

**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 U.S., LLC,**  
**AND GENZYME CORPORATION**

**I. PREAMBLE**

Sanofi US Services Inc. and sanofi-aventis U.S., LLC (Sanofi US); Aventis, Inc.; and Genzyme Corporation (Genzyme) (collectively, Sanofi) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Effective December 19, 2012, Sanofi US entered into a settlement agreement (Hyalgan Settlement Agreement) with the United States to resolve allegations that between 2005 and 2009, Sanofi US violated the False Claims Act by giving physicians free units of its knee injection Hyalgan® (a Class III Medical device) in violation of the Anti-Kickback Statute, to induce them to purchase and prescribe the product. The settlement also resolves allegations that Sanofi US submitted false average sales price (ASP) reports for Hyalgan® that failed to account for free units distributed contingent on Hyalgan® purchases. The government alleges that the false ASP reports, which were used to set reimbursement rates, caused government programs to pay inflated amounts for Hyalgan® and a competing product. Sanofi US also entered into settlement agreements with various states and Sanofi US' agreement to this CIA is a condition precedent for those agreements.

Effective December 20, 2013, Genzyme entered into a settlement agreement with the United States to resolve allegations that between January 1, 2003, and May 18, 2010, Genzyme, through its sales representatives, guided surgical staff and physicians to slice the adhesion barrier Seprafilm® (a Class III Medical Device) into strips and to hydrate it with saline to use in laparoscopic abdominal and pelvic procedures. As a result of this conduct, Genzyme allegedly caused hospitals and other purchasers of Seprafilm® to submit claims to Federal health care programs that were not reimbursable.

Prior to the CIA's Effective Date (as defined below), Sanofi established a voluntary compliance program designed to address Sanofi US and Genzyme's U.S. activities (Sanofi NA Compliance Program). The Sanofi NA Compliance Program includes a Head of Compliance North America and a U.S. Compliance Committee. The Sanofi NA Compliance Program is designed to address, among other things, compliance with Federal health care program requirements and FDA requirements.

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

## **II. TERM AND SCOPE OF THIS CIA**

A. The period of the compliance obligations assumed by Sanofi under this CIA shall be five years from the Effective Date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

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

1. "Covered Persons" includes:
  - a. all owners of Sanofi who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading or in connection with the operation of employee incentive programs);
  - b. all officers and directors of Sanofi;
  - c. except as carved out below in this Section II.C.1, all employees of Sanofi who are based in the United States who

are engaged in or who supervise personnel who are engaged in Promotional and Product Services Related Functions, and all employees of Sanofi or of any foreign subsidiary of Sanofi who are based outside the United States and who are engaged in or who supervise personnel who are engaged in Promotional and Product Services Related Functions; and

- d. all contractors, subcontractors, agents, and other persons who perform any of the Promotional and Product Services Related Functions on behalf of Sanofi, and who in that capacity either (i) interact directly with health care professionals (HCPs), healthcare institutions (HCIs) or consumers in the United States; or (ii) perform activities, provide services or create materials relating to the Promotional and Product Services Related Functions and those activities, services, or materials are not reviewed or supervised by a Sanofi employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Government Reimbursed Products” refers to all Sanofi drugs, devices, and biologics 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. “Relevant Covered Persons” includes all Covered Persons engaged in Promotional and Product Services Related Functions and all individuals who supervise Covered Persons who engage in Promotional and Product Services Related Functions.

4. “Promotional and Product Services Related Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; (b) the development, approval, preparation, or dissemination of promotional and non-promotional materials or information about, or the provision of services relating to, Government Reimbursed Products, including those functions relating Sanofi’s review and approval processes for promotional materials and any applicable review committee(s) and Medical Affairs; and (c) with respect to Government

Reimbursed Products, contracting with HCPs or HCIs in the United States to be speakers, consultants, or to conduct Research, as defined below, on Government Reimbursed Products, and the authorship, publication, and disclosure of results relating to such studies.

5. The term “Third Party Educational Activity” shall mean, as defined in Sanofi’s policies, professional education for HCPs intended to be independent of Sanofi’s control or influence that are conducted by a third party and supported by Sanofi, including but not limited to continuing medical education (CME), disease awareness, or medical conferences.

6. The term “Third Party Personnel” shall mean personnel who engage in Promotional and Product Services Related 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 and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.5. Provided that Sanofi complies with the requirements of Sections III.B.2, V.A.7, and V.B.5, Sanofi shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definitions of Covered Persons.

7. The term “Research” shall mean sponsorship or support by Sanofi of post-marketing research involving human subjects and Government Reimbursed Products. This includes post-marketing clinical trials and other post-marketing studies sponsored by Sanofi and support by Sanofi of investigator-sponsored studies (ISSs) for Government Reimbursed Products.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Sanofi shall continue to maintain a Compliance Program that includes the following elements:

A. **Compliance Responsibilities of Certain Sanofi Employees and the Board of Directors.**

1. *Compliance Officer.* Prior to the Effective Date, Sanofi appointed an individual to serve as the Sanofi NA compliance officer (Compliance Officer) and Sanofi shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer is, and shall continue to be, responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, with Federal health care program requirements and FDA requirements. The Compliance Officer shall be a member of senior management of Sanofi US, shall report directly to the President of Sanofi North America Pharmaceuticals and the Chief Executive Officer of Genzyme. The Compliance Officer shall also report to the Global Compliance Officer of Sanofi's parent corporation. Sanofi shall make periodic (at least quarterly) reports regarding compliance matters directly to the Aventis, Inc. Board of Directors and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer of any Sanofi entity. Accordingly, the Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer of Sanofi US and the General Counsel or Chief Financial Officer of Genzyme. The Compliance Officer shall be responsible for monitoring the day-to-day U.S. compliance activities engaged in by Sanofi US and Genzyme as well as for 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 change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Sanofi formed a U.S. Compliance Committee (Compliance Committee). Sanofi shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant

departments, such as legal, medical affairs, regulatory affairs, safety and medical information, sales, marketing, human resources, finance, audit, research and development, 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 quarterly.

