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

I. PREAMBLE

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

Prior to the Effective Date, Pfizer established a compliance program that Pfizer represents addresses all seven elements of an effective compliance program and that is designed to address compliance with Federal health care program requirements (Compliance Program). Pfizer shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Pfizer may modify the Compliance Program as appropriate. However, at a minimum, Pfizer shall ensure that during the term of this CIA, it shall maintain a compliance program to comply with the obligations set forth 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. 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."

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

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

1. "Covered Persons" includes:

a. all owners of Pfizer who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading);

b. all officers and directors of Pfizer;

c. all U.S. employees of Pfizer who engage in or supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.5); and

d. all U.S. contractors, subcontractors, agents, and other persons (including contract sales personnel) who perform any of the Covered Functions on behalf of Pfizer and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), consumers or independent third-party patient assistance programs; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a Pfizer employee who is a Covered Person prior to execution or dissemination.

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 perform a Covered Function for Pfizer more than 160 hours per year, except that any such individual shall become a "Covered Person" at the point when they work more than 160 hours on a Covered Function for Pfizer during the calendar year.

2. "Government Reimbursed Products" refers to all Pfizer products that are: (a) marketed or sold by Pfizer in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

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

4. The term "Patient Assistance Related Functions" includes: all activities, systems, processes, and procedures relating to the following: (a) any grants, charitable contributions, or cash or in kind donations provided by Pfizer or any entity acting on behalf of Pfizer to any independent third-party patient assistance program (Independent Charity PAP) (collectively, "Independent Charity PAP Related Functions"); and (b) the operation of, or participation in, any patient assistance program by Pfizer or any entity acting on behalf of Pfizer that provides free drugs to patients, including Federal health care program beneficiaries (i.e, Pfizer's internal free drug program) or programs to provide financial assistance to patients in the form of cost-sharing assistance (i.e., co-pay coupons or co-pay cards) (programs described under Section II.C.4.b shall be collectively referred to as "Pfizer PAPs").

5. The term "Covered Functions" refers to "Promotional Functions" and "Patient Assistance Related Functions," collectively.

6. The term "Third Party Personnel" refers to personnel who engage in Promotional Functions who are employees of entities with which Pfizer has entered or may in the future (during the term of this CIA) enter into agreements to promote or co-promote a Government Reimbursed Product or to engage in joint promotional activities relating to such a product. Pfizer represents that: (1) Third Party Personnel are employed by entities other than and independent of Pfizer; (2) Pfizer does not control Third Party Personnel; and (3) it would be commercially impractical to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Pfizer agrees to promote compliance by Third Party Personnel with Federal health care program requirements by complying with the provisions set forth below in Sections III.C.4, V.A.7, and V.B.6. Provided that Pfizer complies with the requirements of Sections III.C.4, V.A.7, and V.B.6, Pfizer shall not be required to fulfill the other CIA obligations that

would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations.

1. *Compliance Officer*. To the extent not already accomplished, within 90 days after the Effective Date, Pfizer shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Pfizer; shall report directly to the Chief Executive Officer of Pfizer; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Pfizer. The Compliance Officer shall be responsible for, without limitation:

a. 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;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Regulatory and Compliance Committee of the Board of Directors of Pfizer and shall be authorized to report on such matters to the Regulatory and Compliance Committee at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by Pfizer as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee*. To the extent not already accomplished, within 90 days after the Effective Date, Pfizer shall appoint a Compliance Committee. 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 sales, marketing, legal, medical affairs/medical information, regulatory affairs, human resources, audit, finance, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Pfizer's risk areas and shall oversee compliance monitoring and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations*. The Regulatory and Compliance Committee of the Pfizer Board of Directors (RCC) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The RCC must include independent (i.e., non-executive) members.

The RCC shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Pfizer's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken,

such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each individual member of the RCC, summarizing its review and oversight of Pfizer's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

> "The Regulatory and Compliance Committee of the Pfizer Board of Directors (RCC) has made a reasonable inquiry into the operations of Pfizer's Compliance Program during the preceding twelve-month period including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the RCC has concluded that, to the best of its knowledge, Pfizer has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

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

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

4. *Management Certifications*: In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Pfizer employees (Certifying Employees) are specifically expected to supervise and oversee activities within their areas of authority and shall annually certify that the applicable Pfizer business unit is compliant with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Vice President, Corporate Responsibility; Regional President North America,

Vaccines; Regional President North America, Oncology; Regional President North America, Inflammation & Immunology; Regional President North America, Rare Disease; Regional President North America, Internal Medicine; US President, Retail; US President, Institutions; and Vice President, US Payer Channel & Access Lead. For each Reporting Period, each Certifying Employee shall sign a certification that states:

> "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Pfizer policies, and I have taken steps to promote such compliance. To the best of my knowledge, the _____ [insert name of department or functional area] of Pfizer is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, Pfizer shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards.

