

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 by its officers, directors, employees, contractors, and agents 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 the applicable statutes, regulations and written directives of the Food and Drug Administration (FDA requirements). Pfizer is a successor-in-interest to Warner-Lambert Company and its Parke-Davis Division. Contemporaneously with this CIA, Pfizer is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. Pfizer also will enter into settlement agreements with various States, and Pfizer's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date (defined below), Pfizer initiated certain voluntary compliance measures, which include, among other actions, the appointment of a Compliance Officer and designated compliance agents, the appointment of a Compliance Committee, a Disclosure Program, screening measures for Ineligible Persons, and regular mandatory training for all employees concerning Pfizer's Code of Conduct. As represented by Pfizer, Pfizer also has in place strong review and disciplinary measures to ensure that its activities: (i) are in compliance with all Federal health care program requirements and FDA requirements, and (ii) meet Pfizer's goals of ensuring high ethical standards in all aspects of its business practices.

Prior to the Effective Date, Pfizer also entered a CIA with the OIG in October of 2002. The prior CIA incorporated voluntary compliance measures that Pfizer had initiated before that CIA. Pfizer has submitted its first annual report (including the

engagement report required by section III.D.6) to the OIG in accordance with the terms of the October 2002 CIA. The obligations of the earlier CIA have been incorporated into this document, and this document supercedes the earlier CIA.

Pfizer shall continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. Pfizer may modify its voluntary compliance measures as appropriate, but, at a minimum, Pfizer shall ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Pfizer under this CIA shall be five years from the Effective Date of this CIA, unless otherwise specified. The Effective Date shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period." Section III.D sets forth the relevant Reporting Periods and time frame of the obligations relating to the Engagements to be conducted under this CIA.

B. Sections VII, VIII, 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 officers directly involved in Pfizer's US Pharmaceuticals operations;
- b. all employees of Pfizer Global Pharmaceuticals, the Corporate Finance Division, and the Pfizer Legal Division located in the United States and engaged in or having responsibilities directly relating to the following functions (as defined below in Section II.C.2): a) Managed Care Contracting Related Functions; b) Medicaid Rebate

Related Functions; and c) Promotional and Product Services Related Functions; and

c. all contractors, subcontractors, agents, and other persons who perform Managed Care Contracting Related Functions, Medicaid Rebate Related Functions, or Promotional and Product Services Related Functions on behalf of Pfizer.

Notwithstanding the above, the term “Covered Persons” does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per calendar year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year. The term “Covered Persons” does not include any contractors or agents retained to provide consulting or business advice to Pfizer and who are not engaged directly in any Managed Care Contracting Related Functions, Medicaid Rebate Related Functions, or Promotional and Product Services Related Functions on behalf of Pfizer. Also specifically excluded from this definition of “Covered Persons” are the personnel of entities with which Pfizer has agreements to co-promote its products. Pfizer shall, however, in good faith seek to obtain assurances that such persons have received appropriate training on proper promotional activities.

2. Other Applicable Definitions:

a. Managed Care Contracting Related Functions:

Managed Care Contracting Related Functions are defined to be the promotion of prescription drug products to managed care entities. The individuals involved in these functions include:

1) the following employees of Pfizer Global Pharmaceuticals located in the United States: i) all employees of the National Accounts Group and the National Healthcare Operations Group within the Healthcare Cluster; ii) all employees who are members of the Managed Care Contracts Group (a sub-division of the Contracts Group); and iii) those managers within the United States

Pharmaceuticals (USP) Finance Group to whom the members of the Managed Care Contracts Group directly report;

2) those employees from the Pfizer Legal Division whose job responsibilities directly relate to managed care entities and/or Managed Care Contracting Related Functions, and all employees who are members of the Grants Committee; and

3) all contractors, subcontractors, agents, and other persons who perform Managed Care Contracting Related Functions on behalf of Pfizer.

b. Medicaid Rebate Related Functions:

Medicaid Rebate Related Functions are defined to be the gathering, calculation, verification or reporting of information for purposes of the Medicaid Rebate Program (codified at 42 U.S.C. § 1396r-8, et seq.) The individuals engaged in these functions include:

1) the following employees of Pfizer Global Pharmaceuticals: i) members of the Government Contracting Group (a sub-division of the Contracts Group); and ii) managers within the USP Finance Group and the Corporate Finance Group, if applicable, to whom the members of the Government Contracting Group directly report;

2) those employees from the Pfizer Legal Division whose job responsibilities directly relate to Medicaid Rebate Related Functions; and

3) all contractors, subcontractors, agents, and other persons who perform Medicaid Rebate Related Functions on behalf of Pfizer.

c. Promotional and Product Services Related Functions:

Promotional and Product Services Related Functions are defined to be the sales, marketing, or promotion of Pfizer products or the

provision of information about or services relating to Pfizer's products. The individuals engaged in these functions are:

- 1) all non-overtime eligible employees of Pfizer's US Pharmaceuticals Division from the following sub-functions: i) USP Sales; ii) USP Product Marketing; iii) Customer and Market Development; iv) Global Market Analytics; and v) USP Medical and Regulatory Affairs, except those employees within USP Medical whose primary job responsibilities relate to management of clinical trials, including, without limitation, Clinical Study Managers, Clinical Directors, and members of the Clinical Operations group;
- 2) those employees from the Pfizer Legal Division whose job responsibilities directly relate to Promotional and Product Services Related Functions;
- 3) to the extent not already covered by Sections II.C.2.c.1-2 above, all employees of Pfizer Global Pharmaceuticals located in the United States who are members of any Review Committee for any Pfizer product; and
- 4) all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions on behalf of Pfizer.

III. CORPORATE INTEGRITY OBLIGATIONS

Pfizer shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Pfizer presently has a Compliance Officer with responsibility for administering Pfizer's Compliance Program. Pfizer shall continue to employ an individual to serve as its Compliance Officer during the term of this CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements.

The Compliance Officer and the Deputy Compliance Officer shall be members of senior management of Pfizer. The Compliance Officer and the Deputy Compliance Officer shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcommittee, in such form or manner as the Board of Directors determines), and both shall be authorized to report on such matters to the Board of Directors at any time¹. The Compliance Officer and the Deputy Compliance Officer shall be authorized to request that the Audit Committee or the Board retain outside counsel in appropriate circumstances. The Compliance Officer and the Deputy 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, any changes in the identity of or any material changes in the position description of the Compliance Officer, or any material actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Pfizer currently has and shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as internal audit, regulatory affairs, sales, marketing, personnel and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Pfizer shall report to OIG, in writing, any material changes in the composition of the Compliance Committee, or any material 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.

¹ In these periodic reports, the Directors shall be notified of Pfizer's continuing activities and obligations under the CIA. Also, the Directors have agreed to abide by a Code of Conduct which they adopted.

B. Written Standards.

1. *Code of Conduct.* Pfizer represents that, prior to the Effective Date, it developed, implemented, and distributed its written code of conduct (known as the Summary of Policies on Business Conduct or the “Blue Book”) or other relevant compliance policies and procedures to all Covered Persons. Pfizer makes and shall continue to make the promotion of, and adherence to, the Blue Book, or other relevant compliance policies and procedures, an element in evaluating the performance of all employees. The Blue Book, or other similar compliance policies and procedures, 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 comply with all government contracting requirements and to market, sell, and promote its products in accordance with such requirements;
- b. Pfizer’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and FDA requirements and with Pfizer’s own Policies and Procedures as implemented pursuant to this 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 Compliance Officer or other appropriate individual designated by Pfizer (such as district managers or other supervisory personnel) suspected violations of any Federal health care program requirements or 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 requirements 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.E, and Pfizer’s commitment to nonretaliation

and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Pfizer represents that within the past 180 days, all Covered Persons have certified, in writing or electronically, that they have received, read, understood, and shall abide by Pfizer's Blue Book or other relevant compliance policies and procedures. New Covered Persons shall receive the Blue Book, or other relevant compliance policies and procedures, and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Annually, Pfizer shall review the Blue Book and other compliance policies and procedures to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any materially revised Blue Book or other compliance policies and procedures shall be distributed within 30 days after any such revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Blue Book, or other compliance policies and procedures, within 30 days after the distribution of the revised Blue Book.

