label promotion may have occurred; and
g. Pfizer's processes and procedures for investigating, documenting, resolving, and taking appropriate

disciplinary action for potential situations involving off-label promotion;

2. Pfizer's policies and procedures applicable to the manner and circumstances under which personnel from Pfizer's Medical Group (e.g., Medical Science Liaisons) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) and the role of the medical personnel at such meetings or events, including the manner in which they handle responses to unsolicited requests about off-label indications of Pfizer's Government Reimbursed Products;

3. Pfizer's systems, policies, processes, and procedures relating to Pfizer's internal review and approval of information and materials related to Pfizer's Government Reimbursed Products disseminated to HCPs or HCIs by Pfizer;

4. Pfizer's systems, polices, processes and procedures relating to incentive compensation (including through salaries, bonuses, and contests) for 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 Pfizer's 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 Pfizer establishes different methods of compensation for different products, the IRO shall review each type of compensation arrangement separately;

5. Pfizer's systems, processes, policies, and procedures relating to the development and review of call plans for Pfizer's 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, among other factors, expected utilization of Pfizer Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

6. Pfizer's systems, processes, policies, and procedures relating to the development, implementation, and review of Sample Distribution Plans. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Pfizer (including, separately, from Pfizer sales representatives and other Pfizer personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by

Pfizer through field sales representatives or are distributed from a central location and the rationale for the manner of distribution;

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

8. Pfizer's systems, processes, policies, and procedures relating to non-speaker related consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, mentorships, 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; and

9. Pfizer's systems, processes, policies, and procedures relating to its Tablet PC System or any other detailing system, including the implementation of the system throughout the Pfizer's field sales forces, the compliance-related data and information available through the system, and the use of such data and information for compliance-related purposes.

B. Promotional and Product Systems Review Report. The IRO shall prepare a report based upon each IRO Systems Review. For each of the Reviewed Systems, 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 Pfizer's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-9 above, including a general description of Pfizer's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Systems, 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.1-9 above are made known or disseminated within Pfizer;

4. findings and supporting rationale regarding any weaknesses in Pfizer's systems, processes, policies, and procedures relating to the Reviewed Systems, Policies, and Procedures, if any; and

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

III. Promotional and Product Related Transaction Review

As described more fully below, the Promotional and Product Related Transactions Review shall include: (1) a review of records relating to a sample of the Payments that are reported by Pfizer pursuant to Section III.O of the CIA and (2) a review of up to three additional items identified by the OIG in accordance with Section III.E.1.b of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Promotional and Product Transactions Review Reports.

A. IRO Review of Physician Payment Listings

1. *Information Contained in Physician Payment Listing.* As set forth in Section III.O of the CIA, Pfizer shall post annual listings and, after June 1, 2011, annual and quarterly listings of physicians and Related Entities who received Payments, as defined in the CIA, directly or indirectly from Pfizer. For purposes of the IRO review as set forth in this Section III.A, each annual listing 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 that the physician or the Related Entity has provided to Pfizer for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter(s) 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.

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 Payment Listing for the 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 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. As set forth more fully below, for each selected physician and/or Related Entity the IRO shall review the entry in the Physician Payment Listing and Control Documents relating to the Payments in order 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 all those 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 Pfizer's policies and procedures;

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

d. Whether the Control Documents reflect that Pfizer'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 Pfizer'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: (1) no

corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or (2) the IRO cannot confirm that Pfizer 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 Pfizer'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 Pfizer 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 Pfizer 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. 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.

B. IRO Review of Additional Items. As set forth in Section III.E.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify Pfizer 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 Pfizer 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 Pfizer's systems, processes, policies, and procedures based on its review of each Additional Item.)

Pfizer may propose to the OIG that its internal audit(s) and/or reviews conducted as part of Field Force Monitoring Program (FFMP) described in Section III.L of the CIA or the Headquarters Monitoring Activities described in Section III.M of the CIA be substituted, subject to the verification 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 Pfizer's internal 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 Pfizer's planned internal audit work and/or reviews conducted under the FFMP or the Headquarters Monitoring Activities, the results of the IRO Transactions Review(s) during prior Reporting Period(s), and Pfizer's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Pfizer's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Pfizer shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of Pfizer's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work shall be subject to verification, at OIG's discretion, by an 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 of at least 20% of the sampling units reviewed by Pfizer in its internal audits.

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

1. *Review Methodology.*

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 Promotional and Product Transactions Review.

2. *Review Findings*. The following results shall be included in each Promotional and Product Review Report:

(Relating to the Physician Payment Listing Reviews)

a. 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;

b. 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 Pfizer policy and procedure; (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 Pfizer's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) any corrective action or disciplinary action was undertaken in those instances in which Pfizer's policies were not followed;

c. 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;

d. 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 Additional Items)

e. for each Additional Item reviewed, a description of the review conducted;

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

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

h. for each Additional Item reviewed, recommendations, if any, for changes in Pfizer's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

Appendix C to Corporate Integrity Agreement

Risk Assessment and Mitigation Planning (RAMP) Review

I. General Description of RAMP

The risk assessment and mitigation planning (RAMP) process was developed by Pfizer as a tool to assess risks associated with many of its Government Reimbursed Products and develop a customized risk mitigation plan for each product. For each Government Reimbursed Product subject to RAMP, a Pfizer Attorney (hereafter "Attorney") completes an electronic risk assessment questionnaire. The questionnaire covers a broad range of potential risks, including promotional risk issues. Each question must be answered from a menu of possible responses. Each answer is given a proposed risk score (green, yellow, or red) based on pre-determined assessments of risk areas addressed by each question. Based on the responses to the questionnaire, the reviewed product is given an overall risk score. A "red" risk score represents a product with Heightened Risk.