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

3. *Board of Directors Compliance Obligations.* The Board of Directors of Aventis, Inc., the common U.S. parent of Sanofi US and Genzyme (Board), shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include an independent (i.e., non-executive) member. The Board shall, at a minimum, be responsible for the following:

a. The Board shall meet at least quarterly to review and oversee Sanofi's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities and performance of the Compliance Officer and Compliance Committee; and

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

At a minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of Sanofi's North America Compliance Program during [add reference to time period], 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, FDA 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 Accountability and Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Sanofi officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Sanofi business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: (i) President of Sanofi North America Pharmaceuticals; (ii) Chief Executive Officer of Genzyme; (iii) Sanofi executives in marketing, sales, regulatory, medical and similar business functions responsible for Government Reimbursed Products; and (iv) to the extent that any business unit performs Promotional and Product Services Related Functions and is not covered by the certifications of one of the above-listed individuals, the presidents, executives, vice-presidents, and/or leaders/heads of business units of Sanofi as would be necessary to ensure that there is a Certifying Employee from each such business unit engaged in Promotional and Product Services Related Functions.

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

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Sanofi Policies and Procedures, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the \_\_\_\_\_ [insert name of department or functional area] of Sanofi is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA. 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 conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons

why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Sanofi developed, implemented, and distributed a written code of conduct to all Covered Persons. This code is known as Sanofi's Code of Ethics and US Supplement (Code of Conduct). Sanofi shall maintain the Code of Conduct during the term of the CIA. Sanofi makes, and shall continue to make, the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct includes, or within 120 days after the Effective Date, shall be revised to address or include the following:

- a. Sanofi's commitment to full compliance with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to Promotional and Product Services Related Functions;
- b. Sanofi's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements, FDA requirements, and with Sanofi's own Policies and Procedures;
- c. the requirement that all of Sanofi's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Sanofi, suspected violations of any Federal health care program requirements, FDA requirements, or of Sanofi's own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.F and Sanofi's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, either in writing or in electronic form, that he or she has received, read, understood, and shall abide by Sanofi's Code of Conduct. New Covered Persons shall receive the Code of

Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Sanofi shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. *Third Party Personnel.* Within 120 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 compliance with all Federal health care program requirements and FDA requirements. The letter shall include a description of the Sanofi NA Compliance Program. Sanofi shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Sanofi's Code of Conduct and a description of the Sanofi NA Compliance Program available to its Third Party Personnel; or (b) represent to Sanofi that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Sanofi shall implement written Policies and Procedures regarding the operation of Sanofi's Compliance Program and Sanofi's compliance with Federal health care program requirements and FDA requirements. At a minimum, the Policies and Procedures must address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in compliance with all applicable FDA requirements;
- c. the development, implementation, and review of call plans for sales representatives who promote and sell Government Reimbursed Products in the United States. For each Government Reimbursed Product, the Policies and Procedures

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

- d. the development, implementation, and review of plans for the distribution of samples of, or coupons or vouchers (if any) for, Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under which, HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples of Government Reimbursed Products (or, if applicable, coupons or vouchers) from Sanofi. The Policies and Procedures shall also require that Sanofi modify the Sample Distribution Plans as necessary to ensure that Sanofi is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program requirements and FDA requirements. The Sample Distribution Plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;
- e. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the consultant arrangements and related events are used for

legitimate and lawful purposes in accordance with applicable Federal health care program requirements and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;

- f. programs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program requirements and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- g. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Sanofi's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- h. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.10 above. These Policies and Procedures shall be designed to ensure that Sanofi's funding and/or sponsorship of such programs complies with all applicable Federal health care program requirements and FDA requirements;

The Policies and Procedures shall require that: 1) to the extent feasible consistent with subsection III.B.3.h.4, Sanofi disclose its financial support of the Third Party Educational Activity and, any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose Sanofi's financial support of the Third Party Educational Activity and to require faculty, speakers, or organizers at such Activity to disclose any financial relationship with Sanofi; 3) the Third Party Educational Activity have an educational focus; 4) the content, organization, and operation of the Third Party

Educational Activity be independent of Sanofi's control; 5) Sanofi supports only Third Party Educational Activity that is non-promotional in tone/nature; and 6) Sanofi's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

- i. review of promotional materials by appropriate qualified personnel (such as regulatory, medical, or legal personnel) intended to be disseminated outside Sanofi in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Sanofi's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program requirements and FDA requirements. The Policies and Procedures shall require that: 1) applicable review committees review all promotional materials about Government Reimbursed Products prior to the distribution or use of such materials; and 2) deviations from the standard review committee practices and protocols (including timetables for the submission of promotional materials for review) shall be documented and referred for appropriate follow-up;
- j. compensation (including through salaries, bonuses, or other means) for sales representatives and their managers. These Policies and Procedures shall: 1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper marketing of Sanofi's Government Reimbursed Products; and 2) include mechanisms, where appropriate, that are designed to exclude from incentive compensation sales that may indicate sales for unapproved uses;
- k. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care

program for the product (Compendia). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on Sanofi's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results). The Policies and Procedures shall include a requirement that Sanofi conduct: (i) a review at the time of submission of information to Compendia to verify that the information submitted to the Compendia (including information about clinical studies and other research) is complete and accurate; (ii) an annual review of all Sanofi Government Reimbursed Product listings and monographs within the Compendia designed to identify errors and ensure the information is complete and accurate; and (iii) an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by Sanofi to any Compendia. Sanofi's legal or compliance personnel shall be involved in this review;

- l. sponsorship or other support of Research involving Government Reimbursed Products by Sanofi, including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes; and uses made of publications relating to Research;
- m. the materials and information that may be distributed by Sanofi sales representatives about Government Reimbursed Products and the manner in which Sanofi sales representatives respond to requests for information about non-FDA approved uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives refer all requests for information about unapproved uses of Government Reimbursed Products to the Medical Affairs group.
- n. the manner and circumstances under which medical personnel

interact with or participate in meetings or events with HCPs or HCIs (either alone or with Sanofi sales representatives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to requests for information and other discussions about unapproved uses of Government Reimbursed Products.

- o. authorship of journal articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all relationships or potential conflicts of interest that might bias the authors' work between the author and Sanofi, the identification of all authors or contributors (including professional writers) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;
- p. disciplinary policies and procedures for violations of Sanofi's Policies and Procedures, including policies relating to Federal health care program requirements and FDA requirements; and
- q. the materials and information that may be distributed by Sanofi's Medical Information department and by field medical personnel and the mechanisms through, and manner in which, Sanofi's Medical Information department and field medical personnel receive and respond to requests for information from an HCP or another individual or entity about unapproved uses of Sanofi's Government Reimbursed Products in the United States; the form and content of information disseminated by Sanofi in response to such requests; and the internal review process for the information disseminated;

The Policies and Procedures shall include a requirement that Sanofi develop a database (or databases) for use by Medical Information and field medical personnel (Inquiries Database(s)). The Database(s) shall track all requests

submitted to Sanofi's Medical Information department or all requests for unapproved uses to field medical personnel for information about Government Reimbursed Products. The Inquiries Database(s) shall include the following items of information for each unique inquiry (Inquiry) received for information about Government Reimbursed Products: (i) date of Inquiry; (ii) form of Inquiry (e.g., fax, phone, etc.); (iii) name of the requesting HCP, HCI, or other individual or entity; (iv) nature and topic of request (including exact language of the Inquiry if made in writing); (v) for requests to Medical Information, an evaluation of whether the Inquiry relates to information about unapproved use for the product; (vi) nature/form of the response from Sanofi (including a record of the materials provided to the HCP or HCI in response to the request); and (vii) the name of the Sanofi sales representative who called on or interacted with the HCP, customer, or HCI, if known or applicable.

