

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
AVENTIS, INC, SANOFI US SERVICES, INC., SANOFI-AVENTIS US, LLC,  
AND GENZYME CORPORATION**

**I. PREAMBLE**

Sanofi US Services, Inc., and Sanofi-Aventis, U.S., LLC (collectively “Sanofi US”), Aventis, Inc., and Genzyme Corporation (collectively, “Sanofi”) 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, Sanofi is entering into a Settlement Agreement with the United States.

The OIG and Sanofi entered into a separate CIA effective September 2, 2015, and the 2015 CIA is still in effect. Sanofi shall continue to fulfill its obligations as required under the 2015 CIA until the term of that CIA is concluded. The term of this CIA has been extended to accommodate both parties’ agreement to complete Sanofi’s obligations under the 2015 CIA prior to the implementation of certain of the new obligations of this CIA.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Sanofi under this CIA shall be five reporting periods, as defined below. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. The first Reporting Period shall be from the Effective Date through December 31, 2021. The second and subsequent Reporting Periods shall be from January 1 through December 31 of each of the subsequent four calendar years.

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

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

1. “Covered Persons” includes:

- a. all owners of Sanofi 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) and all officers and directors of Sanofi;
- b. all U.S. employees of Sanofi; and
- c. all U.S. contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Sanofi.

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 Sanofi 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 Sanofi during the calendar year.

2. “Government Reimbursed Products” refers to all Sanofi products that are: (a) marketed or sold by Sanofi 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 Sanofi’s review and approval processes for promotional materials and any applicable review committee(s).

4. The term “Contribution and Assistance Related Functions” includes: all activities, systems, processes, and procedures relating to the following: (a) grants, charitable contributions, or donations (in cash or in kind) provided by Sanofi or any entity acting on behalf of Sanofi 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

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by Sanofi or any entity acting on behalf of Sanofi that provides free drugs to patients, including Federal health care program beneficiaries (i.e., Sanofi’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 this Section II.C.4.b shall be collectively referred to as “Sanofi PAPs” and the functions described in this Section II.C.4.b shall be collectively referred to as “Patient Assistance Related Functions”). Independent Charity PAP Related Functions and Patient Assistance Related Functions collectively constitute “Contribution and Assistance Related Functions.”

5. The term “Covered Functions” refers to “Promotional Functions,” and “Contribution and 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 Sanofi 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. Sanofi represents that: (1) Third Party Personnel are employed by entities other than and independent of Sanofi; (2) Sanofi 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. Sanofi 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 Sanofi complies with the requirements of Sections III.C.4, V.A.7, and V.B.6, Sanofi 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**

Sanofi 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.* Within 90 days after the Effective Date, Sanofi shall appoint a NA Compliance Officer (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 Sanofi; shall report directly to the *Sanofi Corporate Integrity Agreement*

Head of Sanofi Genzyme and NA Head of General Medicines. The Compliance Officer shall also report to the Global Compliance Officer of Sanofi's French parent corporation 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 Sanofi. 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 Board of Directors of Sanofi and shall be authorized to report on such matters to the Board of Directors 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 Sanofi and 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.

Sanofi shall report to OIG, in writing, any changes 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.* Within 90 days after the Effective Date, Sanofi 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, research and development, human resources, 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 Sanofi's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least

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quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Sanofi 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 Board of Directors (or a committee of the Board) of Aventis, Inc., the common U.S. parent of Sanofi US and Genzyme Corporation, (Board) 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 Board must include an independent (i.e., non-executive) member.

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

- a. meeting at least quarterly to review and oversee Sanofi'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 member of the Board, summarizing its review and oversight of Sanofi's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Sanofi's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge,

Sanofi has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board 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 Sanofi.