Within 120 days after the Effective Date, Pfizer shall implement written policies and procedures regarding the operation of its compliance program in the United States, including the compliance program requirements outlined in this CIA and Pfizer's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Pfizer shall enforce its Policies and Procedures and shall make such compliance an element in evaluating the performance of all employees.

The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

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

b. arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs. These Policies and Procedures shall be designed to ensure that Pfizer's arrangements and interactions comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Pfizer's arrangements and interactions (including donations and sponsorship) comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to, the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014);

c. the operation of, or participation in, any Pfizer PAP. These Policies and Procedures shall be designed to ensure that Pfizer's operation of or in participation in such programs complies with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Pfizer's operation of or participation in any such Pfizer PAP complies with all guidance issued by OIG relating to assistance provided to patients by pharmaceutical manufacturers to reduce or eliminate the cost of copayments for drugs, including but not limited to, the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014);

d. the materials and information that may be distributed by appropriate Pfizer personnel about Independent Charity PAPs or Patient Assistance Related Functions and the manner in, and circumstances under, which appropriate Pfizer personnel may respond to request for information about Independent Charity PAPs or Patient Assistance Related Functions; and

e. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute and the False Claims Act; and (ii) applicable Food and Drug Administration (FDA) requirements.

At least annually (and more frequently, if appropriate), Pfizer shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Training Plan.* Within 90 days after the Effective Date, Pfizer shall develop a written plan (Training Plan) that outlines the steps Pfizer will take to ensure that: (a) all Covered Persons receive at least annual training regarding Pfizer's CIA requirements and Compliance Program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all Pfizer Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the training session(s), schedule for training, and format of the training. Pfizer shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *RCC Training*. Within 90 days after the Effective Date, Pfizer shall provide at least two hours of training to each member of the RCC. This training shall

address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the compliance program. Specifically, the training shall address the unique responsibilities of health care board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the RCC and should include a discussion of OIG's guidance on board member responsibilities.

New members of the RCC shall receive the RCC Training described above within 30 days after becoming an RCC member or within 90 days after the Effective Date, whichever is later.

3. *Training Records*. Pfizer shall make available to OIG, upon request, training materials and records verifying that Covered Persons and RCC members have timely received the training required under this section.

4. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Pfizer shall send a letter, either in hard copy or electronic form, to each entity employing Third Party Personnel. The letter shall outline Pfizer's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of the Pfizer Compliance Program. Pfizer shall attach or otherwise make available a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make Pfizer's Code of Conduct and a description of the Pfizer Compliance Program available to its Third Party Personnel; or (b) represent to Pfizer that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

D. Risk Assessment and Internal Review Process.

Within 120 days after the Effective Date, Pfizer shall develop and implement a centralized annual Risk Assessment and Internal Review Process to identify and address risks associated with each of Pfizer's Government Reimbursed Products and with applicable Federal health care program requirements. The Risk Assessment and Internal Review Process shall require compliance, legal, and department leaders at least annually, to: (1) identify and prioritize risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products and risks associated with Pfizer's operation of any Patient Assistance Related Function and

the company's arrangements and interactions with any Independent Charity PAPs, (2) develop mitigation plans in response to the results of risk assessments performed, and (3) track the implementation of the mitigation plans in order to assess the implementation, status, or effectiveness of such plans. Pfizer shall maintain the Risk Assessment and Internal Review Process for the term of the CIA.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Pfizer shall engage an entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: Systems Reviews and Transactions Reviews relating to the Covered Functions. The Systems Reviews shall assess Pfizer's systems, processes, policies, and procedures relating to the Covered Functions. Except as otherwise set forth in Appendix B, if there are no material changes in Pfizer's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If Pfizer materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

The Transactions Reviews shall be performed for the second through fifth Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

In addition, as set forth in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of Pfizer identified by OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, OIG will consult with Pfizer and may consider internal audit and monitoring work conducted by Pfizer, the Government Reimbursed Product portfolio, the nature and scope of Pfizer's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

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

OIG shall notify Pfizer of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Pfizer shall submit an audit work plan to OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by OIG.

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

4. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to Pfizer a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A. The IRO's certification shall include a summary of current and prior engagements between Pfizer and IRO.

F. Disclosure Program.

Within 90 days after the Effective Date, Pfizer shall establish a Disclosure Program in the United States 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 requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Pfizer shall appropriately publicize the existence of the Disclosure Program and 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. The Disclosure Program also shall include a requirement that all of Pfizer's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Division or appropriate individual(s) designated by Pfizer. 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 it obtains all necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, 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 and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a 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.

G. Ineligible Persons.

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

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

i. is currently excluded from participation in the Federal health care programs; or

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

b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

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

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

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

c. Pfizer shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Pfizer's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. Pfizer understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Pfizer may be liable for overpayments and/or criminal, civil, and

administrative sanctions for employing or contracting with an excluded person regardless of whether Pfizer meets the requirements of Section III.G.

3. *Removal Requirement*. If Pfizer has actual notice that a Covered Person has become an Ineligible Person, Pfizer shall remove such Covered Person from responsibility for, or involvement with, Pfizer's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

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

H. Notification of Government Investigation or Legal Proceeding.

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

I. Reportable Events.

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

a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable

to any Federal health care program for which penalties or exclusion may be authorized;

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

c. the filing of a bankruptcy petition by Pfizer.