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

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

C. Training and Education.

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

- a. CIA requirements; and
- b. Sanofi's Compliance Program, including the Code of Conduct.

To the extent that General Training was provided to Covered Persons from January 1, 2014, it shall satisfy the requirements of Section III.C.1.b above for the first Reporting Period and OIG shall credit the training toward the requirements of Section III.C.1.b for the first Reporting Period. During the first Reporting Period, if Sanofi has already provided two hours of General Training, then Sanofi may satisfy the remaining General Training requirements of Section III.C.1.a by notifying these Covered Persons electronically that Sanofi entered this CIA and by providing them with an explanation of Sanofi's requirements and obligations under the CIA. In order for Sanofi to receive credit in the first Reporting Period for meeting the remaining General Training requirements under Section III.C.1.a, Sanofi must receive and maintain electronic certification that the Covered Person has received and reviewed information regarding Sanofi's requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Promotional and Product Services Training.* Sanofi shall provide annual training to each Relevant Covered Person with responsibilities relating to brand named Government Reimbursed Products or devices or biologics. This training shall be known as Specific Training.

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

This Specific Training shall include a discussion of:

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

- c. all Sanofi Policies and Procedures and other requirements applicable to Promotional and Product Services Related Functions;
- d. FDA requirements relating to medical devices, circumstances under which a medical device is considered a new device, circumstances under which a medical device is considered adulterated, and the penalties applicable to adulterated devices;
- e. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program requirements and FDA requirements and all other applicable legal requirements;
- f. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- g. examples of proper and improper practices related to Promotional and Product Services Related Functions.

New Relevant Covered Persons shall receive their Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later.

To the extent that Specific Training was provided to Covered Persons from January 1, 2014, it shall satisfy the requirements of Section III.C.2 above for the first Reporting Period and OIG shall credit the training toward the requirements of Section III.C.2 for the first Reporting Period.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person with responsibilities relating to brand named Government Reimbursed Products or devices or biologics shall receive at least two hours of Specific Training in each subsequent Reporting Period.

3. *Board Member Training.* Within 120 days after the Effective Date, Sanofi shall provide at least two hours of training to each Board Member, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

To the extent that Board Member Training was provided to a Board Member from January 1, 2014, it shall satisfy the requirements of Section III.C.3 above for the first Reporting Period and OIG shall credit the training toward the requirements of Section III.C.3 for the first Reporting Period. In order for Sanofi to receive credit in the first Reporting Period for meeting the Board Member Training requirement under Section III.C.3, Sanofi must receive and maintain documentation that the Board Member received the training.

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

4. *Certification.* Each individual who is required to complete training shall certify, in writing or in electronic form, if applicable, that he or she has received such training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain these certifications, along with all course materials.

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

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

7. *Computer-based Training.* Sanofi may provide the training required under this CIA through appropriate computer-based training approaches. If Sanofi chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Compliance Assessment and Risk Evaluation Process.

Sanofi represents that prior to the Effective Date, Sanofi began to implement a standardized process to allow Sanofi compliance, legal, and business unit leaders to assess and identify risks associated with Government Reimbursed Products that have field force support in the United States. This program is referred to as the Compliance

Assessment Risk Evaluation (CARE) program and is described in more detail in Appendix C, which is incorporated by reference. The CARE program involves an annual evaluation and mitigation of risks associated with the marketing of Government Reimbursed Products. Sanofi shall maintain a CARE program for the duration of the CIA.

For the duration of the CIA, the CARE program shall include evaluation and mitigation of risks associated with Government Reimbursed Products, including in the areas of: marketing; sales, including the risk of sales for unapproved uses or sales that include misbranded products; adulteration of a device; and healthcare compliance risks. Based on the outcomes of the risk identification and compliance assessment process, Sanofi compliance, in consultation with other personnel, shall centrally develop and implement audit plans to address the identified risk activities. Sanofi shall perform this CARE process throughout the term of the CIA.

E. Review Procedures.

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Sanofi US shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Sanofi in assessing and evaluating its Promotional and Product Services Related Functions and the CARE program. More specifically, the IRO(s) shall conduct reviews that assess Sanofi’s systems, processes, policies, procedures, and practices relating to the relating to the Promotional and Product Services Functions and the CARE program (collectively IRO Reviews).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

- b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendices B and C, the IRO Reviews shall consist of three components: (1) Systems Reviews and Transactions Reviews relating to the Promotional and Product Services Related Functions; (2) Additional Items reviews; and

(3) Systems Reviews and Transaction Reviews relating to the CARE program. The Systems Reviews shall assess Sanofi's systems, processes, policies, and procedures relating to the Promotional and Product Services Related Functions and the CARE program. If there are no material changes in Sanofi's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the periods covering the first and third Reporting Periods. If Sanofi materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform Systems Reviews for the Reporting Period(s) in which such changes were made in addition to conducting a Systems Review for the first and third Reporting Periods, as set forth more fully in Appendices B and C.

The Promotional and Product Services Related Functions Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The CARE Transactions Review shall be conducted for the second through fifth Reporting Periods. The IRO(s) shall perform all components of each Transaction Review. As set forth more fully in Appendices B and C, the CARE Program Transactions Review shall include several components.

In addition to the items specified in Appendices B and C, the Transactions Review shall also include a review of up to three additional areas or practices of Sanofi identified by the OIG in its discretion (hereafter Additional Items). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular IRO Reporting Period, the OIG will consult with Sanofi and may consider internal compliance audits conducted by Sanofi, the Government Reimbursed Product portfolio of Sanofi, the nature and scope of Sanofi's promotional practices and arrangements with HCPs and HCIs, any additional types of non-promotional activities engaged in by Sanofi, including but not limited to advisory boards, post-marketing research, physician publications, and other information.