2. *Policies and Procedures.* Prior to the Effective Date, Pfizer implemented written Policies and Procedures regarding the operation of Pfizer's compliance program and its compliance with Federal health care program and FDA requirements (Policies and Procedures). At a minimum, the Policies and Procedures address and shall continue to address:

- a. the subjects relating to the Blue Book or other relevant compliance policies and procedures identified in Section III.B.1;
- b. the methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program;
- c. methods for selling, marketing, and promoting Pfizer products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b;

- d. methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products in compliance with all applicable FDA requirements;
- e. the manner in which the Medical Information Department receives and responds to requests for information about off-label uses; the form and content of information disseminated by the Medical Information Department in response to such requests; and the internal review process for the information disseminated;
- f. disciplinary sanctions in place for violations of Pfizer's Policies and Procedures, including policies relating to Federal health care program requirements and FDA requirements;
- g. speaker meetings, advisory board meetings, and all other consultant arrangements (including those for speakers, mentors, or preceptors) or related events. The policies shall be designed to ensure that the consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program requirements and with FDA requirements relating to the dissemination of information about off-label uses of products. The policies shall include requirements about the content and circumstances of such arrangements and events;
- h. sponsorship or funding of continuing medical education (CME) programs that are 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 the disclosure of Pfizer's financial support of the CME program and any financial relationships with faculty, speakers, or participants at such CME program; shall require that the CME program have an educational focus; shall require that the CME program be independent; and shall require that the CME program be balanced;

- i. sponsorship or funding of grants (including educational grants) that are designed to ensure that Pfizer's funding and/or sponsorship of such grants complies with all applicable Federal health care program requirements and FDA requirements; and
- j. sponsorship or funding of research or related activities (including clinical trials, market research, or authorship of articles or other publications) that are designed to ensure that Pfizer's funding or sponsorship of such activities complies with all applicable Federal health care program requirements and FDA requirements.

Pfizer represents that it recently distributed the relevant portions of the Policies and Procedures to all Covered Persons whose job functions relate to the Policies and Procedures. Appropriate and knowledgeable staff were and shall continue to 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 material revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on Pfizer's Intranet.

C. Training and Education.

1. *Training Requirements, General Description.* The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, or Pfizer trainers and/or outside consultant trainers selected by Pfizer. Persons providing the training must be knowledgeable about the subject areas of their training.

Pfizer may provide the training required under this CIA through appropriate computer-based approaches. In that event, all applicable references to "hours" in this Section III.C shall mean "normative hours" as that term is used in the computer-based training industry. If Pfizer chooses to provide computer-based training, it shall also make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons who are receiving such training.

New Covered Persons shall receive the training outlined below in Sections III.C.2 and III.C.3 within 30 days after the beginning of their employment or becoming Covered Persons, whichever is later. A Pfizer employee who has completed the training shall review a new Covered Person's work, to the extent that the work directly relates to Managed Care Contracting Related Functions, Medicaid Rebate Related Functions, or Promotional and Product Services Related Functions until such time as the new Covered Person completes the applicable training.

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

2. General Training Provided to Covered Persons. Pfizer represents that within the last eight months, it provided approximately two hours of general training to each Covered Person. The OIG agrees to credit this training toward the general training requirements for the first annual Reporting Period. Pfizer's general training included a discussion of Pfizer's Compliance Program (including the Blue Book and Policies and Procedures as they pertain to general compliance issues). For the remaining term of the CIA, each Covered Person shall receive at least one hour of general training annually.

Pfizer shall notify its directors and all Covered Persons about the CIA and the obligations of Pfizer under the CIA within 120 days after the Effective Date. Pfizer shall include a description of this notification in its Annual Report.

3. Specific Training Provided to Covered Persons. Pfizer represents that it has provided certain specific training as outlined below to most Covered Persons within approximately the past six months, and Pfizer shall provide specific training to the remaining Covered Persons during the first Reporting Period. Thereafter, annually, except for Pfizer's officers who are not also otherwise Covered Persons, all Covered Persons shall receive at least two hours of specific training in addition to the general training required above. The specific training shall be tailored to the Covered Persons' job responsibilities and shall include a discussion of the topics outlined in Sections III.C.3.a-c below, as well as a discussion of Pfizer's CIA obligations.

a. Specific Training for Covered Persons with Managed Care Contracting Related Functions

The specific training for Covered Persons performing Managed Care Contracting Related Functions shall include a discussion of:

1. all applicable Federal health care program requirements (including the sanctions for violations) relating to Managed Care Contracting and Medicaid Rebate Related Functions (including, but not limited to, the Federal anti-kickback statute; the Civil Monetary Penalties law, 42 U.S.C. § 1320a-7a; the civil False Claims Act, 31 U.S.C. §§ 3729-3733; and the Medicaid Drug Rebate statute);
2. the personal obligation of each individual to comply with the legal requirements outlined above in Section III.C.3.a.1; and
3. examples of proper and improper Managed Care Contracting practices.

b. Specific Training for Covered Persons with Medicaid Rebate Related Functions

The specific training for Covered Persons performing Medicaid Rebate Related Functions shall include a discussion of:

1. in detail, Pfizer's systems for gathering relevant data and calculating, verifying and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Rebate Program, including the Government Pricing System (GPS);
2. all applicable Federal health care program requirements (including the sanctions for violations) relating to Medicaid Rebate Related Functions (including the Medicaid Drug Rebate statute);
3. the personal obligation of each individual to comply with the applicable legal requirements outlined above in Section III.C.3.b.2 and to fully track any variations identified within the GPS; and

4. examples of proper and improper practices related to Medicaid Rebate Related Functions.

c. Specific Training for Covered Persons performing Promotional and Product Services Related Functions

The specific training for Covered Persons performing Promotional and Product Services Related Functions shall include a discussion of:

1. all Federal health care program requirements regarding the proper methods for selling, marketing, and promoting Pfizer's products, including, but not limited to, the requirements of the Federal anti-kickback statute; the Civil Monetary Penalties law; the civil False Claims Act; and the Medicaid Drug Rebate statute;
2. all applicable FDA requirements regarding the proper methods for selling, marketing, promoting, and advertising Pfizer's products, and disseminating information about off-label uses of Pfizer's products including, but not limited to, the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations;
3. the personal obligation of each Covered Person involved in the sales, marketing, promotion, advertising, or disseminating information about off-label uses of Pfizer's products to comply with all applicable legal requirements;
4. the legal sanctions for violations of the Federal health care program requirements and FDA requirements; and
5. examples of proper and improper sales, marketing, promotion, and dissemination of information about off-label uses practices.

4. *Certification.* Each Covered Person who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training and shall agree to abide by the principles and Policies and Procedures covered in the training. Pfizer agrees to maintain records specifying the type of training provided to

each Covered Person and the date provided. The Compliance Officer (or designee) shall retain the certifications, the training tracking information, and all course materials. These shall be made available to OIG, upon request.

D. Engagement Procedures

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days after the Effective Date, Pfizer shall retain an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform Engagements to assist Pfizer in assessing and evaluating its systems, processes, policies and practices related to the Medicaid Rebate Program, to Managed Care Contracting Related Functions and to Promotional and Product Services Related Functions.

Each IRO retained by Pfizer shall have expertise in the requirements of the Medicaid Rebate Program, in Federal health care program requirements, and in FDA requirements, as may be appropriate to the specific Engagement for which it is retained. Each IRO shall assess, along with Pfizer, whether it can perform the Engagements in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist.

The IRO(s) shall conduct three types of engagements. One engagement shall address and analyze Pfizer's systems, processes, policies, and practices relating to the Medicaid Rebate Program (Medicaid Rebate Engagement). The second engagement shall address and analyze Pfizer's systems, policies and practices with regard to managed care contracting (Managed Care Contracting Engagement). The third engagement shall address and analyze Pfizer's systems, processes, policies, and practices relating to sales, marketing, and product services activities (Promotional and Product Services Engagement). The Promotional and Product Services Engagement shall consist of two components - a Systems Review

and a Transactions Review. The IRO shall perform all components of each of the Engagements.

b. Frequency of Engagements.