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

2. *Reporting of Reportable Events*. If Pfizer determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Pfizer shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. Pfizer shall not be required to report as a Reportable Event a matter that is the subject of an ongoing investigation or legal proceeding by a government entity or its agents if disclosed under Section III.H above.

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

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws probably violated by the Reportable Event;

c. the Federal health care programs affected by the Reportable Event; and

d. a description of Pfizer's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.I.1.b.* For Reportable Events under Section III.I.1.b, the report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion List screening that Pfizer completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Ineligible Person was identified; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

J. Independent Charity Patient Assistance Program Activities

To the extent that Pfizer makes monetary donations to Independent Charity PAPs, Pfizer shall implement the policies and practices set forth in this Section III.J within 120 days after the Effective Date.

1. Role and Responsibilities of Independent Charity Group. Pfizer shall vest sole responsibility and authority for developing the annual budget for Pfizer's donations to Independent Charity PAPs and for all other activities relating to Pfizer's donations to Independent Charity PAPs (including interactions with such PAPs) in a department or group within Pfizer known as the "Independent Charity Group. The Independent Charity Group shall be separate and independent from the commercial business units of Pfizer (referred to hereafter as the "commercial business units"). For purposes of this CIA, the commercial business units are the business units responsible for engaging in the sales and

marketing of Pfizer's Government Reimbursed Products. The Independent Charity Group shall operate independently from Pfizer's commercial business units. Pfizer's commercial business units shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to Pfizer's donations to Independent Charity PAPs. Nothing in this provision limits the ability of Pfizer Executive Leadership Team (ELT) members to review, approve, and adjust the total amount available for donations in accordance with Pfizer's policies and procedures.

2. Communications Regarding Pfizer's Donations to Independent Charity PAPs. Pfizer shall vest in the Independent Charity Group sole responsibility and authority for communicating with Independent Charity PAPs regarding Pfizer's donations to such PAPs. The commercial business units shall not communicate with, influence, or be involved in any communications with, or receive information from Independent Charity PAPs.

3. Budgeting Process. Pfizer shall establish a budget process to be followed for Pfizer's donations to Independent Charity PAPs. The Independent Charity Group shall develop the annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the legal department with input from the legal and compliance departments. The commercial business units shall have no involvement in the budget or allocation process, and the budget to be used for donations to Independent Charity PAPs shall not be based on monies allocated to the Independent Charity Group from the commercial business units. The ELT (or a subset thereof) shall approve the total annual amount available for donations to Independent Charity PAPs. After the total annual amount is approved, the Independent Charity Group shall have sole responsibility for allocating the approved amount across donations to Independent Charity PAPs and to any disease state fund established by the Independent Charity PAP.

The Independent Charity Group shall have sole responsibility for handling requests for additional or supplemental funding from Independent Charity PAPs outside of the annual approved amount and for requesting additional funding and seeking approval from the ELT (or a subset thereof), for donations to Independent Charity PAPs outside of the annual approved amount. Such requests shall be assessed against objective criteria established by the Independent Charity Group. Pfizer legal and compliance personnel shall also be involved in the review and approval of requests for additional or supplemental funding. The purpose of this review shall be to ensure that any

supplemental funding to the Independent Charity PAP is provided in accordance with applicable Federal health care program requirements, OIG guidance, and Pfizer policies and procedures.

4. Criteria Relating to Donations to Independent Charity PAPs. The Independent Charity Group (with input from the legal and compliance departments) shall establish objective written criteria that govern donations to Independent Charity PAPs and any specific disease state funds of such PAPs. The criteria shall be designed to ensure compliance with Federal health care program requirements and OIG guidance.

Pfizer's Independent Charity Group shall gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the independent charity or over its assistance program. Pfizer shall not influence or attempt to influence, directly or indirectly, the identification, delineation, establishment, or modification of, or the parameters relating to, any disease fund by the Independent Charity PAP.

Personnel from Pfizer's legal and compliance departments shall review all proposed donations and arrangements between Pfizer and any Independent Charity PAP. Pfizer shall not make any donations to any Independent Charity Group or to any disease state fund of an Independent Charity PAP until after the legal and compliance review has occurred.

Pfizer agrees that it will donate to an Independent Charity PAP only if the following criteria are satisfied:

a. Pfizer does not and shall not exert (directly or through any affiliate) any influence or control over the identification, delineation, establishment, or modification of any specific disease funds operated by the Independent Charity PAP. Among other things, Pfizer has not made and shall not make (directly or through any affiliate) suggestions or requests to the Independent Charity PAP about the identification, delineation, establishment, or modification of disease state funds;

b. Pfizer does not and shall not exert (directly or through any affiliate) any direct or indirect influence or control over the Independent

Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program;

c. Pfizer does not and shall not solicit or use any data or information it receives from an Independent Charity PAP (either directly, indirectly, or through third parties) to correlate the amount or frequency of its donations with the Independent Charity PAP's support for Pfizer's products or services; and

d. Pfizer does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Pfizer's products.