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

The 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 applicable IRO Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Sanofi shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

- c. *Retention of Records.* The IRO and 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 IRO Reviews.
2. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A through C.
3. *Validation Review.* In the event OIG has reason to believe that: (a) any of Sanofi's IRO Reviews fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Sanofi shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Sanofi's final

Annual Report shall be initiated no later than one year after Sanofi's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Sanofi of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Sanofi may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. Sanofi agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Sanofi prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

F. Disclosure Program.

Prior to the Effective Date, Sanofi established 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 conduct, practices, or Policies and Procedures with respect to a Federal health care program requirement or an FDA Requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Sanofi shall maintain such a Disclosure Program throughout the term of the CIA. Sanofi shall appropriately publicize the existence of the Disclosure Program and the Compliance telephone line (e.g., via internal posting systems or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, non-retaliation policy and shall include a reporting mechanism for anonymous communications for which

appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the 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 necessary information to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, 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, which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. This disclosure log shall be made available to OIG upon request.

G. Ineligible Persons.

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

Award Management (SAM) (available through the Internet at <http://www.sam.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 Exclusions Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Sanofi shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.
- c. Sanofi shall implement and maintain a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section III.G affects Sanofi's responsibility, if applicable, 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 by excluded persons 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 programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If 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, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Sanofi shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Sanofi conducted or brought by a U.S.-based 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 shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Reportable Events.

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

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

- d. the filing of a bankruptcy petition by 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 Sections III.I.1.a-c.* For Reportable Events under Sections III.I.1.a-c, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;
- b. a description of Sanofi's actions taken to correct the Reportable Event; and
- c. any further steps Sanofi plans to take to address the Reportable Event and prevent it from recurring.

Sanofi shall not be required to report as a Reportable Event a matter which is a subject of an ongoing investigation or legal proceeding by a government entity or its agents previously disclosed under Section III.H above.

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

J. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Sanofi and the FDA that materially discusses Sanofi's or a Covered Person's actual or potential unlawful or improper promotion or other improper activity involving Sanofi's products (including adulteration of a device or any improper dissemination of information about unapproved uses), Sanofi shall provide a copy of the report, correspondence, or communication to the OIG. Sanofi shall also provide written notice to the OIG within 30 days after the

resolution of any such disclosed adulteration of a device or off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

K. Field Force Monitoring and Review Efforts.

Within 120 days after the Effective Date, Sanofi shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales representatives' interactions regarding Government Reimbursed Products with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs and HCIs and to identify potential improper promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: 1) a Speaker Monitoring Program; 2) direct field observations (Observations) of sales representatives; and 3) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to speaker programs, Sanofi shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use Sanofi approved materials and may not directly or indirectly promote the product for unapproved uses. Sanofi shall maintain a centralized electronic system through which all speaker programs are initiated, administered, and tracked. The system shall include controls designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program requirements and FDA requirements. The controls shall also be designed to ensure that there is a legitimate need for the speaker programs.

This system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by Sanofi. Sanofi shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, Sanofi shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. Sanofi shall require the completion of certifications by sales representatives or other Sanofi personnel regarding whether a speaker program complied with Sanofi requirements, and in the event of non-compliance, Sanofi shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, Sanofi shall institute a Speaker Monitoring Program under which appropriately trained Sanofi personnel who are independent from the functional area being monitored or third party consultants appropriately trained by Sanofi and under the supervision of Sanofi (Monitoring Personnel) shall attend speaker programs regarding Government Reimbursed Products during each Reporting Period and conduct live audits of 40 of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected using either a risk-based targeting approach or a random sampling approach. For each program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Sanofi representative activities during the program to assess whether the programs were conducted in a manner consistent with Sanofi's Policies and Procedures. Sanofi shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Sanofi Monitoring Personnel shall conduct observations of sales representatives for Government Reimbursed Products to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with Sanofi's Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by Sanofi compliance personnel using either a risk-based targeting approach or a random sampling approach, include a review of each therapeutic area and actively promoted Government Reimbursed Product, and be conducted across the United States.

At the completion of each Observation, Sanofi Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Sanofi Monitoring Personnel;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Sanofi Policies and Procedures; and
- 6) the identification of any potential improper promotional activity.

Sanofi Monitoring Personnel shall conduct at least 40 Observations during each Reporting Period.

3. *Records Reviews.* As a component of the FFMP, Sanofi shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs in order to identify potential or actual compliance violations. For each Reporting Period, Sanofi shall develop and implement a plan for conducting Records Reviews associated with at least five Government Reimbursed Products and a sampling of the representatives promoting those products in every separate region.

These Records Reviews shall include the monitoring and review of: 1) records and, to the extent necessary, systems relating to sales representatives' interactions with HCPs and HCIs (including records from the electronic detailing system for the particular sales representative, sales communications from managers, records relating to speaker program activities, sample distribution records, if applicable, and expense reports); 2) records relating to requests for medical information about, or inquiries relating to, Government Reimbursed Products; 3) records relating to tutorials and preceptorships; 4) if available, message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales representatives' interactions with HCPs and HCIs; 5) sales representative call notes; 6) sales representatives' e-mails and other electronic records; and 7) recorded results of the Observations of sales representatives and applicable notes or information from the sales representatives' managers.

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

Sanofi shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Sanofi also shall provide the OIG with copies of the Observation report for any instances in which it was determined that

improper promotion or other improper conduct occurred and a description of the action(s) that Sanofi took as a result of such determinations. Sanofi shall make the Observation reports for all other Observations available to the OIG upon request.

- L. Notice to Health Care Providers and Entities. Within 30 days after the Effective Date, Sanofi shall post in a prominent place on the main page of the health care professional section of its company website (or other placement agreed to in advance by the OIG), <http://www.sanofi.us/l/us/en/layout.jsp?scat=55C8BD8F-8CC5-4165-AE15-14AFFA8516A7> and <http://www.genzyme.com/Products/Resources-for-Health-Care-Professionals.aspx> a copy of a letter signed by Sanofi's President, North America Pharmaceuticals and the President and Chief Executive Officer of Genzyme containing the language set forth below:

As you may be aware, in December 2013, a Sanofi company, Genzyme Corporation, entered into a civil settlement under the False Claims Act with the United States in the connection with the promotion of Septrafilm, which is a device now owned by Sanofi. In addition, in December 2012, Sanofi US Services, Inc. and sanofi-aventis U.S., LLC entered into a separate civil settlement with the United States in connection with the provision of free units of Hyalgan, a knee injection, to physicians. This letter provides you with additional information about the settlement, explains sanofi-aventis U.S., LLC's, Sanofi US Services, Inc.'s, and Genzyme Corporation's commitments going forward, and provides you with access to information about those commitments.