After completion of the questionnaire, the Attorney is provided with a set of automated risk mitigation options for the reviewed product based on the risk scores for the questionnaire responses. Proposed mitigation options are broken into categories based on the identified risks.

Many of the mitigation options fall within Pfizer's customary practices with regard to its Government Reimbursed Products. However, certain of the mitigation steps identified for those products identified as having a Heightened Risk are mandatory rather than optional, and they entail enhanced monitoring and evaluation activities. These activities are referred to as "Required Monitoring Activities."

After reviewing all proposed risk mitigation options, the Attorney develops a risk mitigation plan for the product. For each identified risk area, the risk mitigation plan must specify: (i) the risk mitigation approach; (ii) the party who is primarily accountable for implementing the mitigation; (iii) the parties who must be consulted, if any; and (iv) the expected date of completion. The Attorney then reviews the completed risk mitigation plan with other Pfizer personnel, including Pfizer Legal and personnel within the applicable Business Unit for the product.

Following mitigation plan development, those designated as "primarily accountable" in the plan are responsible for completing the specified risk mitigation activities. Remedial actions completed during the specified period are entered into the RAMP online system under "Remedial Actions Taken." The Attorney must provide a documented explanation for any mitigation plan activities that were not completed during the period specified in the finalized mitigation plan.

Among other mitigation options, for all Government Reimbursed Products having a yellow or red risk score for applicable questions in the Promotion Category, the assigned Attorney shall review the incentive compensation available for field sales representatives who promote such products and shall review the call plans and Sample Distribution Plans associated with the each product. More specifically, where appropriate to mitigate and minimize risk, incentive compensation for a product shall be modified to: 1) exclude specified physician specialties from the credit and quota system for a product; 2) base incentive compensation on both individual and group performance goals; and/or 3) base incentive compensation on non-sales activities (such as the completion of data collection activities or other non-traditional performance goals.) Where appropriate to mitigate and minimize risk of improper promotion, Pfizer shall modify call plans to ensure that field sales representatives promote Government Reimbursed Products in a manner that is consistent with the FDA-approved label for the product and with all Federal health care program and FDA requirements. Similarly, where appropriate to mitigate and minimize risk relating to the distribution of samples, Pfizer shall modify Sample Distribution Plans to ensure that samples are distributed in a manner consistent with Federal health care program and FDA requirements, including, where appropriate, requiring that samples be distributed from a central location rather than permitting field sales representatives to provide the samples.

II. RAMP Reviews, General Description

A. As specified more fully below, Pfizer shall retain an Outside Reviewer to assist Pfizer in assessing and evaluating its systems, processes, policies, procedures, and practices relating to the Promotion Category of RAMP (RAMP Review).[1] The RAMP Review shall consist of two components - a systems review (the "RAMP Systems Review") and a transactions review (the "RAMP Transactions Review") as described more fully below. Pfizer may engage, at its discretion, a single Outside Reviewer to perform both components of the RAMP Review provided that the entity has the necessary expertise and capabilities to perform both.

B. If there are no material changes in Pfizer's systems, processes, policies, and procedures relating to RAMP, the Outside Reviewer shall perform the RAMP Systems review for the first and fourth Reporting Periods. If Pfizer materially changes its systems, processes, policies, and procedures relating to RAMP, the Outside Reviewer shall perform a RAMP Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods. The additional RAMP Systems Review(s) shall consist of: (1) an identification of the material changes; (2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and (3)

[1] In the event of material changes to RAMP during the term of the CIA, including to the items covered in the Promotion Category of RAMP, Pfizer shall consult with the OIG about the change. The OIG may require that the scope of the RAMP Review include categories in addition to, or instead of, the Promotion Category.

a review of the systems, processes, policies, and procedures that materially changed. The Outside Reviewer shall conduct the RAMP Transactions Review for the second, third, fourth, and fifth Reporting Periods of the CIA.