Pfizer shall continue to maintain the Independent Charity PAP processes described above (or equivalent processes) throughout the term of the CIA, and shall notify OIG in writing at least 60 days prior to the implementation of any modifications to the process described above.

5. Independent Charity PAP Review Program. Within 120 days after the Effective Date, Pfizer shall establish an Independent Charity PAP Review Program (Independent Charity PAP Review Program) through which members of the compliance department or other appropriate personnel (either Pfizer employees or outside resources) (Monitoring Personnel) shall conduct annual monitoring of ten (10) or fifty percent (50%) (whichever is a greater number) of Pfizer's donations to disease state funds of Independent Charity PAPs. The Independent Charity PAP Review Program shall select donations for review through both a risk-based targeting approach and a random sampling approach.

With respect to the donations subject to monitoring, Monitoring Personnel shall review: (a) budget documents; (b) documents relating to the decision to provide donations to a particular Independent Charity PAP; (c) any written agreements in place between Pfizer and the Independent Charity PAPs; (d) correspondence, emails, and other documents reflecting communications and interactions between Pfizer and the Independent Charity PAPs; and (e) other available information relating to the arrangements and interactions between Pfizer and the Independent Charity PAPs. The purpose of the Independent Charity PAP Review Program shall be to assess whether the activities were conducted in a manner consistent with Pfizer's policies and procedures described above and with OIG guidance.

In the event that a compliance issue, including but not limited to any potential improper conduct or noncompliance with Pfizer's policies and procedures or legal or compliance requirements, is identified during any portion of the Independent Charity PAP Review Program, Pfizer shall address the incident consistent with established policies and procedures for the handling of compliance issues. Findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.I above, as applicable. Results from the Independent Charity PAP Review Program, including the identification of potential violations of policies and procedures, shall be compiled and reported to the Compliance Officer for review and follow-up as appropriate. Any compliance issues identified during the PAP Review Program and any corrective action shall be recorded in the files of the Compliance Officer.

Pfizer shall include a summary of the Independent Charity PAP process and the PAP Review Program outlined in this section III.J in the Implementation Report. In addition, Pfizer shall include a description of any changes to the Independent Charity PAP process and the results of the PAP Review Program as part of each Annual Report.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Pfizer proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or a proposed purchase, Pfizer wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Pfizer must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within 150 days after the Effective Date, Pfizer shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

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

3. the names of the members of the RCC who are responsible for satisfying the compliance obligations described in Section III.A.3;

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

5. a list of the Policies and Procedures required by Section III.B.3;

6. the Training Plan required by Section III.C.1 and a description of the RCC training required by Section III.C.2 (including a summary of the topics covered in the training for Covered Persons and for the RCC, the length of each type of training, and when the training was provided);

7. (a) a copy of the letter (including all attachments) required by Section III.C.4 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' response to Pfizer's letter;

8. a description of the Risk Assessment and Internal Review Process required by Section III.D;

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate

that the IRO has the qualifications outlined in Appendix A; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Pfizer;

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

11. a description of the Ineligible Persons screening and removal process required by Section III.G;

12. a description of the Independent Charity PAP process and the Independent Charity PAP Review Program required by Section III.J;

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

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

15. the certifications required by Section V.C.

B. Annual Reports.

Pfizer shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, a current list of the RCC, and a current list of the Certifying Employees, along with any changes made during the Reporting Period to the Compliance Committee, RCC, and Certifying Employees;

2. the dates of each report made by the Compliance Officer to the RCC (written documentation of such reports shall be made available upon request);

3. the RCC resolution required by Section III.A.3 and a description of the documents and other materials required by the RCC, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

4. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;

5. a description of any changes to Pfizer's Training Plan developed pursuant to Section III.C and a summary of any RCC training provided during the Reporting Period;

6. (a) a copy of the letter (including all attachments) required by III.C.4 sent to each party employing Third Party Personnel; (b) a list of all entities employing Third Party Personnel with whom Pfizer has entered into such co-promotion and other similar agreements; and (c) a description of the entities' response to Pfizer's letter;

7. a summary of changes to the Risk Assessment and Internal Review Process required by Section III.D, including the reasons for such changes;

8. a summary of the following components of the Risk Assessment and Internal Review Process during the Reporting Period: (a) mitigation plans developed; and (b) steps taken to track the implementation, status, and effectiveness of the mitigation plans. Copies of any mitigation plans, and documents relating to the implementation, status and effectiveness of the mitigation plans shall be made available to OIG upon request.