In the December 2013 settlement, Genzyme resolved allegations that between January, 2003, and May 18, 2010, Genzyme improperly promoted Septrafilm, and agreed to pay the United States \$22.28 million. More information about this settlement may be found at the address linked below. In December 2012, Sanofi U.S. Services, Inc. and sanofi-aventis U.S., LLC paid \$109 million to resolve separate False Claims Act allegations. [The letter shall include links to the Department of Justice and Sanofi websites.]

To resolve issues surrounding the settlements, Aventis, Inc., sanofi-aventis U.S., LLC, Sanofi US Services, Inc., and Genzyme Corporation entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. This CIA is available at <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>. Under this agreement, these companies agreed to undertake certain obligations designed to promote compliance with Federal health care program and Food and

Drug Administration (FDA) requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by any of Sanofi's representatives to Sanofi's Compliance Department or the FDA using the information set forth below.

Please call Sanofi at (800) 648-1297 if you have questions about the settlement referenced above or to report any instances in which you believe that a Sanofi representative inappropriately promoted a product or engaged in questionable conduct, including adulteration of a device. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a Sanofi representative to the FDA's Office of Prescription Drug Promotion at (301) 796-1200 or improper conduct associated with adulteration of a device to the Center for Device and Radiological Health, Office of Compliance at (301) 796-5500. You should direct medical questions or concerns regarding Sanofi products to (800) 633-1610 option 1 (Sanofi US) or (800) 745-4447 (Genzyme).

The notice shall remain posted for a period of at least 180 days. The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notice shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Sanofi shall provide to the OIG a summary of the calls and messages received.

M. Monitoring of Non-Promotional Activities.

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

1. *Consultant Arrangement Activities.* To the extent that Sanofi engages U.S. HCPs or HCIs for services that relate to Promotional and Product Services Related Functions other than for speaker programs (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as "Consultants." Sanofi shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the

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

Within 120 days after the Effective Date, Sanofi shall establish a process to develop annual budgeting plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year. The Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. Sanofi's legal and compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable Federal health care program requirements and FDA requirements and Sanofi Policies and Procedures.

Within 120 days after the Effective Date, Sanofi shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Sanofi legal and compliance personnel.

Within 120 days after the Effective Date, Sanofi shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Sanofi received the work product generated by the Consultant.

Within 120 days after the Effective Date, Sanofi shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 15 Consultant arrangements with HCPs. The Consultant Monitoring Program shall select Consultant arrangements for review using either a risk-based targeting approach or a random sampling approach. The Consultant Monitoring Program shall audit at least one of each type of Consultant activity. Sanofi Monitoring Personnel conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Sanofi's Policies and Procedures. Results from the Consultant Program

Audits, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or designee) for review and follow-up as appropriate.

2. *Third Party Educational Activity.* Within 120 days after the Effective Date, Sanofi shall establish a grants management system or systems as the exclusive mechanism through which requestors may seek or be awarded grants for Third Party Educational Activities.

The grants management system(s) shall ensure that the Sanofi sales and marketing departments have no involvement in, or influence over, the review and approval of Third Party Educational Activities. Grant requests for Third Party Educational Activities shall be submitted through a centralized grants management system or systems and processed in accordance with standardized, objective criteria developed by Sanofi (such as based upon the qualifications of the requestor, or the quality of the program funded by the grant). In addition, the grants for Third Party Educational Activities shall be provided only pursuant to a written agreement with the funding recipient, and if payments to the funding recipient are consistent with the written agreement. To the extent not already accomplished, within 120 days after the Effective Date, Sanofi shall develop a system or systems for grant submission and processing by a centralized office which is not part of the sales or marketing division. Sanofi shall continue the Third Party Educational Activity process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

Within 120 days after the Effective Date, Sanofi shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 grants for Third Party Educational Activity. The Grants Monitoring Program shall select grants for review using either a risk-based targeting approach or a random sampling approach. Sanofi Monitoring Personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant office's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with Sanofi's Policies and Procedures. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or designee) for review and follow-up as appropriate.

3. *Publication Activities.* To the extent that Sanofi engages U.S. HCPs or U.S. HCIs to produce articles or other publications relating to Government Reimbursed Products (collectively "Publication Activities") such HCPs or HCIs shall be referred to as Authors. Sanofi shall require all Authors to enter into written agreements describing the scope of work to be performed, the fees to be paid in connection with the Publication Activities, if any, and compliance obligations of the Authors. If fees to Authors are made, such payments shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Sanofi. Authors shall confirm that they satisfy International Committee of Medical Journal Editors (ICMJE) authorship criteria, including providing final approval of the publication to be published.

Within 120 days after the Effective Date, Sanofi shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various Publication Activities (Publications Plans). The annual Publications Plans shall also identify the budgeted amounts to be spent on Publication Activities. Sanofi's legal and compliance personnel shall be involved in the review and approval of such annual Publications Plans, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities and related events are used for legitimate purposes in accordance with Sanofi Policies and Procedures and with applicable Federal health care program requirements and FDA requirements.

Within 120 days after the Effective Date, Sanofi shall establish a needs assessment process for Publication Activities. This process shall ensure that a needs assessment has been completed prior to the retention of an Author to undertake a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work). Any deviations from the Publications Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Sanofi legal and compliance personnel.

Within 120 days after the Effective Date, Sanofi shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 Publication Activities. The Publication Monitoring Program shall select publications for review both on a risk-based targeting approach and on a sampling approach.

Sanofi Monitoring Personnel shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to

assess whether the activities were conducted in a manner consistent with Sanofi's Policies and Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of Policies and Procedures, shall be compiled and reported to the Compliance Officer (or designee) for review and follow-up, as appropriate.

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

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

N. Reporting of Physician Payments.

1. *Reporting of Payment Information.* On or before March 31, 2016, and 90 days after the end of each subsequent calendar year during the term of the CIA, Sanofi shall post on its website a report of the cumulative value of the Payments provided to all Physician Covered Recipients from Sanofi during the prior applicable calendar year. Each annual report shall be easily accessible and readily searchable.

Each report posted pursuant to this Section III.N shall include a complete list of all Physician Covered Recipients to whom Sanofi made Payments in the preceding year. Each report shall be arranged alphabetically according to the Physician Covered Recipient's last name. The Payment amounts in the reports shall be reported in the actual amount paid for all Physician Covered Recipients on the report. For each Physician

Covered Recipient, the applicable report shall include the following information: (i) physician's full name; (ii) city and state that the physician has provided to Sanofi for contact purposes; and (iii) the aggregate value of the Payment(s) in the preceding year.