1. Medicaid Rebate Engagement. If there are no material changes in Pfizer's Medicaid Rebate Program-related systems, processes, policies, and practices during the term of the CIA, the IRO shall perform the Medicaid Rebate Engagement for the third Reporting Period. If Pfizer materially changes its systems, processes, policies and practices relating to the Medicaid Rebate Program, then the IRO shall perform a Medicaid Rebate Engagement for the Reporting Period in which such changes were made in addition to conducting the Medicaid Rebate Engagement for the third Reporting Period.

2. Managed Care Contracting Engagement. The Managed Care Contracting Engagement shall be performed annually for the first four Reporting Periods² and shall cover each of the following periods (hereinafter "Managed Care Contracting Review Periods"):

- 1) October 24, 2003 through October 23, 2004
- 2) October 24, 2004 through October 23, 2005
- 3) October 24, 2005 through October 23, 2006
- 4) October 24, 2006 through October 23, 2007.

3. Promotional and Product Services Systems Review Engagement. The Promotional and Product Services Systems Review Engagement shall be performed for the periods

²Prior to the Effective Date, Pfizer performed and submitted a report for the Managed Care Contracting Engagement as required under the October 2002 CIA which, as explained in the Preamble, has been superceded.

covering the first and fourth Reporting Periods provided there are no material changes in Pfizer's systems, processes, policies, and practices relating to sales, marketing, and product services activities³. If Pfizer materially changes such systems, processes, policies, and practices, then the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review Engagement for the first and fourth Reporting Periods.

4. *Promotional and Product Services Transactions Review Engagement.* Pfizer represents that it is modifying certain internal systems that will serve as the basis for the Promotional and Product Services Transactions Review Engagement. To allow for time for the modifications to be completed, the Promotional and Product Services Transactions Review shall be performed on an annual basis for the second through fifth Reporting Periods.

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 Engagements.

2. *Medicaid Rebate Engagement.* As more fully set forth in Attachment A, the Medicaid Rebate Engagement shall be an engagement that addresses Pfizer's systems, processes, policies, and practices associated with the tracking, gathering, and accounting for all relevant data for purposes of appropriately calculating the Best Prices reported under the Medicaid Rebate Program.

3. *Managed Care Contracting Engagement.* As set forth more fully in Attachment A, the Managed Care Contracting Engagement shall review the Managed

³ The Promotional and Product Services Systems Review for the first Reporting Period shall only cover the last nine months of the first reporting Period to allow time for Pfizer to modify its internal systems relevant to this Review.

Care Related Expenditures paid to a sample of Managed Care Customers during the relevant Managed Care Contracting Review Period.

4. *Promotional and Product Services Systems Review Engagement.* As set forth more fully in Attachment C, as part of the Promotional and Product Services Engagement, the IRO shall perform a Promotional and Product Services Systems Review of Pfizer's systems, processes, policies, and practices relating to specified sales marketing, promotion, product information, contracting, funding, and compensation practices.

5. *Promotional and Product Services Transactions Review Engagement.* As set forth more fully in Attachment C, as part of the Promotional and Product Services Engagement, the IRO shall perform a Promotional and Product Services Transactions Review of identified sales, marketing, and product services related activities.

6. *Engagement Reports.* The IRO shall prepare a report (or reports) based upon each Medicaid Rebate Engagement, Managed Care Contracting Engagement, and Promotional and Product Services Engagement (including both the Systems and Transaction Reviews) performed (collectively "the Engagement Reports"). Information to be included in the Engagement Reports is detailed in Attachments A and C.

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

or relevant information to clarify the results of any Engagement Review or to correct the inaccuracy of any Engagement; (c) propose alternatives to the proposed Validation Review. Pfizer shall provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Engagement Review issue 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.

8. *Independence/Objectivity Certification.* Pfizer shall undertake a good faith effort to obtain from each IRO a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Engagement and that it has concluded that it is, in fact, independent and/or objective, and the IRO(s) shall include such certification in its report(s) to Pfizer. After undertaking good faith efforts to secure one, the failure to obtain an independence certification from the IRO(s) shall not constitute a breach of this CIA (whether a material breach or otherwise) and shall not constitute a basis upon which the OIG may impose Stipulated Penalties; however, such a failure shall constitute a basis upon which the OIG may initiate a Validation Review, as described in Section III.D.7 above, the costs of which shall be borne by Pfizer.

E. Disclosure Program.

Pfizer presently has a disclosure program designed to facilitate communications relating to compliance with Federal health care program requirements and FDA requirements and Pfizer's policies (the "Disclosure Program"). During the term of this CIA, Pfizer shall maintain its Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Pfizer's policies, conduct, practices, or procedures with respect to a Federal health care program requirements or FDA requirements 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 nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which

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

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

F. Ineligible Persons.

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

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

Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).

2. *Screening Requirements.* Pfizer shall ensure that all current Covered Persons are not Ineligible Persons, and that it will not hire or engage any prospective Covered Persons who are Ineligible Persons, by implementing the following screening requirements.

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

b. For all current Covered Persons, Pfizer shall screen all such 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.

3. *Removal Requirement.* If Pfizer has actual notice that a Covered Person has become an Ineligible Person, Pfizer shall remove such person from responsibility for, or involvement with, Pfizer's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the 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 person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Pfizer has actual notice that a person identified in Section III.F.2 is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, Pfizer shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at Pfizer's New York headquarters, Pfizer shall notify the OIG, in writing, of any ongoing U.S.-based investigation or legal proceeding known to Pfizer conducted or brought by a 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 the OIG within 30 days after the resolution of the matter, and shall provide the OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Notification of Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves a matter, brought to the attention of senior management at Pfizer's New York headquarters, that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program, and/or applicable to any FDA requirements relating to the off-label promotion of drugs, for which penalties or exclusion may be authorized. 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 the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Pfizer's actions taken to correct the Reportable Event; and

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

Pfizer's submission to OIG of any Reportable Event pursuant to this CIA does not preclude Pfizer from making the same disclosure through the OIG's Self-Disclosure Protocol.

I. Notification of Communications Regarding Off-Label Uses Issues.

Within 30 days after the date of any written report, correspondence, or communication from Pfizer to the FDA in connection with Pfizer's or a Covered Person's promotion, discussion, or dissemination of information about off-label uses of Pfizer's products, 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.

J. Review of Records Reflecting the Content of Detailing Sessions

At least 90 days prior to the beginning of the second Reporting Period and each Reporting Period thereafter, Pfizer shall provide to OIG a list and explanation of all actively promoted Pfizer products and, if available from third parties, information about the estimated relative usage (*e.g.*, the percentage) of those products for off-label purposes. Prior to the start of the second Reporting Period and every Reporting Period thereafter, based on the information provided and other information known to it, and after consultation with Pfizer, the OIG shall select up to three Pfizer products to be the basis for a review of records reflecting the content of detailing sessions and shall notify Pfizer of the Pfizer products selected as the basis for the review. These identified products shall be known as the "Covered Products." The parties already have identified the Covered Products for the first Reporting Period.

Each Reporting Period, Pfizer shall obtain commercially available non-Pfizer records reflecting the purported content and subject matter of detailing interactions between sales representatives and HCPs for the Covered Products (*e.g.*, Verbatims or similar records). For each Covered Product, Pfizer shall randomly select one week within each of the first three quarters of the Reporting Period. For each Covered Product, Pfizer shall obtain records reflecting the purported content and subject matter of detailing

sessions that occurred during the identified week in all regions across the United States. Pfizer shall review the records obtained and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of the Covered Products. Pfizer shall make findings based on its review (Off-Label Findings) and shall take any responsive action it deems necessary. If necessary for purposes of its review, Pfizer shall endeavor to collect additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report, Pfizer shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of Pfizer's Off-Label Findings, and a description of the action(s), if any, Pfizer took in response to the Off-Label Findings.