Sanofi shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board’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 Sanofi employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Sanofi division or business unit is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Head, Established Products; Head of CV Sales and Marketing; Head of US Market Access; Head of Regulatory Affairs, NA and GEM; Head of Regulatory Affairs, Sanofi Genzyme; Head, DCV Sales; Head of Diabetes Marketing; NA Medical Head of Primary Care; NA Region Head, MS, Oncology and Immunology; Head of NA Medical Affairs Oncology; Head, Medical NA MS/Neuro; Head of NA Rare Disease Medical Affairs; Head of Communications, Specialty Care; Medical Immunology Head; Head of Global Medical Affairs; Head of North America Medical Affairs, Sanofi Genzyme; US Head Rare Disease & Blood Disorders; NA Medical Head Rare Blood Disorders; Head of External Affairs; and Head of Global Business Operations. 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 Sanofi 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 Sanofi 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 90 days after the Effective Date, Sanofi 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, Sanofi shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Sanofi’s compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Sanofi shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures 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 Contribution and Assistance Related Functions in compliance with all applicable Federal health care program requirements, including but not limited to, the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) 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 Sanofi’s arrangements and interactions comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Sanofi’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 Sanofi PAP. These Policies and Procedures shall be designed to ensure that Sanofi'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 Sanofi's operation of or participation in any such Sanofi 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 Sanofi personnel about Independent Charity PAPs or Contribution and Assistance Related Functions and the manner in, and circumstances under, which appropriate Sanofi personnel may respond to requests for information about Independent Charity PAPs or Contribution and 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 Federal Food and Drug Administration (FDA) requirements.

At least annually (and more frequently, if appropriate), Sanofi 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.

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

C. Training and Education.

1. *Covered Persons Training.* Within 90 days after the Effective Date, Sanofi shall develop a written plan (Training Plan) that outlines the steps Sanofi will take to ensure that: (a) all Covered Persons receive at least annual training regarding Sanofi'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 Sanofi 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. Sanofi shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 90 days after the Effective Date, each member of the Board of Directors shall receive training that addresses 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 Board and should include a discussion of OIG's guidance on Board member responsibilities.

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

3. *Training Records.* Sanofi shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Board 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, Sanofi shall send a letter, either in hard copy or electronic form, to each entity employing Third Party Personnel. The letter shall outline Sanofi's obligations under the CIA and its commitment to full *Sanofi Corporate Integrity Agreement*

compliance with all Federal health care program requirements. The letter shall include a description of the Sanofi Compliance Program. Sanofi request the entity employing Third Party Personnel to either: (a) make a description of the Sanofi Compliance Program available to its Third Party Personnel; or (b) represent to Sanofi that it has and enforces a substantially comparable compliance program for its Third Party Personnel.

D. Risk Assessment and Mitigation Process.

No later than January 1, 2021, Sanofi shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each of Sanofi'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 Sanofi's operation of any Sanofi PAP and the company's arrangements and interactions with any Independent Charity PAPs, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Sanofi 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, Sanofi shall engage an entity (or entities), such as an accounting, auditing, 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 Sanofi shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Sanofi) related to the reviews.

- c. *Access to Records and Personnel.* Sanofi shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

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

The Transactions Review shall be cover each of the five Reporting Periods. The IRO(s) shall perform all components of each Transactions Review.

As set forth more fully in Appendix B, the Transactions Review shall include several components. In addition to the items specifically identified in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of Sanofi 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 Sanofi and may consider internal audit and monitoring work conducted by Sanofi, the Government Reimbursed Product portfolio, the nature and scope of Sanofi's promotional practices and arrangements with health care professionals and health care institutions, and other information known to it.

As set forth more fully in Appendix B, Sanofi 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 Sanofi's internal audit and monitoring work to be substituted for any portion of the Additional Items review conducted by the IRO.

OIG shall notify Sanofi 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 Sanofi shall submit an *Sanofi Corporate Integrity Agreement*

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 Sanofi 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 Sanofi and the IRO.

F. Disclosure Program.

Within 90 days after the Effective Date, Sanofi shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Sanofi's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Sanofi shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Sanofi's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Sanofi. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Sanofi 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 any Federal health care program; 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.* Sanofi shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

- c. Sanofi shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If Sanofi has actual notice that a Covered Person has become an Ineligible Person, Sanofi shall remove such Covered Person from responsibility for, or involvement with, Sanofi'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 Sanofi 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, Sanofi 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, Sanofi shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Sanofi conducted or brought by a U.S. governmental entity or its agents involving an allegation that Sanofi 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. Sanofi also shall 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 Sanofi.