2. *Definitions and Miscellaneous Provisions.*

- a. Sanofi shall make each annual report of Payments available on its website during the term of the CIA. Sanofi shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual report of Payments. Nothing in this Section III.N affects the responsibility of Sanofi to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to Physician Covered Recipients.
- b. For purposes of Section III.N.1, "Payments" is defined to include all "direct or indirect payments or other transfers of value" as that term is defined in 42 U.S.C. § 1320a-7h and applicable regulations and guidance (including FAQs) published by CMS. The term Payments includes the types of payments or other transfers of value enumerated in 42 U.S.C. § 1320a-7h(a)(1)(A)(vi) and applicable regulations. The term includes all indirect payments or other transfers of value made to a Physician Covered Recipient through a third party where Sanofi requires, instructs, directs, or otherwise causes the third party to provide the Payment to the Physician Covered Recipient. The term also includes direct and indirect payments or other transfers of value provided to a third party at the request of or designated by Sanofi on behalf of a Physician Covered Recipient.
- c. For purposes of its annual website postings as described above, and only with regard to Payments made pursuant to product research or development agreements and clinical investigations as set forth in 42 U.S.C. § 1320a-7h(c)(1)(E), Sanofi may delay the inclusion of such Payments on its website listings consistent with 42 U.S.C. § 1320a-7h(c)(1)(E) and any regulations promulgated thereunder.

- d. The term “Payments” does not include direct or indirect payments or other transfers of value or other items that are not included in or are excluded from the definition of “payment” or otherwise excluded from reporting under 42 U.S.C. § 1320a-7h and applicable regulations and guidance (including FAQs) published by CMS.
- e. For purposes of this Section III.N, the term “Physician Covered Recipient” is defined to include any physician, except for a physician who is a bona fide employee of Sanofi, as that term is defined in 42 U.S.C. § 1320a-7h(e)(6) and applicable regulations.

O. Other Transparency/Disclosure Initiatives

To the extent not already accomplished, within 120 days after the Effective Date of the CIA, Sanofi shall post the following information regarding Sanofi grants and charitable contributions to HCPs and HCIs: (1) the ultimate recipient organization’s name; (2) a brief description of the program for which the grant or charitable contribution was requested; and (3) the amount of the grant or charitable contribution. Sanofi shall continue to post and provide updates to the above-described information about grants and charitable contributions throughout the term of this CIA. Sanofi shall notify the OIG in writing at least 60 days prior to any change in the substance of their policies regarding the funding of grants and charitable contributions or posting of the above-referenced information relating to such funding.

To the extent not already accomplished, within 120 days after the Effective Date of the CIA, Sanofi shall ensure that it has registered all clinical studies and report results of such clinical studies on the National Institutes of Health (NIH) sponsored website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)) in compliance with all current federal requirements. Sanofi shall continue to comply with Federal health care program requirements, or other applicable requirements relating to the registration and results reporting of clinical studies during the term of this CIA. In addition, if there is a change in Federal health care program requirements, FDA requirements or NIH requirements or other applicable requirements relating to registration and results reporting of clinical study information, Sanofi shall fully comply with such requirements.

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. **Change or Closure of Unit or Location.** In the event that, after the Effective Date, Sanofi changes locations or closes a business unit or location related to or engaged in any of the Promotional and Product Services Related Functions, Sanofi shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

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

C. **Sale of Unit.** In the event that, after the Effective Date, Sanofi proposes to sell any or all of its business units that are related to Promotional and Product Services Related Functions, Sanofi shall notify OIG of the proposed sale no later than five days after the sale is publicly disclosed by Sanofi. This notification shall include a description of the business unit to be sold, a brief description of the terms of the sale, and the name and contact information of the purchaser. This CIA shall be binding on the purchaser of such business unit, unless otherwise determined and agreed to in writing by the OIG.

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. **Implementation Report.** Within 150 days after the Effective Date, 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 members of the Board of Directors referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Sanofi's Code of Conduct required by Section III.B.1;
6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all 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's letter;
8. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to OIG upon request);
9. the following information regarding each type of training required by Section III.C:
  - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
  - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

10. a description of the CARE program required by Section III.D;

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between Sanofi and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Sanofi;
12. a description of the Disclosure Program required by Section III.F;
13. a description of the process by which Sanofi fulfills the requirements of Section III.G regarding Ineligible Persons;
14. a certification from the Compliance Officer that, if required under Section III.N and to the best of his/her knowledge, information regarding Payments has been posted on Sanofi's website as required by Section III.N;
15. a certification by the Compliance Officer that the notice required by Section III.L was posted in the manner required by Section III.L and a summary of the calls or messages received in response to the notice;
16. a list of all of Sanofi's locations engaged in Promotional and Product Services Related Functions (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of any each Federal health care program contractor to which Sanofi currently submits claims (if applicable);
17. a description of Sanofi's corporate structure, including identification of any U.S. parent and sister companies, subsidiaries, and their respective lines of business; and
18. the certifications required by Section V.C.

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

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, or the group of Certifying Employees described in Sections III.A.1-4;
2. a copy of the resolution by the Board required by Section III.A.3;
3. a summary of any changes or amendments to Sanofi's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;
4. the number of individuals required to review Sanofi's Code of Conduct and complete the certifications required by Section III.B.1, the percentage of individuals who have completed such certifications, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
5. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all 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;
6. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.3 and the reasons for such changes (e.g., change in applicable requirements);
7. the following information regarding each type of training required by Section III.C:
  - a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
  - b. the number of individuals required to complete the initial and annual training, percentage of individuals who completed the training, and an explanation of any exceptions.

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

8. a summary of any significant changes to the CARE program required by Section III.D and a description of the reasons for such changes;

9. a complete copy of all reports prepared pursuant to Sections III.E and Appendices A-C, along with a copy of the IRO's engagement letter;

10. Sanofi's response to the reports prepared pursuant to the reviews outlined in Sections III.E and Appendices A-C, along with corrective action plan(s) related to any issues raised by the reports;

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

12. certifications from the IRO regarding its professional independence and objectivity with respect to Sanofi;

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

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

15. 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;

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

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

18. a summary of the FFMP and the results of the FFMP required by

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

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

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

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

22. a description of all changes to the most recently provided list of Sanofi's locations (including addresses) as required by Section V.A.16; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

23. the certifications required by Section V.C.