9. a complete copy of all reports prepared pursuant to Section III.E and Appendix B and Pfizer's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

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

11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure; (b) the date the disclosure was received; (c) the resolution of the disclosure; and (d) the

date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

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

14. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

15. a summary of any changes to the Independent Charity PAP process or the Independent Charity PAP Review Program outlined in section III.J and the results of the PAP Review Program, including a description of any instances in which it was determined that improper conduct or policy violations occurred and a description of the action(s) that Pfizer took as a result of such determinations;

16. a description of all changes to the most recently provided list of Pfizer's locations (including addresses) as required by Section V.A.13; and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 120 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

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

2. *Compliance Officer and Chief Executive Officer*. The Implementation Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise

described in the report, Pfizer is in compliance with the requirements of this CIA; and

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

3. *Compliance Officer and Chief Executive Officer*. Each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise described in the report, Pfizer is in compliance with the requirements of this CIA;

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

c. for each disease fund of an Independent Charity PAP to which Pfizer made a donation during the Reporting Period, the facts and circumstances relating to the donation were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Pfizer's policies and procedures (including those outlined in Section III.J); and

d. for each Pfizer PAP (as defined in Section II.C.4.b above), the facts and circumstances relating to each program were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Pfizer's policies and procedures.

D. Designation of Information.

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

Pfizer:

Chief Compliance and Risk Officer
235 East 42nd Street
New York, NY 10017-5755
Tel: (212) 573-2352
Fax: (212) 351-1049

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Pfizer may be

required to provide OIG with an electronic copy of each notification or report required by this CIA in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine and/or request copies of or copy Pfizer's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Pfizer's locations for the purpose of verifying and evaluating: (a) Pfizer's compliance with the terms of this CIA and (b) Pfizer's compliance with applicable Federal health care programs 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, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Pfizer's owners, employees, contractors and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Pfizer shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Pfizer's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Pfizer present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

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

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

a. a Compliance Officer;

b. a Compliance Committee;

c. the RCC compliance obligations;

d. the management certification obligations;

e. written Policies and Procedures;

f. training and education of Covered Persons and RCC Members;

g. a Risk Assessment and Internal Review Process;

h. a Disclosure Program;

i. Ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings;

k. reporting of Reportable Events; and

l. the Independent Charity PAP processes and Independent Charity PAP Review Program required by Section III.J.

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 and use an IRO as required by Section III.E, Appendix A, or Appendix B.

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

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

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

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Pfizer as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by 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 the date 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 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 days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

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

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

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

4. *Independence from Material Breach Determination*. Except as set forth in Section X.D.1.d, 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. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

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

c. a failure to engage and use an IRO in accordance with Section III.E, Appendix A or Appendix B; or

d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.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. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Pfizer has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Pfizer of: (a) Pfizer's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

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

a. the alleged material breach has been cured; or

b. 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. Reinstatement to program participation is not automatic. At 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. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

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 whether Pfizer was in material breach of this CIA and, if so, whether:

a. Pfizer cured such breach within 30 days of its receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Pfizer's receipt of the Notice of Material Breach: (i) Pfizer had begun to take action to cure the material breach within that period; (ii) Pfizer pursued such action with due diligence; and (iii) Pfizer provided to OIG within that period a reasonable timetable for curing the material breach.

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

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or

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

XI. EFFECTIVE AND BINDING AGREEMENT

Pfizer and OIG agree as follows:

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

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

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Pfizer's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

D. The undersigned Pfizer signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

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

ON BEHALF OF PFIZER INC.

___/Rady Johnson/_____ ____May 21, 2018_____
RADY JOHNSON DATE
Executive Vice President
and Chief Compliance and Risk Officer
Pfizer Inc.

____/John Rah/_____ ____May 22, 2018_____
JOHN RAH DATE
Counsel for Pfizer Inc.
DLA Piper

___/Joshua Levy/_____ ____May 22, 2018_____
JOSHUA LEVY DATE
Counsel for Pfizer Inc.
Ropes & Gray

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

____/Lisa Re/_____ ___5-23-18_____
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

___/Mary E. Riordan/_____ ___5/22/18_____
MARY E. RIORDAN DATE
Senior Counsel
Office of Counsel to the Inspector General

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Pfizer shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by Pfizer in response to a request by OIG, whichever is later, OIG will notify Pfizer if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Pfizer may continue to engage the IRO.

2. If Pfizer engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Pfizer shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Pfizer at the request of OIG, whichever is later, OIG will notify Pfizer if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Pfizer may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in Federal health care program requirements (including but not limited to, the Federal Anti-Kickback Statute and the False Claims Act) applicable to the Covered Functions being reviewed;

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

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

C. IRO Responsibilities

The IRO shall:

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

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

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

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

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

D. IRO Independence and Objectivity

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

E. IRO Removal/Termination

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

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Pfizer in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Pfizer shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Pfizer regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Pfizer in writing that Pfizer shall be required to engage a

new IRO in accordance with Paragraph A of this Appendix. Pfizer must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Pfizer to engage a new IRO shall be made at the sole discretion of OIG.

CIA with Pfizer Inc.
Appendix B

I. IRO Engagement, 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 procedures related to Covered Functions as defined in the CIA (IRO Reviews). The IRO Reviews shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Pfizer may engage, at its discretion, a single entity to perform both components of the IRO Reviews provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Pfizer's systems, processes, policies, and procedures relating to Independent Charity PAP Related Functions or the Independent Charity PAP Review Program, the IRO shall perform the Systems Review outlined in Sections II.A.1 and II.B below (relating to Independent Charity PAP Related Functions and the Independent Charity PAP Review Program, respectively) for the first and fourth Reporting Periods.