This Section III.J is subject to the availability of the records described above, and Pfizer shall make good faith efforts to obtain such records. If Pfizer is unable to obtain such records, Pfizer shall so notify the OIG and shall describe to the OIG the efforts undertaken to obtain the records for each Covered Product.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Pfizer establishes or acquires new business units or locations engaged in Managed Care Contracting Related Functions, Medicaid Rebate Related Functions, or Promotional and Product Services Related Functions, Pfizer shall notify the OIG of this fact as soon as possible, but no later than within 30 days after the date of establishment or acquisition. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider and/or supplier number, and any corresponding contractor's name and address that has issued each provider or supplier number. Each new business unit or location shall be subject to all the requirements of this CIA. In the event that Pfizer acquires a pharmaceutical manufacturer within 120 days after the Effective Date, nothing in this CIA shall apply to any Managed Care Contracting, Medicaid Rebate, or Promotional and Product Services Related Function of the acquired company until 90 days after the closing date of such acquisition.

V. IRO SELECTION NOTIFICATION AND ANNUAL REPORTS

A. IRO Selection Notification. Within 120 days after the Effective Date, Pfizer shall submit a written notification to OIG containing the following information regarding

the IRO: (i) the identity, address and phone number; (ii) a copy of the engagement letter(s); (iii) a summary and description of any and all current and prior engagements and agreements between Pfizer only and the IRO; (iv) the proposed start and completion dates of the Engagements identified in section III.D; and (v) a certification from the IRO regarding its professional independence and/or objectivity with respect to Pfizer.

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. to the extent any exist since Pfizer's most recent Annual Report to the OIG, a description of any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
2. to the extent there are material changes in the Blue Book or other compliance policies and procedures, a copy of Pfizer's Blue Book or the policies required by Section III.B.1;
3. for the first Reporting Period, a copy of all Policies and Procedures required by Section III.B.2, to the extent not previously provided; for subsequent Reporting Periods, 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 contractor policy) and copies of any compliance-related Policies and Procedures. This requirement specifically includes, among other things, Policies and Procedures contained in Pfizer's "Rules and Regulations: Field Guide" (also referred to as the "Orange Book") and elsewhere relating to the promotion, discussion, or dissemination of information about off-label uses of Pfizer products;
4. the number of Covered Persons required to complete the Blue Book 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. 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.

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

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

8. a summary/description of all current and prior engagements and agreements between Pfizer only and the IRO(s), if different from what was previously submitted;

9. a certification from the IRO(s) regarding its professional independence and/or objectivity with respect to Pfizer;

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

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

12. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
13. a description of the notification to directors and all Covered Persons as required by Section III.C.2;
14. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs or the FDA issues addressed in this CIA;
15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
16. a summary describing any ongoing communication with the FDA required to have been reported pursuant to Section III.I. The summary shall include a description of any such matters, and the status of the matter with the FDA;
17. as required by Section III.J, a copy of Pfizer's Off-Label Findings and the underlying records reflecting the content of detailing sessions between HCPs and Covered Persons, and a description of responsive action, if any, taken by Pfizer in connection with its Off-Label Findings;
18. a description of all changes to the most recently provided list of Pfizer's locations (including addresses) that house Covered Persons, except for offices operated out of an individual's residence; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider, and/or supplier number(s); and the name and address of each Federal health care program contractor to which Pfizer currently submits claims; and

19. to the extent not already furnished to the OIG, an overall description of Pfizer's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and a modified description of Pfizer's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business relevant to the requirements of the CIA; and

20. 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. Except as otherwise stated above, the Annual Reports shall include a certification by the Compliance Officer that:

1. Pfizer's: (i) Policies and Procedures as referenced in Section III.B.2 above; (ii) templates for standardized contracts and certifications associated with Promotional and Product Services Related Functions as set forth in Pfizer's Orange Book; and (iii) promotional materials that are reviewed by a Review Committee and are submitted to the FDA; have been reviewed by legal counsel for compliance with the requirements of the Federal anti-kickback statute and other Federal health care program requirements, and FDA requirements, as applicable;
2. to the best of his or her knowledge, except as otherwise described in the applicable report, Pfizer is in compliance with all of the requirements of this CIA;
3. the Compliance Officer has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information in the Annual Report is accurate and truthful; and
4. if applicable, Pfizer has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such

denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs.

Each Annual Report shall also include the certification set forth in Attachment B to this CIA.

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:

Douglas M. Lankler, Esq., Deputy Compliance Officer
Pfizer Inc
235 East 42nd Street (150/5/22)
New York, NY 10017
Phone: 212.733.3026
Fax: 212.464.7736

With a copy to:

Lynn Shapiro Snyder, Esq.
Epstein, Becker & Green, P.C.
1227 25th Street, N.W.
Washington, D.C. 20037
Phone: 202.861.0900
Fax: 202.296.2882

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Pfizer's books, records, and other documents and supporting materials (to the extent such items are not protected under appropriately asserted legal privilege) 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 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's employees shall have the right to be represented by counsel and any such employees may, at his or her option, be accompanied by counsel for Pfizer and/or their personal counsel at any interview by 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. Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to

interviews, and Pfizer shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA.

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).

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). The OIG shall provide the pre-disclosure notice required pursuant to 45 C.F.R. §5.65(d) to the Compliance Officer with a copy to Pfizer's legal representative at the address provided in Section VI. Nothing in this CIA or any communication or report made pursuant to this CIA shall constitute or be construed as a waiver by Pfizer of Pfizer's attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect Pfizer's obligation to comply with the provisions of the CIA.

X. BREACH AND DEFAULT PROVISIONS

Pfizer is expected to fully and timely comply with all of its CIA obligations. A breach of this CIA does not constitute a breach of the Settlement Agreement between Pfizer and the United States or the settlement agreements with the individual States referred to in the Preamble. Any breach of the terms of those agreements does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. Section X of this CIA specifies all of the remedies available to the OIG if Pfizer fails to satisfy its obligations under this CIA. The remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against Pfizer under appropriate authorities.

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 and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct (i.e., the Blue Book);
- d. written Policies and Procedures;
- e. the training of Covered Persons; and
- f. a Disclosure Program.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Pfizer fails to engage an IRO as required in Section III.D 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 meet any deadlines for the submission of the IRO Selection Notification or the Annual Reports to OIG as described in Section V.

4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Pfizer hires or engages as a Covered Person an Ineligible Person and that person: (a) has responsibility for, or involvement with, Pfizer’s business operations related to the Federal health care programs; or (b) is in a position for which the person’s salary or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or

otherwise with Federal funds (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which Pfizer can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.F) as to the status of the person).

5. A Stipulated Penalty of \$1,500 for each day Pfizer fails to grant access to the information or documentation 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 IRO Selection Notification, 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"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

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 certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that 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 failure by Pfizer to report a Reportable Event and take corrective action, as required in Section III.H;

- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D and Appendices A and C.

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 after 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

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

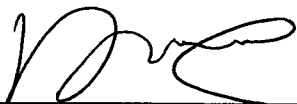
- A. This CIA shall be binding on the successors, assigns, and transferees of Pfizer;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA and the CIA will be subject to modifications if so required by any change in Federal health care program requirements or FDA requirements as referenced in the Preamble 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.
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

ON BEHALF OF PFIZER INC



Beth Levine, Esq.
General Counsel
U.S. Pharmaceuticals
Pfizer Inc

5/11/04
DATE



Douglas Lankler, Esq.
Deputy Compliance Officer
Pfizer Inc

5/11/04
DATE

Lynn Shapiro Snyder, Esq.
John Rah, Esq.
Epstein Becker & Green, P.C.

DATE

Stuart Gerson, Esq.
Epstein Becker & Green, P.C.

DATE

Corporate Integrity Agreement
Pfizer Inc



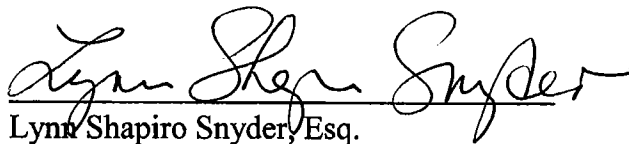
ON BEHALF OF PFIZER INC

Beth Levine, Esq.
General Counsel
U.S. Pharmaceuticals
Pfizer Inc

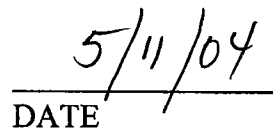
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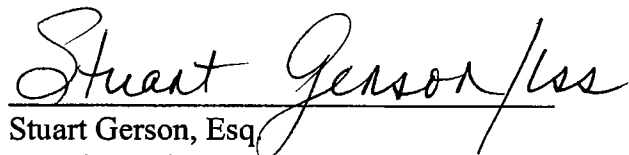
Douglas Lankler, Esq.
Deputy Compliance Officer
Pfizer Inc

DATE

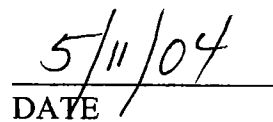


Lynn Shapiro Snyder, Esq.
John Rah, Esq.
Epstein Becker & Green, P.C.