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

C. Certifications.

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

2. Compliance Officer: In each Implementation Report and Annual Report, Sanofi shall include the following individual certification by the Compliance Officer:

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

- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;
- c. Sanofi's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program requirements and FDA requirements. In addition, Sanofi's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Sanofi have been reviewed by competent regulatory, medical, or legal counsel, as appropriate, in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by Sanofi and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program requirements and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and
- d. Sanofi's call plans and Sample Distribution Plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3) and, for each Government Reimbursed Product the call plans and Sample Distribution Plans were found to be consistent with Sanofi's policy objectives as referenced above in Section III.B.3.
- e. For each "buy and bill" Government Reimbursed Product for

which Sanofi distributed samples during the Reporting Period, Sanofi reviewed the Average Sales Price (ASP) and other pricing information reported to government payers for such products to ensure that the reported ASPs and other pricing information appropriately accounted for price concessions including, but not limited to, discounts, rebates, and free goods contingent on any purchase requirement. The certification shall identify each buy and bill Government Reimbursed Product for which Sanofi distributed samples during the Reporting Period.

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: Karen Patruno Sheehy  
Vice President  
Head of Compliance, Sanofi North America  
Sanofi US  
55 Corporate Drive  
Bridgewater, New Jersey 08807  
Telephone: 908-981-6780

Facsimile: 908-981-7719

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

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of 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 the Federal health care programs in which it participates and with all applicable FDA requirements. 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, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Sanofi's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Sanofi shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Sanofi's employees 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 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. § 5.65(d).

**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 and implement 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, including the resolution from the Board;
- d. the management accountability and certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the training of Covered Persons, Relevant Covered Persons, and Board Members;
- h. a CARE process as required in Section III.D and Appendix C;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;

- k. notification of Government investigations or legal proceedings;
- l. reporting of Reportable Events;
- m. notification of written communications with FDA as required by Section III.J;
- n. a program for FFMP as required by Section III.K;
- o. a program for Monitoring Non-Promotional Activities as required by Section III.M;
- p. posting of any Payments as required by Section III.N;
- q. notification to HCPs and HCIs as required in Section III.L; and
- r. implementation of the other transparency/disclosure requirements described in Section III.O.

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 in Sections III.E and Appendices A-C.

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

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

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, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day 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 Sanofi receives this notice from OIG of the failure to comply). A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. 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 business 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 business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that 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 is 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. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by 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 and Appendices A-C;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Sanofi constitutes an independent basis for Sanofi's exclusion from participation in the Federal health care programs. 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 is hereinafter 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 to OIG’s satisfaction that:

- a. Sanofi is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) 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 hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Sanofi’s receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, 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.

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 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:

- a. whether Sanofi was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Sanofi had begun to take action to cure the material breach within that period; (ii) Sanofi has pursued and is pursuing such action with due diligence; and (iii) Sanofi provided to OIG within that period a reasonable timetable for curing the material breach and Sanofi has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for 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 be binding on the successors, assigns, and transferees of Sanofi;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;
- D. The undersigned 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 capacity and that they are authorized to execute this CIA.
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles 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**

/Karen Sheehy/

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**KAREN SHEEHY**  
Vice President, Head of Compliance  
Sanofi North America

8/17/2015

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DATE

/Robert DeBerardine/

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**ROBERT DEBERARDINE**  
Senior Vice President and General Counsel  
Sanofi North America

8/17/2015

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DATE

/Tracy Quarles/

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**TRACEY QUARLES**  
Senior Vice President and General Counsel  
Genzyme Corporation

8/17/2015

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DATE

/John S. Rah/

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John S. Rah  
Morgan Lewis & Bockius LLP

8/17/2015

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Date

/Tisha Schestopol/

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Tisha Schestopol  
Morgan Lewis & Bockius LLP

8/17/2015

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Date

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

/Robert K. DeConti/

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Robert K. DeConti  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

9/2/15

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Date

/Christina K. McGarvey/

Christina K. McGarvey <sup>U</sup>  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

9/2/15

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Date

## **Appendix A to CIA for Sanofi**

### **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.**

Sanofi shall engage an IRO (or IROs) that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D, below. Within 30 days after OIG receives the information identified in Section V.A.10 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.

If Sanofi engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Sanofi shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by 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 and medical device industries and have expertise in applicable Federal health care program and FDA requirements that relate to the Promotional and Product Services Related Functions. The assigned individuals shall also be experienced in risk identification and mitigation in relation to pharmaceutical product and medical device marketing and promotion. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care programs under which Sanofi Government Reimbursed Products are reimbursed. The assigned individuals shall also have expertise in FDA requirements and Federal health care program requirements relating to the CARE process;

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

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

C. IRO Responsibilities.

The IRO shall:

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

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

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

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

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

D. Independence and Objectivity.

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

E. IRO Removal/Termination.

1. *Sanofi Termination of 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 its reasons for termination or the reason for 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 the termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or

objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Sanofi to engage a new IRO in accordance with Paragraph A of this Appendix. Sanofi must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Sanofi to engage a new IRO, OIG shall notify Sanofi of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Sanofi may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Sanofi prior to requiring Sanofi to terminate the IRO. However, 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 TO CIA FOR SANOFI**

### **INDEPENDENT REVIEW ORGANIZATION REVIEWS**

#### **I. Covered Functions Review, General Description**

As specified more fully below, Sanofi shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist Sanofi in assessing and evaluating its systems, processes, policies, procedures, and practices related to certain of Sanofi's Promotional and Product Services Related Functions. The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Sanofi may engage, at its discretion, a single IRO 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 the Promotional and Product Services Related Functions, the IRO shall perform the Systems Review for the first and third Reporting Periods. If Sanofi materially changes its systems, processes, policies, and procedures relating to the Promotional and Product Services 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 for the first and third Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

#### **II. IRO Systems Review**

##### **A. Description of Reviewed Policies and Procedures**

The Systems Review shall be a review of Sanofi's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain of the Promotional and Product Services 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 in accordance with the preceding sentence.