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

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

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 types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities 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 that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event; and

- d. a description of Sanofi'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 Sanofi 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.c, 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 Sanofi makes monetary donations to Independent Charity PAPs, it shall implement the policies, procedures, and practices set forth in this Section III.J within 120 days after the Effective Date. Sanofi shall continue the Independent Charity PAP policies, procedures, and practices described below (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 such policies, procedures, and practices.

1. *Independent Charity Group.* Sanofi shall vest sole responsibility and authority for budgeting and all other activities relating to Independent Charity PAPs



in a department or group within Sanofi known as the “Independent Charity Group” that has the following roles and responsibilities:

- a. The Independent Charity Group shall be separate and independent from Sanofi’s commercial organization.
- b. The Independent Charity Group shall operate independently from Sanofi’s commercial organization and Sanofi’s commercial organization shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to Independent Charity PAPs.
- c. Sanofi shall vest in the Independent Charity Group sole responsibility and authority for communicating with Independent Charity PAPs regarding Sanofi’s donations to such PAPs and Sanofi’s commercial organization shall not communicate with, influence, or be involved in any communications with, or receive information from the Independent Charity PAPs.
- d. Sanofi’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 PAP or over its assistance program.
- e. For purposes of this CIA, the “commercial organization” shall be defined as the sales and marketing organization of Sanofi.

2. *Budgeting Process.* Sanofi’s Independent Charity Group shall establish a budget process to be followed for Sanofi’s donations to Independent Charity PAPs that meets the following requirements:

- a. The Independent Charity Group shall develop an 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 compliance department.

- b. Sanofi shall approve the annual budget for donations to Independent Charity PAPs at a level within the organization above the commercial organization (e.g., at the executive level).
- c. The Independent Charity Group shall have sole responsibility for allocating the approved budget across donations to Independent Charity PAPs and to any disease state fund established by the Independent Charity PAP.
- d. The Independent Charity Group shall have sole responsibility for assessing requests for additional or supplemental funding from Independent Charity PAPs outside of the annual budget using standardized, objective criteria established by the Independent Charity Group. Any such requests also shall be subject to legal and compliance personnel review and approval, 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 Sanofi Policies and Procedures.
- e. The commercial organization shall have no involvement in the budget 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 organization.

3. *Criteria Relating to Donations to Independent Charity PAPs.* The Independent Charity Group (with input from the legal department and compliance departments) shall establish standardized, objective written criteria that govern donations to Independent Charity PAPs and any specific disease state funds of such PAPs, designed to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from Sanofi to patients and does not impermissibly influence patients' drug choices. In addition, Sanofi agrees that it will donate to an Independent Charity PAP only if the following criteria are satisfied:

- a. Sanofi 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, Sanofi 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. Sanofi 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. Sanofi does not and shall not solicit or receive (directly or indirectly through third parties including hubs or pharmacies) any data or information from the Independent Charity PAP that would enable it to correlate the amount or frequency of its donations with support for Sanofi's products or services.
- d. Sanofi does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Sanofi's products.
- e. Personnel from Sanofi's legal and compliance departments shall review all proposed donations and arrangements between Sanofi and any Independent Charity PAP prior to such donations being made or arrangements being entered into by Sanofi.

#### **IV. SUCCESSOR LIABILITY**

In the event that, after the Effective Date, Sanofi 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. Sanofi shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Sanofi 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, Sanofi 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 120 days after the Effective Date, Sanofi 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 Board members 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 and a written copy of the process to be followed by Certifying Employees in connection with completing the required certifications;
  5. a list of the Policies and Procedures required by Section III.B;
  6. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the 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 Sanofi' letter;
- Sanofi Corporate Integrity Agreement*

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 Sanofi;

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 policies, procedures, and practices required by Section III.J;

13. a list of all of Sanofi's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers, and the location's Medicare and state Medicaid program provider and/or supplier numbers (if any);

14. a description of Sanofi'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.