DATE



Stuart Gerson, Esq.
Epstein Becker & Green, P.C.


DATE

Corporate Integrity Agreement
Pfizer Inc



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

Larry J. Goldberg

LARRY J. GOLDBERG
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

11 May 2004

DATE

**Attachment A to CIA for Pfizer Inc
Medicaid Rebate and Managed Care Contracting Engagements**

I. IRO Engagements, General Description

As specified more fully below, Pfizer shall retain an Independent Review Organization ("IRO") to perform engagements to assist Pfizer in assessing and evaluating its systems, processes, policies and practices related to the Medicaid Rebate Program and to Managed Care Contracting. Pfizer may engage, at its discretion, a single entity to perform the Medicaid Rebate Engagements and the Managed Care Contracting Engagements, provided that the entity has the necessary expertise and capabilities to perform both.

The Medicaid Rebate Engagement shall be a review of Pfizer's systems, processes, policies and practices (including the controls on those systems, processes, policies and practices) as they relate to the Medicaid Rebate Program. If there are no material changes in Pfizer's systems, processes, policies and practices during the term of the CIA, the IRO shall perform the Medicaid Rebate Engagement covering the first and fourth Reporting Periods. If Pfizer materially changes its systems, processes, policies and practices as they relate to the Medicaid Rebate Program, the IRO shall perform a Medicaid Rebate Engagement covering the Reporting Period in which such changes were made in addition to conducting the Medicaid Rebate Engagement for the first and fourth Reporting Periods.

The Managed Care Contracting Engagement shall be a review of documentation relating to Managed Care Related Expenditures associated with a sample of 20 Managed Care Customers. The Managed Care Contracting Engagement shall be conducted annually and shall cover each of the following periods ("Managed Care Contracting Review Periods"): 1) for the first year of the CIA, December 1, 2002, through the first anniversary of the Effective Date of the CIA; and 2) for the remaining years of the CIA, each successive Reporting Period.

A. Medicaid Rebate Engagement

1. General Description of Medicaid Rebate Engagement

For at least the first and fourth Reporting Periods, the IRO shall review Pfizer's systems, processes, policies and practices associated with the tracking of, gathering of, and appropriate accounting for all data relevant for purposes of calculating the Best Prices reported to the Centers for Medicare and Medicaid Services ("CMS").



In general terms, the IRO shall review the following:

a) what systems, processes, policies, and practices are in place to track, gather, and appropriately account for those contract terms with Managed Care Customers that are relevant to the Medicaid Rebate Program.

Specifically, this includes a review of:

1) the process used to determine whether discounts or rebates in Discount Agreements are included in the calculation of the Medicaid Best Price for any product (this includes: (a) a review of the data or information flow process by which relevant contract terms are included in or reflected in the calculation of the Medicaid Best Price; and (b) a review of any Pfizer inquiries to CMS regarding Medicaid Best Price and any responses to those inquiries);

2) the computer or accounting systems (e.g., the Government Pricing System ("GPS")) used to calculate the Medicaid Best Price; and

3) the policies and practices of the Government Contracts Group in examining GPS system reports for variations that require critical evaluation (including a review of the basis upon which variations are identified and the follow-up activities taken to identify the cause of the variations).

b) the effectiveness of the systems, processes, policies and practices to track, gather, and appropriately account for contract terms with Managed Care Customers that are relevant for Medicaid Rebate purposes (i.e., whether the systems, processes, policies and practices result in the inclusion of all appropriate and relevant contract terms in the calculation of the Medicaid Best Price).

2. Medicaid Rebate Engagement Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Medicaid Rebate Engagement. (This report may be combined with the report for the Managed Care Contracting Engagement.) Each report shall include the following items:

a) a description of the systems, processes, policies, and practices in place to track, gather, and appropriately account for those contract terms with Managed Care Customers that are relevant to the Medicaid Rebate Program;



b) a description of the documentation, information, and systems reviewed and the personnel interviewed, if any, including a description of Pfizer's inquiries to CMS regarding Medicaid Best Price and any responses to those inquiries; and

c) observations, findings, and recommendations on possible improvements to Pfizer's systems, processes, policies, and practices.

B. Managed Care Contracting Engagement

1. General Description of Managed Care Contracting Engagement

Pfizer's Policies and Procedures (referenced in section III.B.2. of the CIA) set forth certain requirements relating to promotional activities. For each Managed Care Contracting Review Period, the IRO shall examine the extent to which Area Managers are aware of Pfizer's policies and procedures relating to promotional activities directed at Managed Care Customers. For each Managed Care Contracting Review Period, the IRO also shall select and review Managed Care Related Expenditures to a randomly selected sample of 20 Managed Care Customers to assist Pfizer in assessing whether the requisite documentation relating to the Managed Care Related Expenditure exists and whether the documentation was completed in accordance with Pfizer's Policies and Procedures.

The following definitions apply for purposes of the Managed Care Contracting Engagement:

A "Managed Care Customer" is a for profit or not-for-profit entity: (a) whose principal business is managing or providing pharmacy and/or other healthcare benefits, including but not limited to health maintenance organizations, preferred provider organizations, and pharmacy benefit management companies; and (b) that has entered into a Discount Agreement with Pfizer that was in effect during the relevant Managed Care Contracting Review Period. The term "Managed Care Customer" does not include hospitals or health care providers.

A "Discount Agreement" is an agreement between Pfizer and a Managed Care Customer for discount payments made in connection with Pfizer pharmaceutical prescription products, and includes, but is not limited to, rebate agreements.

A "Managed Care Related Expenditure" is a payment by Pfizer to a Managed Care Customer made during the relevant Managed Care Contracting Review Period in connection with any corporate sponsorship or other promotional activities, including, but not limited to, the following types of activities: (a) speaker programs; (b) CME programs; (c) grants; (d) promotional or service programs (including, for example, speaker programs; patient information programs;

sponsorship of booths or displays; co-promotion information; disease management programs; compliance programs; and informational presentations); and, (e) charitable contributions.

2. Initial Engagement

a. Selection of Documentation for Managed Care Related Expenditures

For each Managed Care Contracting Engagement, the IRO shall obtain from Pfizer a listing of all its Managed Care Customers for the relevant Managed Care Contracting Review Period and shall randomly select 20 of those customers as the basis for the Engagement. Specific to the identified 20 Managed Care Customers, the IRO shall review any Discount Agreement(s) and documentation related to Managed Care Related Expenditures ("Control Documentation"). For example, the Control Documentation could include any expense report or check request reflecting any such expenditure to Managed Care Customers; grant request letters and other grant-related documents; CME agreements; certifications for non-CME educational activities, etc.

The Discount Agreement(s) and Control Documentation associated with each of the 20 Managed Care Customers shall be treated as a separate universe for purposes of this Engagement.

The IRO shall review all Discount Agreement (s) and Control Documentation for all Managed Care Related Expenditures. The Managed Care Related Expenditures shall be reviewed based on the supporting documentation available at Pfizer or under Pfizer's control.

b. Attributes to Be Tested

During each Managed Care Contracting Review Period, the IRO shall review each universe to assess:

1. whether the appropriate and requisite Control Documentation exists in connection with each Managed Care Related Expenditure. This includes a review of whether all required supporting documentation (e.g., receipts) and follow-up documentation (e.g., progress and final reports produced in connection with grants) exist in accordance with Pfizer's Policies and Procedures;
2. whether the Discount Agreement(s) and Control Documentation were completed in accordance with the requirements set forth in Pfizer's Policies and Procedures. This includes a review of whether

all required written approvals were obtained in accordance with Pfizer's Policies and Procedures; and,

3. whether any corrective action has been taken to comply with Pfizer's policies and procedures prior to IRO review of the relevant Managed Care Contracting Review Period.