If there are no material changes in Pfizer's systems, processes, policies, and procedures relating to Pfizer PAPs (as defined in Section II.C.4.b of the CIA), the IRO shall perform the Systems Review outlined in Section II.A.2 below (relating to Pfizer PAPs) for the second and fourth Reporting Periods.

If Pfizer materially changes its systems, processes, policies, and procedures relating to Patient Assistance Related Functions or the Independent Charity PAP Review Program, the IRO shall perform a Systems Review for the Reporting Period(s) in which such material changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed.

The IRO shall conduct the Transactions Review for the second through fifth Reporting Periods of the CIA.

II. IRO Systems Review

The 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 Patient Assistance Related Functions and the Independent Charity PAP Review Program. Where practical, Pfizer personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Pfizer pursuant to the preceding sentence.

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

A. Patient Assistance Related Functions

1) Pfizer's systems, policies, processes, and procedures relating to arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs.

This review shall include an assessment of the following:

a. Pfizer's organizational structure as it relates to arrangements and interactions with Independent Charity PAPS, including:

i. the identification of those individuals, departments, or groups within Pfizer (e.g., the Independent Charity Group, legal, compliance) that have responsibility for, or involvement with, such arrangements and interactions;
ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, arrangements and interactions with Independent Charity PAPs;
iii. the identification of those individuals, departments, or groups within Pfizer (e.g., the commercial business units) that are precluded from involvement with arrangements and interactions with Independent Charity PAPs; and
iv. methods that Pfizer uses to separate Independent Charity PAP-related responsibilities from the commercial business units.

b. Pfizer's written policies and procedures as they relate to arrangements and interactions with Independent Charity PAPs, including:

i. the criteria governing whether and under what circumstances Pfizer would donate to an Independent Charity PAP or any specific disease state fund of such a PAP;
ii. communications (including any limitations on such communications) between any representatives of Pfizer and any Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications including the exchange of any data);
iii. communications (including any limitations on such communications) between those individuals, departments, or groups within Pfizer with responsibility for Independent Charity PAPs and the commercial business units of Pfizer (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications); and
iv. communications (including any limitations on such communications) between representatives of Pfizer and health care providers or patients regarding assistance available through any Independent Charity PAP.

c. Pfizer's policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs as outlined in Section III.J.3 of the CIA, including as it relates to initial or annual donation amounts and any supplemental amounts;

d. Pfizer's policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to donate (or continue to donate) to a particular Independent Charity PAP; and ii) the amount of the donation (including any initial or annual amount and any supplemental amount);

e. Pfizer's policies and practices as they relate to donations made by Pfizer to any Independent Charity PAPs as referenced in Section III.J.4, including the internal review process followed in connection with any donations to Independent Charity PAPs; and

f. Pfizer's policies and practices as they relate to information provided, directly or indirectly, to the public about the availability of patient assistance for Pfizer's products.

2) Pfizer's systems, policies, processes, and procedures relating to any Pfizer PAPs.

This review shall include an assessment of the following:

a. The general elements of Pfizer PAPs, including: i) the types of assistance that are made available through Pfizer PAPs; ii) the types of patients to whom each type of assistance is made available; iii) the eligibility criteria for the various types of assistance provided; and iv) the controls used to implement the eligibility criteria (i.e., controls employed to ensure that appropriate patients receive the various types of assistance);

b. Pfizer's policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to provide (or continue to provide) the various types of assistance through any Pfizer PAP; and ii) the amount (or value) of the assistance to be provided through each program (including any initial or annual amount and any supplemental amount); and

c. Pfizer's policies and practices as they relate to any contracts or agreements entered between Pfizer and outside entities relating to any Pfizer PAPs or the distribution of free product, including the individuals, groups, or departments involved in the negotiation process, the requirements and terms of the contracts or agreements, and the review and approval of such contracts or agreements.

B. Independent Charity PAP Review Program

1) Pfizer's systems, policies, processes, and procedures related to its Independent Charity PAP Review Program.

This review shall include a review to understand the following:

a. Pfizer's systems, processes, policies and procedures related to Pfizer's Independent Charity PAP Review Program required by Section III.J.5 that are designed to identify and manage relevant risks arising under Federal health care program requirements associated with donations by pharmaceutical manufacturers to Independent Charity PAPs;

b. The process or factors that Pfizer uses to identify the following:

i which donation arrangements with Independent Charity PAPs will be reviewed for the particular Reporting Period;

ii. the relevant Pfizer colleague roles that Pfizer will include in the Independent Charity PAP Review Program for a particular Reporting Period; and

iii. the relevant records, documents or other information that Pfizer will include as part of its Independent Charity PAP Review Program for a particular Reporting Period;

c. The frequency or timing of when Pfizer conducts the Independent Charity PAP Review Program;

d. The experience and background of individuals who are engaged in the Independent Charity PAP Review Program and a review of any relevant training or other guidance provided to these individuals; and

e. The systems, policies, processes and procedures to review initial results of the Independent Charity PAP Review Program that are related to donations to Independent Charity PAPs and to remediate any issues identified as a part of the Independent Charity PAP Review Program.

III. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review.

A. Independent Charity PAP Related Functions

For each of the Reviewed Policies and Procedures identified in Section II.A.1 above, the report shall include the following items:

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

2) a detailed description of Pfizer's systems, policies, processes, and procedures relating to the items identified in Section II.A.1 above, including a general description of Pfizer's control and accountability systems (e.g., documentation

and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

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

4) a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP and the donations or other assistance provided in response to such requests;

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

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

B. Pfizer PAPs

For each of the Reviewed Policies and Procedures identified in Section II.A.2 above, the report shall include the following items:

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

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

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.2 above are made known or disseminated within Pfizer;

4) a detailed description of any system(s) used to track donations or other assistance provided in response to requests through any Pfizer PAP;

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

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

C. Independent Charity PAP Review Program

For each of the systems, processes, policies and procedures reviewed pursuant to Section II.B above, the report shall include the following items:

1) A description of the documentation reviewed and personnel interviewed as part of the Independent Charity PAP Review Program Systems Review;

2) A description of the systems, processes, policies and procedures that Pfizer uses to conduct the Independent Charity PAP Review Program and to remediate and escalate issues related to donations to Independent Charity PAPs;

3) A description of the background and experience of the individuals who perform the Independent Charity PAP Review Program;

4) Whether the Independent Charity PAP Review Program processes, policies and procedures related to the Independent Charity PAP Review Program are reasonably designed to identify, prioritize and manage relevant risks;

5) Whether the systems, processes, policies and procedures are reasonably designed to escalate identified issues and/or remediate such issues;

6) Recommendations to improve any of the systems, policies, processes, or procedures relating to the Independent Charity PAP Review Program, if any.

IV. IRO Transactions Review

As described more fully below in Sections IV.A-C, the Transactions Review shall include: (1) a review of Pfizer's arrangements with selected Independent Charity PAPs; and (2) a review of up to three additional items identified by OIG in accordance with Section III.E.2 of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. IRO Review of Arrangements with Independent Charity PAPs

The IRO shall conduct a review and assessment of Pfizer's compliance with the Independent Charity PAP processes, policies, and procedures outlined in Section III.J of the CIA. More specifically, the IRO shall review fifty percent (50%) of the donation arrangements that Pfizer entered into with Independent Charity PAPs during the Reporting Period for which the IRO is conducting the Transactions Review.

As a matter of practice, Pfizer enters a separate agreement with an Independent Charity PAP for each disease state fund of the PAP to which Pfizer makes a donation. Pfizer shall provide the IRO with a list of all Independent Charity PAPs with which Pfizer entered into a donation agreement during the Reporting Period under review (the applicable Reporting Period.) The IRO will randomly select and review 50% of these donation arrangements for the applicable Reporting Period.

For purposes of the Independent Charity PAP Transactions Review, the term "Reviewed Materials" shall mean the following for each Independent Charity PAP arrangement reviewed:

1) the Annual Notice from Pfizer to Independent Charity PAPs (which announces Pfizer's willingness to consider written requests for contributions and seeks information regarding anticipated patient need for particular disease state funds; patient eligibility criteria used by the Independent Charity PAPs; and information about the Independent Charity PAPs);

2) responses from Independent Charity PAPs to the Annual Notice (which includes information on anticipated patient need for particular disease state funds; details regarding patient eligibility criteria used by the Independent Charity PAPs; and information about the Independent Charity PAPs (e.g., information about administrative fees, patient grant amounts, average processing time to assist patients, etc.));

3) patient needs assessment documentation related to a donation arrangement with an Independent Charity PAP (which includes information on the assessment of patient need in disease states based on non-patient-specific or drug-specific information from eligible Independent Charity PAPs, other publicly available information, and Pfizer's internal free drug program);

4) allocation documentation that shows the objective criteria used to evaluate Independent Charity PAPs and the allocation of the approved budget across disease states and Independent Charity PAPs (e.g., patient needs assessment information for disease state funds, information about Pfizer's historical donations; eligibility criteria of the Independent Charity PAPs; and other relevant information, as applicable);

5) documents regarding donations to Independent Charity PAPs required by Pfizer policy to evidence or document the review and approval of a decision to provide a donation to a particular fund of an Independent Charity PAP (i.e., minutes from Pfizer's Independent Charity PAP Review Committee that memorialize donation decisions, including budget allocation across disease states and Independent Charity PAPs, and final determinations (approvals or rejections) on proposed donations to Independent Charity PAPs);

6) to the extent not covered by item 2 above, all correspondence between Pfizer and an Independent Charity PAP relating to any donation arrangement with the Independent Charity PAP;

7) any donation agreement entered into between Pfizer and an Independent Charity PAP during the relevant Reporting Period; and

8) payment documentation required by Pfizer policy reflecting: a) the total amount of donations Pfizer agreed to make to an Independent Charity PAP broken down by disease fund, if applicable; b) the schedule of such payments, if applicable; c) the actual payments made; and d) any decisions to change the initial donation amount agreed to by Pfizer.