Sanofi shall submit to OIG a written 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. (a) any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; (b) a current list of the Compliance Committee members; (c) a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations; (d) a current list of the Certifying Employees, along with any changes made during the Reporting Period to the Compliance Committee, Board of Directors, and Certifying Employees; and (e) a description of any changes to the process to be followed by Certifying Employees including the reasons for the changes;

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

3. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, 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 developed during the Reporting Period under Section III.B;

5. a description of any changes to Sanofi's Training Plan developed pursuant to Section III.C and a summary of any Board of Directors 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 Sanofi has entered into such co-promotion and other similar agreements; and (c) a description of the entities' response to Sanofi's letter;

7. a description of any 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) work plans developed; (b) internal audits performed; (c) corrective action plans developed in response to internal audits; and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

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9. a complete copy of all reports prepared pursuant to Section III.E and Appendix B and Sanofi'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 Sanofi;

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 description of any changes to the Independent Charity PAP policies, procedures, and practices outlined in section III.J including the reasons for such changes;

16. a description of all changes to the most recently provided list of Sanofi's locations as required by Section V.A.13;

17. a description of any changes to Sanofi's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

18. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the *Sanofi Corporate Integrity Agreement*

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, Sanofi shall include the certifications of Certifying Employees required by Section III.A.4;

2. *Compliance Officer, Head of Sanofi Genzyme and NA Head of General Medicines.* The Implementation Report shall include a certification by the Chief Compliance Officer, the Head of Sanofi Genzyme, and the NA Head of General Medicines that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Sanofi is in compliance with all of 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, Head of Sanofi Genzyme and NA Head of General Medicines.* Each Annual Report shall include a certification by the Compliance Officer, the Head of Sanofi Genzyme, and the NA Head of General Medicines that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Sanofi is in compliance with all of 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. he or she understands that the certification is being provided to and relied upon by the United States;
- d. for each disease fund of an Independent Charity PAP to which Sanofi 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 Sanofi policies and procedures (including those outlined in Section III.J); and

- e. for each Sanofi PAP (as defined in Section II.C.4.b above), the facts and circumstances relating to the 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 Sanofi policies and procedures.

D. Designation of Information.

Sanofi 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. Sanofi 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

Sanofi:

Shannon Kelley  
50 Binney Street  
Cambridge, MA 02142  
Tel: 617.685.5670  
Fax: 617.252.7553

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, Sanofi may be required to provide OIG with an additional copy of each notification or report required by this CIA in the OIG's requested format (electronic or paper).

## **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 conduct interviews, examine and/or request copies of or copy Sanofi's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Sanofi's locations for the purpose of verifying and evaluating: (a) Sanofi's compliance with the terms of this CIA and (b) Sanofi's compliance with the requirements of Federal health care programs. The documentation described above shall be made available by Sanofi 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 Sanofi'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. Sanofi shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Sanofi's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Sanofi present.

## **VIII. DOCUMENT AND RECORD RETENTION**

Sanofi 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  
*Sanofi Corporate Integrity Agreement*

make a reasonable effort to notify Sanofi prior to any release by OIG of information submitted by Sanofi pursuant to its obligations under this CIA and identified upon submission by Sanofi as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Sanofi shall have the rights set forth at 45 C.F.R. § 5.42(a).

**X. BREACH AND DEFAULT PROVISIONS**

Sanofi 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, Sanofi 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 Sanofi 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 Board of Directors compliance obligations;
- d. the management certification obligations;
- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons and Board 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 policies, procedures, and practices 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 Sanofi 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 Sanofi 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 Sanofi 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 Sanofi fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Sanofi fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Sanofi 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 \$2,500 for each day Sanofi fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E, and for each day Sanofi fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A.

8. A Stipulated Penalty of \$1,000 for each day Sanofi fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Sanofi stating the specific grounds for its determination that Sanofi has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Sanofi shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Sanofi

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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- 7 of this Section.

B. Timely Written Requests for Extensions. Sanofi 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 Sanofi 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 Sanofi 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 Sanofi 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 Sanofi of: (a) Sanofi's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Sanofi 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 Sanofi elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Sanofi 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 Sanofi 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 Sanofi 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 Sanofi constitutes an independent basis for Sanofi'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 Sanofi has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Sanofi of: (a) Sanofi's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Sanofi shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate 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) Sanofi has begun to take action to cure the material breach; (ii) Sanofi is pursuing such action with due diligence; and (iii) Sanofi has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Sanofi fails to satisfy the requirements of Section X.D.3, OIG may exclude Sanofi from participation in the Federal health care programs. OIG shall notify Sanofi in writing of its determination to exclude Sanofi. (This letter shall be referred to 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 Sanofi’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, Sanofi 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 Sanofi 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, Sanofi 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 Sanofi was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Sanofi shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if *Sanofi Corporate Integrity Agreement*