The IRO shall review the Control Documentation using the criteria set forth above and shall identify any errors in the Control Documentation. The IRO shall identify both material and non-material errors in the Control Documentation. For purposes of the review, the Control Documentation will be found to have a Material Error if: 1) the appropriate and required Control Documentation does not exist and no corrective action has been taken prior to IRO review of the relevant Managed Care Contracting Review Period; or 2) information or data is omitted from key fields in the documentation that restricts the IRO's ability to understand the nature of the expenditure or activity and/or assess compliance with Pfizer's Policies and Procedures and no corrective action has been taken prior to IRO review of the relevant Managed Care Contracting Review Period. All other errors shall be considered non-material.

3. Additional Engagement if Material Errors Rates Are Discovered

In instances in which the IRO finds Material Errors, it shall conduct an Additional Engagement of the expenditures or activities reflected in the erroneous Control Documentation. The IRO shall perform this Additional Engagement in a manner designed to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the errors.

4. Documentation Engagement Report

The IRO shall annually prepare a report based upon each Managed Care Contracting Engagement performed. Each report shall include the following:

a. Elements to Be Included:

1. Managed Care Contracting Engagement Objectives: A clear statement of the objectives intended to be achieved by the review;
2. Engagement Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit and universe utilized in performing the procedures; and



3. Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Managed Care Contracting Engagement.

b. Results to Be Included:

The following results shall be included in each Managed Care Contracting Engagement Report:

1. for each universe of Control Documentation, the IRO shall describe, in general terms, the terms of any contract(s) and the types of expenditures made in connection with the Managed Care Customer during the Managed Care Contracting Review Period;
2. for each universe of Control Documentation, the IRO shall describe the procedures performed and state its findings and supporting rationale as to whether: a) appropriate and requisite Control Documentation exists in connection with each Managed Care Related Expenditure; and b) the Control Documentation was completed in accordance with the requirements set forth in Pfizer's Policies and Procedures;
3. for each universe of Control Documentation reviewed, the IRO shall identify all Material and non-material errors discovered. For the non-material errors, the IRO shall describe, in general terms, what the errors were. The IRO shall describe those situations when corrective action was taken prior to IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action;
4. if any Material Errors were discovered, the IRO shall describe the error and the Additional Engagement procedures it performed, and shall state its findings as to the root cause of the Material Errors; and
5. the findings regarding awareness of Area Managers of policies and procedures regarding promotional activities and a description of the methodology used to achieve those findings.



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Attachment B

Certification for CIA with Pfizer Inc

CERTIFICATION

In accordance with the Corporate Integrity Agreement (“CIA”) entered between Pfizer Inc (Pfizer) and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information and belief:

- 1) Pfizer has in place policies and procedures describing in all material respects the methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (“CMS”) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program (“Medicaid Rebate Policies and Procedures”);
- 2) the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with Pfizer’s obligations under the Medicaid Drug Rebate Program; and,
- 3) Pfizer’s Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Best Price for Pfizer’s products for each of the following four quarters: [identify each specific quarter.]

Signature
[Insert Name and Title]
Compliance Officer

Date



**Attachment C to CIA for Pfizer Inc
Promotional and Product Services Engagement**

I. IRO Engagement, General Description

As specified more fully below, Pfizer shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist Pfizer in assessing and evaluating its systems, processes, policies, and procedures related to sales, marketing, and product services activities (Promotional and Product Services Engagement). The Promotional and Product Services Engagement shall consist of two components - a systems review (the Promotional and Product Services Systems Review) and a transactions review (the Promotional and Product Services Transaction Review), as described more fully below. Pfizer may engage, at its discretion, a single entity to perform both components of the Promotional and Product Services Engagement, provided that the entity has the necessary expertise and capabilities to perform both.

The Promotional and Product Services Systems Review shall be a review of Pfizer's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to sales, marketing, and product services activities. If there are no material changes in Pfizer's applicable systems, processes, policies, and procedures during the term of the CIA, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If Pfizer materially changes its systems, processes, policies, and procedures relating to sales, marketing, and product services activities, the IRO shall perform a Promotional and Product Services Review Engagement covering the Reporting Period in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods.

The Promotional and Product Services Transactions Review shall include two elements: 1) reviews of samples of Control Documents, as defined below in Sections III.A-B; and 2) interviews with sales representatives, supervisory personnel and others as necessary to investigate any Material Errors. Pfizer represents that it is modifying the internal systems (USMI 30 and BETSY, discussed below) that will serve as the basis for the Transactions Review. To allow time for the modifications to be completed, the Promotional and Product Services Transactions Review shall be performed on an annual basis for the second through fifth Reporting Periods.



II. Promotional and Product Services Systems Review

A. General Business Policies and Practices for Review

For at least the first and fourth Reporting Periods¹, the IRO shall review Pfizer's systems, processes, policies, and procedures associated with the following (General Business Practices and Policies):

1) Pfizer's systems, policies, processes, and procedures applicable to personnel in USP Sales in connection with their handling of requests or inquiries they may receive relating to off-label uses of products and in connection with their dissemination of information, if any, relating to off-label uses;

2) Pfizer's systems, policies, processes, and procedures through which requests and inquiries from HCPs and/or USP Sales relating to off-label uses of products are to be handled by the Medical Information Department (including a review of the manner in which the Medical Information Department receives and responds to such requests, the form and content of information disseminated by the Medical Information Department, and the internal review process for the information disseminated). The IRO shall also review the manner and circumstances under which members of the Medical Information Department accompany or participate with sales representatives in meetings or events with physicians or other HCPs (including detailing visits), if any, and the role of the Medical Information Department personnel at such meetings or events;

3) Pfizer's systems, policies, processes, and procedures relating to consulting arrangements or other contracts initiated by either Cluster A or Cluster X personnel of USP Sales and entered with HCPs. This shall include a review of:

¹The Promotional and Product Services Systems Review for the first Reporting Period shall only cover the last nine months of the first Reporting Period to allow time for Pfizer to modify its internal systems relevant to this Review.



- (i) the criteria used to determine whether, how many, and under what circumstances and venue such contracts will be entered and performed;
- (ii) the processes and criteria used to identify and select which HCPs with whom Pfizer enters consultant or other contractual arrangements;
- (iii) Pfizer's tracking or monitoring of services provided or the work performed by the consultants (including the receipt of the consultants' work product, if any);
- (iv) the uses made of work product received from consultants or other contractors if any;
- (v) Pfizer's processes for establishing the rates paid to HCPs and the reasons or justifications for any differentials in the amounts paid to different HCPs;
- (vi) whether and in what manner USP Sales tracks or monitors the prescribing habits or product use of individuals or entities with whom it enters consulting or other contractual arrangements, if any; and
- (vii) the budget funding source within Pfizer (*e.g.*, department or division) for the consulting or contractual arrangement;

4) Pfizer's systems, policies, processes, and procedures relating to grants or charitable contributions initiated by either Cluster A or Cluster X personnel of USP Sales. This review shall include a review of the following items:

- (i) the processes and procedures used to approve grants or charitable contributions that are followed by personnel in Cluster A and Cluster X of USP Sales and the Grants Committee;
- (ii) the criteria used to determine whether and under what circumstances the funding will be provided;
- (iii) the processes and criteria used to approve recipients of the funding from Pfizer;
- (iv) Pfizer's policies and procedures for requiring the recipient or the recipient's agent to disclose Pfizer's support of the funding and any financial relationship Pfizer may have with the speakers, faculty, or other participants;



- (v) Pfizer's policies or procedures for seeking and memorializing the amounts paid to funding recipients and the purpose or justifications for the amounts paid;
- (vi) Pfizer's policies and procedures relating to the independence of the programs sponsored through the funding;
- (vii) Pfizer's policies and procedures relating to the content and balance of the programs sponsored through the funding;
- (viii) whether and in what manner USP Sales tracks or monitors the prescribing habits or product use of individuals or entities receiving the funding, if any; and
- (ix) the budget funding source within Pfizer (*e.g.*, department or division) for the funding provided;