For each Independent Charity PAP donation arrangement selected as part of the IRO review, the IRO shall assess the Reviewed Materials to evaluate whether the Independent Charity PAP Related Functions were conducted in a manner consistent with Pfizer's policies and procedures, including those described in Section III.J of the CIA, and with OIG guidance. In addition, the IRO may interview members of Pfizer's Independent Charity Group regarding the Reviewed Materials and Pfizer's policies and process relating to donations to Independent Charity PAPs.

Based upon the Reviewed Materials and any interviews of the Independent Charity Group, the IRO shall evaluate and identify:

1) Whether activities relating to arrangements with the Independent Charity PAP were undertaken by the appropriate individuals, departments, or groups within Pfizer in accordance with the company's policies and procedures including those outlined in Section III.J.1 of the CIA;

2) Whether Pfizer's commercial business units influenced or were involved in the Independent Charity Group's decisions to enter into an arrangement with an Independent Charity PAP in violation of Pfizer's policies and procedures or OIG guidance;

3) Whether Pfizer followed the budgeting policies and practices outlined in Section III.J.3 of the CIA with regard to any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;

4) Whether Pfizer followed the decision-making and approval process required by Pfizer's policies and procedures and outlined in Section III.J of the CIA with regard to any decisions: i) whether to donate (or continue to donate) to the Independent Charity PAP; ii) the amount of the donation (including any initial or annual amount and any supplemental amount); and iii) the criteria governing whether Pfizer would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;

5) Whether Pfizer followed the policies and practices outlined in Section III.J.4 in connection with all donations made by Pfizer to any Independent Charity PAP, including as they pertain to the internal review of potential donations and adherence to the criteria set forth in Section III.J.4;

6) Any communications that occurred between any representatives of Pfizer and the Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications (including the exchange of any data)) and whether any such communications complied with Pfizer's policies and procedures and OIG guidance;

7) Whether for each donation made to the Independent Charity PAP, Pfizer complied with the requirements outlined in Section III.J.4; and

8) Whether, based on its review, the IRO found that Pfizer exerted influence or control over the Independent Charity PAP in violation of Pfizer's policies and procedures, including those outlined in Section III.J.4.

B. IRO Review of Additional Items

As set forth in Section III.E.2 of the CIA, for each Reporting Period OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). The Additional Items may include activities undertaken by Pfizer in connection with Promotional Functions, as defined in Section III.C.3 of the CIA. The Additional Items Review could also include activities undertaken by Pfizer in connection with any Pfizer PAP, including the provision of free product to patients.

No later than 150 days prior to the end of the applicable Reporting Period, OIG shall notify Pfizer of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO shall submit an audit work plan to OIG for approval.

The IRO shall conduct the review of the Additional Items based on a work plan approved by OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Pfizer's systems, processes, policies, and procedures based on its review of each Additional Item).

Pfizer may propose to OIG that relevant internal audit(s) or monitoring and/or other reviews conducted by outside entities at Pfizer's request be substituted for one or more of the Additional Item reviews that would otherwise be conducted by the IRO for the applicable Reporting Period. OIG retains sole discretion over whether, and in what manner, to allow Pfizer's internal audit work or monitoring and/or other reviews conducted by outside entities to be substituted for a portion of the Additional Items review conducted by the IRO.

If OIG denies Pfizer's request to permit its internal audit work or monitoring and/or other reviews conducted by outside entities to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Pfizer shall engage the IRO to perform the Review as outlined in this Section IV.B. If OIG agrees to permit certain of Pfizer's internal audit work or other reviews for a given Reporting Period to be substituted for a portion of an Additional Items review, such work or reviews may be subject to verification by the IRO (Verification Review). In such an instance, OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

C. Transactions Review Report

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

1. General Elements to Be Included in Report

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

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

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

2. Results to be Included in Report

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

(for the review of Independent Charity PAP arrangements)

a) a list of the Independent Charity PAP funds to which Pfizer made donations during the Reporting Period;

b) for each Independent Charity PAP arrangement reviewed by the IRO, a description of the review conducted by IRO;

c) for each Independent Charity PAP arrangement reviewed by the IRO, findings regarding each element specified above in Sections IV.A.1-8;

d) for each Independent Charity PAP arrangement reviewed by the IRO, a statement as to whether Pfizer identified any compliance issues associated with the arrangement;

e) the findings and supporting rationale regarding any overall weaknesses in Pfizer's systems, processes, policies, procedures, and practices relating to its arrangements and interactions with Independent Charity PAPs; and

f) recommendations, if any, for changes in Pfizer's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to its arrangements and interactions with Independent Charity PAPs.

(Relating to the Review of Additional Items)

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

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

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

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