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 Sanofi to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Sanofi 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 Sanofi was in material breach of this CIA and, if so, whether:

- a. Sanofi 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 Sanofi's receipt of the Notice of Material Breach:
  - (i) Sanofi had begun to take action to cure the material breach within that period; (ii) Sanofi pursued such action with due diligence; and (iii) Sanofi 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 Sanofi, only after a DAB decision in favor of OIG. Sanofi's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Sanofi 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 Sanofi 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. Sanofi 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 Sanofi, Sanofi 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**

Sanofi 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) Sanofi'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 Sanofi 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 capacities 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 copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF SANOFI US SERVICES, INC., SANOFI-AVENTIS U.S., LLC AND  
GENZYME CORPORATION**

/Shannon Kelley/  
SHANNON KELLEY  
NA COMPLIANCE OFFICER

2/28/20  
DATE

/John Rah/  
JOHN RAH  
DLA PIPER  
COUNSEL FOR SANOFI

2/28/2020  
DATE

/Benjamin D. Klein/  
BENJAMIN D. KLEIN  
DLA PIPER  
COUNSEL FOR SANOFI

2/28/20  
DATE

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

/Lisa M. Re/  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and Human Services

2/28/2020  
DATE

/Mary E. Riordan/  
MARY E. RIORDAN  
Senior Counsel  
Office of Counsel to the Inspector General

2/28/2020  
DATE

## 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. Sanofi 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 E. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Sanofi in response to a request by OIG, whichever is later, OIG will notify Sanofi if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Sanofi may continue to engage the IRO.

2. If Sanofi 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, Sanofi shall submit the information identified in Section V.A.8 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 Sanofi at the request of OIG, whichever is later, OIG will notify Sanofi if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Sanofi 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 all applicable Federal health care program and FDA requirements relating to the Covered Functions, including but not limited to expertise relating to marketing and promotional activities associated with pharmaceutical products and the Federal Anti-Kickback Statute and False Claims Act.

2. assign individuals to design and select the samples for the IRO 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 Reviews in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in the IRO Reviews;
3. respond to all OIG inquires in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Sanofi Responsibilities

Sanofi shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.E of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

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

F. IRO Removal/Termination

1. *Sanofi and IRO.* If Sanofi terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Sanofi 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. Sanofi 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 E or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Sanofi in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Sanofi 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 Sanofi regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Sanofi in writing that Sanofi shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Sanofi 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 Sanofi to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### CIA WITH SANOFI

#### I. IRO Engagement, General Description

As specified more fully below, Sanofi shall retain an Independent Review Organization (IRO) to perform engagements to assist Sanofi 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. Sanofi 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 Sanofi's systems, processes, policies, and procedures relating to Contribution and Assistance Related Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. More specifically, for the first Reporting Period, the Systems Review shall cover the time period from June 30, 2020, through December 31, 2020. If Sanofi materially changes its systems, processes, policies, and procedures relating to Contribution and Assistance Related Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review 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 each Reporting Period of the CIA. The first Transactions Review shall cover the time period January 1, 2021, through December 31, 2021, and shall include a review of donation arrangements into which Sanofi entered with an Independent Charity PAP for this period. For the second and subsequent Reporting Periods, the Transactions Review shall include a review of donation arrangements entered with Independent Charity PAPs for each applicable calendar year as described below.

#### II. IRO Systems Review

General Description. The Systems Review shall be a review of Sanofi's systems, processes, policies, and procedures (including the controls on those systems, processes,

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policies, and procedures) relating to select Contribution and Assistance Related Functions. Where practical, Sanofi 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 Sanofi pursuant to the preceding sentence.

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

- 1) Independent Charity PAP Related Functions: Sanofi's systems, policies, processes, and procedures relating to arrangements and interactions with (including donations to and sponsorship of) independent third-party patient assistance programs (Independent Charity PAPs).