5) Pfizer's systems, policies, processes, and procedures relating to how personnel in Cluster A or Cluster X of USP Sales handle or respond to requests or inquiries from any HCPs or institutions regarding the possibility of participating in a Pfizer-sponsored clinical trial or the possibility of Pfizer sponsorship of independent research, including the referral of any such requests or inquiries to other components of Pfizer;

6) Pfizer's general policies, processes, and procedures relating to advisory board arrangements or relationships entered between Pfizer and HCPs. Specifically, through a review of Pfizer's policies and discussions with key personnel, the IRO shall seek to verify that advisory board arrangements that are entered in connection with the promotion of Pfizer products and that are handled by USP Marketing at Pfizer's headquarters, are reviewed by the appropriate Review Committees, which include a representative from the Pfizer Legal Division;

7) Pfizer's systems, policies, processes, and procedures relating to its internal system for tracking and budgeting promotional programs (BETSY), including: i) the manner and processes through which information is input, maintained, and updated in BETSY; ii) the controls and approval processes relating to requested financial programs or relationships; iii) the exceptions processes in BETSY; and iv) a verification that a sales representative may only initiate and fund financial programs or relationships with HCPs through BETSY as described below in Section III.B, and that, with the exception of funding for exhibits and displays, BETSY does not provide a



mechanism for sales representatives to initiate funding for other types of financial activities with HCPs, including advisory board arrangements;

8) Pfizer's systems, policies, processes, and procedures relating to its internal systems associated with USMI 30 and the Sales QA Alert Policy, including: (i) the manner and process through which requests for medical information are suspended based upon a QA Alert generated by Pfizer's USMI 30 inquiry management system; and (ii) the follow-up activities required by USMI 30 and the Sales QA Alert Policy for all such suspended requests, including any appropriate disciplinary action;

9) Pfizer's policies, processes, and procedures relating to the disciplinary actions that Pfizer may impose in the event a Covered Person violates a Pfizer policy or procedure; and

10) Pfizer's systems, policies, processes and procedures for compensating (including with salaries and bonuses) non-Overtime Eligible employees in Cluster A and Cluster X of USP Sales. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance.

B. Promotional and Product Services Systems Review Report

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

- a) a description of the documentation (including policies) reviewed and any personnel interviewed;
- b) a detailed description of Pfizer's systems, policies, processes, and practices with regard to the items identified in Sections II.A.1-6 above, including a general description of Pfizer's control and accountability systems (*e.g.*, documentation and approval requirements, tracking mechanisms) and written policies regarding the General Business Practices and Policies reviewed;



- c) 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.1-6 above are made known or disseminated within Pfizer;
- d) a detailed description of BETSY, USMI 30 and the Sales QA Alert Policy, including copies of USMI 30 and the Sales QA Alert Policy, and a description of the items enumerated in section II.A.7 and 8 above;
- e) a general description of the disciplinary measures Pfizer has established for failure to comply with its systems, processes, policies and procedures relating to the General Business Practices and Policies reviewed;
- f) a detailed description of Pfizer's compensation system (including salaries and bonuses) for non-Overtime Eligible employees in Cluster A and Cluster X of USP Sales, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Pfizer may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
- g) findings and supporting rationale regarding any weaknesses in Pfizer's promotional and product services related systems, processes, policies, and practices reviewed, if any; and
- h) recommendations to improve any of the reviewed promotional and product information related systems, policies, processes, or practices, if any.

Prior to the IRO's submission of the report to the OIG, Pfizer shall be provided with a copy of the report and an opportunity to respond to each comment made by the IRO. Provided it does not delay the timely filing of the Annual Reports, any responses by Pfizer may be included in the IRO report submitted to the OIG. Otherwise, any responses by Pfizer to the IRO's findings may be submitted separately to the OIG following the Annual Report submission.



III. Promotional and Product Services Transactions Review

The IRO shall conduct a Promotional and Product Services Transactions Review for each of the last four Reporting Periods (*i.e.*, for Reporting Periods two through five). The Transactions Review shall include two general elements: (1) reviews of samples of USMI 30 Control Documents and Promotional Activities Control Documents as defined below; and (2) interviews with sales representatives, contract sales representatives, managers, and other supervisory personnel relating to any identified Material Errors.

A. USMI 30 Transactions Review

1) Background on USMI 30 and Related Policies

Prior to the Effective Date, Pfizer voluntarily implemented policies and procedures that Pfizer's U.S. Medical Information Department (USMI) utilizes to help Pfizer ensure that requests Pfizer receives from HCPs are unsolicited. Generally, this policy, referred to as USMI 30, establishes a process whereby USMI investigates and handles alerts that are generated by an inquiry management system used by Pfizer's USMI. These alerts, referred to as QA Alerts, are generated by the inquiry management system under certain circumstances, including when the number of medical inquiries received from a Pfizer sales representative exceeds certain frequency thresholds. When the appropriate circumstances are met, including when certain frequency thresholds are exceeded (as set forth in USMI 30), USMI 30 requires USMI to:

- a) suspend all pending medical information requests received from the identified sales representative;
- b) conduct certain follow-up activities with managers from the sale force before such medical information requests are fulfilled; and
- c) in connection with this follow-up activity, create and maintain certain documents, including, but not limited to, a spreadsheet of potential suspected unsolicited request for medical information, e-mails to relevant district manager or regional managers, and documentation from district managers or regional managers regarding potentially unsolicited requests for medical information.

A corresponding policy exists for Pfizer's sales force, and it is referred to as Sales QA Alert Policy. Similar to USMI 30, such policy requires sales force management to:



- a) conduct certain follow-up activities with managers from the sale force before such medical information requests are fulfilled; and
- b) in connection with this follow-up activity, create and maintain certain documents, including, but not limited to, e-mails and other documentation regarding potentially unsolicited requests for medical information.

Together, USMI 30 and the Sales QA Alert Policy assist Pfizer in determining whether or not the requests for medical information from the HCP were unsolicited.

Pursuant to USMI 30, all medical information requests that are still pending following the generation of a QA Alert will be suspended until the requirements of Sales QA Alert Policy are satisfied. If it is ultimately determined that the requests were unsolicited, then USMI will fulfill the suspended requests. If it is ultimately determined that the requests were not unsolicited, USMI will not fulfill these requests and certain disciplinary action will be taken, as appropriate to the circumstances and in accordance with Pfizer's policies.

2) Selection of USMI 30 Control Documents for Review

The IRO shall obtain from Pfizer a listing of all the QA Alerts that occurred during the relevant Reporting Period. For each relevant Reporting Period, the IRO shall randomly select 20 QA Alerts or an amount equal to 10 percent (10%) of the QA Alerts, whichever is greater, as the basis for this portion of the Transactions Review. Specific to the selected QA Alerts, the IRO shall review all Control Documents required by USMI 30 and the Sales QA Alert Policy (collectively, "USMI 30 Control Documents") that may relate to these QA Alerts that were generated during the relevant Reporting Period. The IRO shall evaluate whether such USMI 30 Control Documents were created and maintained in accordance with USMI 30 and the Sales QA Alert Policy.

For purposes of the USMI 30 Transaction Reviews, USMI 30 Control Documents shall be those documents that are required pursuant to USMI 30 and the Sales QA Alert Policy. USMI 30 Control Documents shall include, but not be limited to, the QA Alerts, the QA Alert Spreadsheet and all necessary documents, correspondence, written explanations, and records of disciplinary action as required by USMI 30 and the Sales QA Alert Policy.



3) Identification of Material Errors and Additional Review

The IRO will find there to be a Material Error in connection with a QA Alert and shall note such Material Errors, if either of the following is identified:

- a) a USMI 30 Control Document does not exist and through follow-up the IRO is unable to determine that: (i) corrective action was taken prior to the IRO review, or (ii) that Pfizer otherwise followed its USMI 30 and/or the Sales QA Alert Policy; or
- b) a review of all Control Documents and any other relevant documentation indicates that the USMI 30 and/or Sales QA Alert Policy and procedures were not followed.