III. RAMP Systems Review

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

1. A review of all of the risk assessment questions included in the Promotion Category of the RAMP questionnaire to assess whether the questions are designed to identify all relevant risks for Pfizer's Government Reimbursed Products associated with: (a) FDA requirements related to the promotion of Pfizer's products, and (b) Federal health care program requirements;

2. An assessment of whether additional questions should be added to the Promotion Category of the RAMP questionnaire to identify relevant risks or whether questions should be reworded or rephrased to elicit more appropriate or consistent responses to the questionnaire;

3. An assessment of the frequency with which questions in the Promotion Category of the RAMP questionnaire are reviewed by Pfizer to ensure that the questions identify all relevant promotional risks for Pfizer's products;

4. A description of the experience and background of individuals who are required to complete the RAMP questionnaire and the completeness of the relevant training, policies, procedures, standard operating procedures, and guidance regarding completion of the RAMP questionnaire;

5. An assessment of whether the risk scores assigned to each response provided on the Promotion Category of the RAMP questionnaire are appropriate and are designed to ensure that Pfizer is reasonably identifying the level of risk associated with the situation described;

6. An assessment of whether the mitigation options (including Required Monitoring Activities) provided in response to the completed Promotion Category of the RAMP questionnaire are designed to: (i) adequately address all relevant identified risks, (ii) identify any actual problems that have occurred in connection with the identified potential risk, and (iii) ensure that the activity associated with an identified risk does not occur in the future;

7. An assessment of whether the proposed mitigation options (including Required Monitoring Activities) provided in response to a completed RAMP questionnaire should be: (i) enhanced, revised, or refined, (ii) expanded by adding mitigation options to be considered based upon specific identified risks, (iii) reviewed more frequently than prescribed by current policies or guidance to ensure that the options address all relevant promotional risks for the specific products reviewed;

8. A review of systems, policies, procedures, and processes designed to ensure that the Attorney completing a RAMP questionnaire consults with other relevant Pfizer personnel to design a risk mitigation plan based upon all identified risks; and

9. An assessment of whether systems, policies, procedures and processes ensure that the promotional risk mitigation plans developed through the RAMP process (including Required Monitoring Activities) are appropriately implemented and that all implemented mitigation approaches are documented.

B. The Outside Reviewer shall prepare a report based upon each Systems Review performed (System Review Report). The Systems Review Report will include the Outside Reviewer's findings, recommendations, observations, and comments on items 1-9 above, including but not limited to: (i) whether the risk assessment questions included in the Promotion Category of the RAMP questionnaire reasonably identify and prioritize relevant risks; (ii) whether the mitigation options for the Promotion Category of RAMP provided to an Attorney through the RAMP process reasonably address and potentially mitigate identified risks; and (iii) whether sufficient controls exist to reasonably ensure that all agreed-upon risk mitigation activities are completed according to the mitigation plan.

III. RAMP Transactions Review

A. At least thirty (30) days prior to the end of each Reporting Period, Pfizer shall submit to OIG a list of all Government Reimbursed Products determined in the most recent RAMP cycle to be products with Heightened Risk. Prior to the end of the applicable Reporting Period, OIG shall select three Government Reimbursed Products (each a "Selected Product" and together the "Selected Products") to be reviewed in connection with the RAMP Transactions Review.

B. For each Reporting Period and for each Selected Product, the Outside Reviewer shall conduct a review of a completed Promotion Category of the RAMP questionnaire, documents and materials related to the development of the risk mitigation plan, and documents and materials relating to the implementation of the risk mitigation

plan (including the Required Monitoring Activities). The Outside Reviewer shall also interview the Attorney and other personnel involved in the RAMP process for the Selected Product. The objective of the Outside Reviewer shall be to: (i) determine whether all RAMP questions for the Promotion Category were answered for the Selected Products and to understand the underlying factual basis for such responses; (ii) determine whether, based on the answers to the RAMP questions, a risk mitigation plan for the Selected Product was formulated in accordance with Pfizer's policies and procedures, including whether Required Monitoring Activities were incorporated into the plan; and (iii) assess Pfizer's implementation and tracking of the Required Monitoring Activities required under RAMP as a result of the risk assessment for the particular products.

C. The Outside Reviewer will prepare a report based on each RAMP Transactions Review performed (Transactions Review Report). The Transactions Review Report shall include the Outside Reviewer's findings, recommendations, observations and comments regarding:

1. Whether Pfizer completed the Promotion Category of the RAMP questionnaire for the each of the Selected Products;

2. Whether, based on the answers to the RAMP questions for each of the Selected Products, Pfizer developed a risk mitigation plan for each of the products in accordance with its policies and procedures (including whether Required Monitoring Activities were incorporated into the risk mitigation plan);

3. A description of the expertise and background of the Attorney and other personnel who completed the RAMP questionnaire and developed the risk mitigation plan for each of the Selected Products;

4. A description of the Required Monitoring Activities for the Promotion Category proposed for each of the Selected Products;

5. Whether the Required Monitoring Activities set forth in the risk mitigation plan for each of the Selected Products were implemented and tracked in accordance with the mitigation plan and Pfizer's policies and procedures; and

6. Whether: i) the Outside Reviewer made any recommendations regarding the RAMP process as applied to each of the Selected Products, including any recommendations regarding the implementation and tracking of Required Monitoring Activities, and, if so, a description of the recommendation(s); and ii) if the Outside Reviewer made recommendations whether: (a) Pfizer implemented the recommendations and, if so, a

description of the implementation steps undertaken by Pfizer; or (b) if Pfizer did not implement the recommendations, a description of the rationale for Pfizer's decision not to implement the recommendations.