This review shall include an assessment of the following:

- a. Sanofi'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 Sanofi responsible for reviewing and approving requests for donations to Independent Charity PAPs and 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 Sanofi (e.g., the commercial organization) that are precluded from involvement with arrangements and interactions with Independent Charity PAPs; and
  - iv. the manner by which the separation of Independent Charity PAP-related responsibilities from the commercial organization is enforced.
- b. Sanofi'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 Sanofi 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 Sanofi 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 Sanofi with responsibility for Independent Charity PAPs and the commercial organization of Sanofi (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 Sanofi and health care providers or patients regarding assistance available through any Independent Charity PAP.
- c. Sanofi's policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs as outlined in Section III.J.2 of the CIA, including as it relates to initial or annual donation amounts and any supplemental amounts;
- d. Sanofi'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. Sanofi's criteria, policies, and practices as they relate to donations made by Sanofi to any Independent Charity PAPs as referenced in Section III.J.3, including the internal review process followed in connection with any donations to Independent Charity PAPs; and
- f. Sanofi's policies and practices as they relate to information provided, directly or indirectly, to the public about the availability of patient assistance for Sanofi's products.

- 2) Patient Assistance Related Functions: Sanofi’s systems, policies, processes, and procedures relating to any Sanofi PAP that was formed or is funded, controlled, or operated (directly or indirectly) by Sanofi or any person or entity acting on behalf of Sanofi (including, but not limited to, its employees, agents, vendors, officers, shareholders, or contractors). This shall include any programs designed to provide free product based on financial need or to provide other assistance (i.e., coupons or copay cards) to patients to reduce or eliminate the cost of copayments for drugs.

This review shall include an assessment of the following:

- a. Sanofi’s organizational structure as it relates to Sanofi PAPs, including:
  - i. the identification of those individuals, departments, or groups within Sanofi that have responsibility for, or involvement with Sanofi PAPs; and
  - ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, Sanofi PAPs.
- b. Sanofi’s written policies and procedures as they relate to Sanofi PAPs, including:
  - i. the nature and amounts (or value) of the assistance provided to patients under each of the Sanofi PAPs;
  - ii. the eligibility criteria governing whether and under what circumstances Sanofi provides assistance to patients under each of the Sanofi PAPs;
  - iii. Sanofi’s external communications about the Sanofi PAPs;
  - iv. the maintenance of records regarding free product and other assistance provided to or through Sanofi PAPs;
  - v. ensuring effective communication between Sanofi, Sanofi PAPs, or both, and Medicare Part D plans; and
  - vi. billing for free product provided to or through Sanofi PAPs.
- c. Sanofi’s policies and practices as they relate to the budgeting process for financial or in-kind assistance provided under any Sanofi PAPs, including as they relate to initial or annual donation amounts and any supplemental amounts;

- d. Sanofi'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) assistance through any Sanofi 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
- e. Sanofi's policies and practices as they relate to any contracts or arrangements entered between Sanofi and outside entities relating to any Sanofi 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 arrangements, and the review and approval of such contracts or arrangements.

### **III. IRO Systems Review Report**

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II 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 Sanofi's systems, policies, processes, and procedures relating to the items identified in Sections II.1-2 above, including a general description of Sanofi'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.1-2 above are made known or disseminated within Sanofi;
- 4) a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP;
- 5) a detailed description of any system(s) used to track donations or other assistance provided in response to requests from Independent Charity PAPs;
- 6) a detailed description of any system(s) used to track requests for donations or other assistance from or through any Sanofi PAP;

- 7) a detailed description of any system(s) used to track donations or other assistance provided in response to requests from or through any Sanofi PAP;
- 8) findings and supporting rationale regarding any weaknesses in Sanofi's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 9) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

#### **IV. IRO Transactions Review**

As described more fully below in Sections IV.A-B, the Transactions Review shall include: (1) a review of Sanofi's arrangements with 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 Sanofi'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 the arrangements and interactions with all Independent Charity PAPs or disease state funds with which Sanofi entered charitable donation arrangements during the Reporting Period for which the IRO is conducting the review.