If a USMI 30 Control Document does not exist or is misplaced but Pfizer has taken corrective action prior to the IRO review, or the IRO can otherwise determine the USMI 30 and/or the Sales QA Alert Policy was followed, the IRO shall not consider this to be a Material Error, but rather an exception and it shall be reported as such.

If the IRO finds any Material Errors, it shall conduct an Additional Engagement to review the activities reflected in the erroneous USMI 30 Control Documents. The IRO shall perform this Additional Engagement in a manner designed to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation or conduct interviews with appropriate personnel to identify the root cause of the errors.

B. Promotional Activities Transactional Review

1) Background on BETSY and Related Policies

Pfizer has developed policies and procedures relating to financial programs or relationships with HCPs that may be initiated by personnel in Cluster A and Cluster X of USP Sales. These policies and procedures are included in Pfizer's "Rules and Regulations: Field Guide" (referred to hereafter as the "Orange Book.") Pfizer has disseminated the Orange Book to personnel in Cluster A and Cluster X of USP Sales, and Pfizer has provided training on the Orange Book to all relevant personnel. Pfizer has also implemented a computer system through which information and documentation relating to the financial programs or relationships that may be initiated by personnel in Cluster A and Cluster X is tracked and the budgeting for such arrangements is handled (hereafter



“BETSY”). Pfizer has represented that all financial programs or relationships with HCPs that may be initiated by personnel in Cluster A and Cluster X are initiated, budgeted, and tracked through the BETSY system.

More specifically, BETSY is used to initiate, budget, and track the following types of financial programs or relationships (hereafter “Promotional Activities”):

- c) Speaker Programs. Sales representatives may request funding for speaker programs. Three general types of speakers programs are tracked in BETSY: (i) in-person speaker programs; (ii) speaker programs by teleconference (*i.e.*, Telenet); and (iii) one-on-one sales representatives mentor programs. BETSY tracks Pfizer’s expenditures for honoraria paid to approved speakers and expenditures for travel expenses generated by approved speakers for these speaker programs;
- d) Grants. Sales representatives may request educational grant funding for activities in four broad categories: (i) CME by accredited providers; (ii) non-CME physician education; (iii) patient or community education; and (iv) disease screening; and
- e) Charitable contributions. Sales representatives may request funding for contributions to charitable organizations. Pfizer defines such donations to be contributions made to a charitable organization (as that term is defined in Section 501(c)(3) of the Internal Revenue Code.)

2) Description of Promotional Activities Control Documents

Promotional Activities Control Documents shall be those documents associated with or reflecting expenditures for the financial programs outlined in Section III.B.1 above that are initiated by sales representatives in PD2, Vista, Neurology Alliance and Endocrine Care (the “Designated Sales Force”). As soon as practicable after any such change occurs, Pfizer shall notify the OIG of any material changes in the following items, which material change would effect any of the following items as they existed on the Effective Date: (i) the headcount for Cluster A and Cluster X; (ii) the headcount for the Designated Sales Force; and (iii) the key product responsibilities for the Designated Sales Force. The OIG and Pfizer shall discuss what, if any, changes shall be made to Attachment C as a result of any material change as outlined above.



Promotional Activities Control Documents shall include reports generated through BETSY and all documents required by the Orange Book or any other relevant Pfizer policy in connection with financial program or relationship initiated, tracked, or budgeted through BETSY, except for funding for exhibits and displays. Control Documents include, but are not limited to, CME and non-CME agreements; speaker agreements, grant request letters on the requestor's letterhead, documents demonstrating that the event occurred, *etc.*

3) Reviews of Promotional Activities Control Documents

The IRO also shall review and evaluate the Control Documents associated with each of the following samples of Promotional Activities. For Speaker Programs, the IRO shall review Control Documents associated with one hundred (100) engagements, which shall consist of a review of (i) seventy-five (75) Speaker Programs for speakers that were recommended by a Pfizer sales representative and activated into the BETSY speakers bureau during the relevant Reporting Period and used during the relevant Reporting Period, and (ii) twenty-five (25) Speaker Programs for speakers that already were activated within the BETSY speakers bureau prior to the start of the relevant Reporting Period and used during the relevant Reporting Period.

For Grants, the IRO shall review Control Documents associated with fifty (50) Grants, which shall consist of a review of: (i) twenty (20) non-CME Grants in excess of \$10,000, (ii) ten (10) CME Grants in excess of \$10,000, (iii) six (6) non-CME Grants between \$3,000 and \$10,000, (iv) four (4) CME Grants between \$3,000 and \$10,000, (v) six (6) non-CME Grants under \$3,000, and (vi) four (4) CME Grants under \$3,000.

For Charitable Contributions, the IRO shall review Control Documents associated with ten (10) Charitable Contributions.

For Mentorships, the IRO shall review Control Documents associated with thirty (30) Mentorships.

For Telenets, the IRO shall review Control Documents associated with ten (10) Telenets.

The IRO shall review the Control Documents associated with each selected sample of Promotional Activities to evaluate the following:

- a) for each Promotional Activity reviewed, whether all required Control Documents (*e.g.*, grant request letters and letters sent in connection with grant checks) exist in accordance with Pfizer's policies;



- b) whether the Promotional Activities Control Documents were completed and archived in accordance with the requirements set forth in Pfizer's policies; and
- c) whether the Promotional Activities Control Documents reflect that all required written approvals were obtained in accordance with Pfizer's policies.

4) Identification of Material Errors and Additional Engagement

The IRO will find there to be a Material Error for a transaction and shall note such Material Errors, if any of the following is identified:

- a) a Promotional Activities Control Document does not exist and through follow-up the IRO is unable to determine that: (i) corrective action was taken prior to the IRO review, or (ii) that Pfizer otherwise followed its Promotional Activities Policies and Procedures; or
- b) information or data is omitted from key fields in the Promotional Activities Control Documents that prevents the IRO from verifying compliance with Pfizer's policies and procedures; or
- c) a review of all the Control Documents and any other relevant documentation indicates that Pfizer's policies related to its Promotional Activities were not followed.

If a Promotional Activities Control Document does not exist or is misplaced but Pfizer has taken corrective action prior to the IRO review, or the IRO can otherwise determine that the Promotional Activities policies were followed, the IRO shall not consider this to be a Material Error, but rather an exception and it shall be reported as such.

If the IRO finds any Material Errors, it shall conduct an Additional Engagement to review the transaction reflected in the erroneous Promotional Activities Control Documents. The IRO shall perform this Additional Engagement in a manner designed to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the errors.

C. Promotional and Product Services Transactions Review Report

Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services Transactions Review. The report shall be organized into two parts, one each relating to: (1) USMI 30 Transaction Review, and (2) BETSY Transaction Review. Both parts, where applicable, shall include the following:

1. Elements to Be Included:



- d) Promotional and Product Services Transactions Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
- e) Engagement Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit and universe utilized in performing the procedures for each review; and
- c) Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Promotional and Product Services Transactions Reviews.

2. Results to Be Included:

The following results shall be included in both the USMI 30 and the BETSY portions of the Promotional and Product Services Transactions Reports:

- a) a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (*e.g.*, for the various types of speaker programs, grants, and charitable contributions) and an identification of the types of Control Documents reviewed for each type of sample unit;
- b) for each sample unit, the IRO shall state its findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed and archived in accordance with all requirements set forth in the applicable Pfizer's policy; (iii) 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 (iv) any disciplinary action was taken in those instances in which a Pfizer policy was not followed;
- c) for each sample unit reviewed, the IRO shall identify all exceptions discovered. For the exceptions, the IRO shall describe in general terms what the errors were. The IRO shall describe those situations where corrective action was taken prior to the IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- d) for each sample unit reviewed, the IRO shall identify any Material Errors were discovered. For the Material Error, the IRO shall describe the Material Error in detail and shall describe the additional review procedures it performed. The IRO shall state its findings as to the root cause of each Material Error(s);
- e) the IRO's recommendations, if any, for changes in Pfizer's systems, processes, policies, and practices, in order to correct or address any



weaknesses or deficiencies uncovered during the Transactions Review. The IRO shall provide findings and supporting rationale for any such recommendations.

A handwritten signature in black ink, consisting of stylized, cursive letters that appear to be 'JSS'.