For purposes of this IRO review, the term "Reviewed Materials" shall include the following for each Independent Charity PAP reviewed:

- 1) the Annual Notice from Sanofi to Independent Charity PAPs (which announces Sanofi'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 Sanofi'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 Sanofi's historical donations; eligibility criteria of the Independent Charity PAPs; and other relevant information, as applicable);
- 5) documents required by Sanofi 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 (e.g., minutes from Sanofi's PAP Governance 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 Sanofi and an Independent Charity PAP relating to any donation arrangement with the Independent Charity PAP;
- 7) any donation agreement entered into between Sanofi and an Independent Charity PAP during the applicable Reporting Period; and
- 8) payment documentation required by Sanofi policy reflecting: the total amount of donations Sanofi agreed to make to an Independent Charity PAP broken down by disease fund, if applicable; the schedule of such payments, if applicable; the actual payments made;

and any decisions to change the initial donation amount agreed to by Sanofi.

In addition to reviewing documents and written materials, the IRO may also interview individuals at Sanofi who have responsibility for arrangements and interactions with Independent Charity PAPs.

For each Independent Charity PAP arrangement or interaction reviewed, the IRO shall assess the Reviewed Materials and any interviews conducted by the IRO to evaluate whether the Independent Charity PAP-related activities were conducted in a manner consistent with Sanofi's policies and procedures including those described in Section III.J and with OIG guidance. More specifically, the IRO Review shall evaluate and identify:

- 1) Whether activities relating to arrangements and interactions with the Independent Charity PAP were undertaken by the appropriate individuals, departments, or groups within Sanofi in accordance with the company's policies and procedures including those outlined in Section III.J;
- 2) Whether Sanofi's commercial organization (as defined in Section III.J) influenced or was involved in decisions to enter any arrangement or interaction with the Independent Charity PAP in violation of Sanofi's policies and procedures or OIG guidance;
- 3) Whether Sanofi followed the budgeting policies and practices outlined in Section III.J.2 with regard to any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;
- 4) Whether Sanofi followed the decision-making and approval process 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 Sanofi would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;
- 5) Whether Sanofi followed the criteria, policies, and practices outlined in Section III.J.3 of the CIA in connection with all donations made by Sanofi to any Independent Charity PAP, including as they pertain to the internal review of potential donations and the adherence to the criteria specified in Section III.J.3;
- 6) Any communications that occurred between any representatives of Sanofi 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 Sanofi's policies and procedures and OIG guidance;

- 7) Whether, for each donation from Sanofi to any Independent Charity PAP, Sanofi complied with the requirements outlined in Section III.J.3; and
- 8) Whether, based on its review, the IRO found that Sanofi exerted influence or control over the Independent Charity PAP in violation of Sanofi's policies and procedures, including those outlined in Section III.J.3.

#### 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 Sanofi in connection with Promotional Functions, as defined in Section II.C.3 of the CIA. For the second through fifth Reporting Periods, the Additional Items Review may include activities undertaken by Sanofi in connection with any Sanofi 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 Sanofi of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Sanofi 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 Sanofi's systems, processes, policies, and procedures based on its review of each Additional Item).

Sanofi may propose to OIG that relevant internal audit(s) and/or other reviews conducted by outside entities at Sanofi'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 Sanofi's internal monitoring or audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

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

If OIG agrees to permit certain of Sanofi's internal audit or other monitoring work for a given Reporting Period to be substituted for a portion of an Additional Items review, such internal work 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.

## **V. Transactions Review Reports**

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

- A. 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.
- B. Results to be Included in Report

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

(Relating to the review of Independent Charity PAP arrangements)

- a) a list of the Independent Charity PAPs with which Sanofi entered charitable donation arrangements during the Reporting Period;



- b) for each Independent Charity PAP for which the IRO reviewed arrangements or interactions during the Reporting Period: i) a description of the review conducted by IRO; and ii) a summary of all instances in which it appears that Sanofi failed to follow its policies and procedures and/or OIG guidance regarding its arrangements or interactions with an Independent Charity PAP;
- c) for each Independent Charity PAP reviewed by the IRO, findings regarding each element specified above in Sections IV.A.1-8;
- d) the findings and supporting rationale regarding any overall weaknesses in Sanofi's systems, processes, policies, procedures, and practices relating to its arrangements and interactions with Independent Charity PAPs; and
- e) recommendations, if any, for changes in Sanofi'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 Sanofi'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 Sanofi's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.