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

1) Sanofi's systems, processes, policies, and procedures applicable to the manner in which Sanofi's sales representatives and field medical personnel (including sales personnel and marketing personnel) and personnel from the Medical Information department handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including unapproved uses of Government Reimbursed Products) and adulteration of devices and the dissemination of materials relating to the uses of these products. This review shall include:

- a) the manner in which Sanofi sales representatives and field medical personnel handle requests for information about unapproved uses of Government Reimbursed Products and adulteration of devices (including requiring sales representatives to refer all such requests to Medical Information personnel at Sanofi);
- b) the manner in which Medical Information personnel, including those at Sanofi's headquarters, and field medical personnel in Medical Affairs handle and respond to requests for information about unapproved uses of Government Reimbursed Products and adulteration of devices (including tracking the requests and using pre-approved materials for purposes of responding to the request);
- c) the form and content of information and materials related to Government Reimbursed Products disseminated to HCPs and HCIs (as defined in section II.C.2 of the CIA) and government payers by Sanofi;
- d) Sanofi's systems, processes, policies, and procedures (including the Inquiries Database) to track requests to Medical Information or field based medical personnel for information about unapproved uses and adulteration of Government Reimbursed Products and responses to those requests;

- e) the manner in which Sanofi collects and supports information reported in any systems used to track and respond to requests to Medical Information or field based medical personnel for Government Reimbursed Product information, including its Inquiries Database;
- f) the processes and procedures by which Medical Affairs, the Compliance Officer, or other appropriate individuals within Sanofi identify situations in which it appears improper marketing or adulteration of a Government Reimbursed Product may have occurred; and
- g) Sanofi's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper marketing or adulteration of a Government Reimbursed Product.

2) Sanofi's systems, processes, policies, and procedures applicable to the manner and circumstances under which its Medical Affairs personnel participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of the Medical Affairs personnel at such meetings or events including the manner in which they handle responses to requests for information about unapproved uses of drugs or modifications of devices;

3) Sanofi's systems, processes, policies, and procedures relating to Sanofi's internal review of materials related to Government Reimbursed Products disseminated to HCPs, HCIs and government payers and individuals or entities (*e.g.*, PBMs) acting on behalf of HCPs, HCIs or government payers;

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

5) Sanofi's systems, processes, policies, and procedures relating to the development and review of Call Plans (as described in Section III.B.3.c of the CIA) for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the Call Plans based on expected utilization of Government Reimbursed Products for FDA-approved uses;

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

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

8) Sanofi's systems, processes, policies, and procedures relating to engagement of non-speaker related consultants or other fee-for-service arrangements entered into with HCPs or HCIs and all events and expenses associated with such activities;

9) Sanofi's systems, processes, policies, and procedures relating to Sanofi's funding, directly or indirectly, of Third Party Educational Activities (as defined in Section II.C.5 of the CIA) and all events and expenses relating to such activities; and

10) Submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information, (e.g., any changes based on Sanofi's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia). The review shall also assess Sanofi's processes relating to Sanofi's annual review of information in the Compendia about Sanofi's Government Reimbursed Products during the Reporting Period to any Compendia and Sanofi's annual review of all arrangements,

processing fees, or other payments or financial support (if any) related to Government Reimbursed Products provided to any Compendia.

## B. IRO Systems Review Report

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

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Sanofi's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-11 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.A.1-11 above are made known or disseminated within Sanofi;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products (including the Inquiries Database);
- 5) a detailed description of Sanofi's incentive compensation system for Covered Persons who are sales representatives and their direct managers, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Sanofi may establish compensation differently for different Government Reimbursed Products, the IRO shall report separately on each such type of compensation arrangement;
- 6) 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
- 7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### III. IRO Transactions Review

As described more fully below in Sections III.A-F, the Transactions Review shall include: (1) a review of a sample of Inquiries reflected in Medical Information's Inquiries Database; (2) a review of Sanofi's Call Plans and Sanofi's Call Plan review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by Sanofi pursuant to Section III.N of the CIA; and (5) a review of up to three additional items identified by the OIG in accordance with Section III.E.1.b of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

#### A. Review of Inquiries and Inquiries Database

##### 1) Description of Inquiries Database

As set forth in Section III.B.3 of the CIA, Sanofi shall use a database or databases to track information relating to requests for information received by Sanofi Medical Information Personnel or requests for information about unapproved uses by Field Medical Personnel about its Government Reimbursed Products (hereafter "Inquiries"). Specifically, Sanofi shall document and record Inquiries received from HCPs or HCIs regarding Government Reimbursed Products in a database(s) (the "Inquiries Database") in accordance with Section III.B.3.q of the CIA. Sanofi shall record in the Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of requesting HCP or HCI or other individual or entity; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) for requests to Medical Information, an evaluation of whether the Inquiry relates to information about an unapproved use for the product or the adulteration of a device; 6) nature/form of the response from Sanofi Medical Information or field medical personnel (including a record of any materials provided in response to the request); and 7) the name of the Sanofi representative who called on or interacted with the HCP, customer, or HCI, if known, or applicable.

## 2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer (or designee) shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters (“Inquiry Report”). The Compliance Officer (or designee) shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper promotion or improper adulteration of a device may have occurred in connection with any Inquiry(ies). If the Compliance Officer (or designee), in consultation with other appropriate Sanofi personnel, suspects that improper promotion may have occurred in connection with any Inquiry, the Compliance Officer (or designee) shall undertake a follow-up review of the Inquiry (Inquiries Follow-Up Review), make specific findings based on his/her Inquiries Follow-Up Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.I of the CIA, if applicable). If the Compliance Officer (or designee), in consultation with other appropriate Sanofi personnel, suspects that adulteration of a device may have occurred in connection with any Inquiry, the Compliance Officer (or designee) shall undertake a follow-up review of the Inquiry (Device Adulteration Review), make specific recommendations based on his/her Device Adulteration Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting the conduct, including disclosing Reportable Events pursuant to Section III.I of the CIA, if applicable).

## 3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of at least 50 Inquiries from among the Inquiries reflected in the Inquiries Database for Medical Information related to Government Reimbursed Products for each Reporting Period. 40 of the Inquiries for Medical Information reviewed by the IRO shall be Inquiries for which Sanofi conducted an Inquiries Follow-Up Review or a Device

Adulteration Review, and the remainder of the random sample shall be Inquiries for which Sanofi did not conduct either an Inquiries Follow-Up Review or Device Adulteration Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Compliance Officer (or designee) conducted an Inquiries Follow-Up Review or Device Adulteration Review, the basis for suspecting that improper promotion may have occurred or that adulteration of a device may have occurred; the steps undertaken as part of the Inquiries Follow-Up Review or Device Adulteration Review; the findings of the Compliance Officer (or designee) as a result of the Inquiries Follow-Up Review or Device Adulteration Review; and any follow-up actions taken by Sanofi based on the Inquiries Follow-Up Review findings or Device Adulteration Review findings.

#### B. IRO Review of Sanofi's Call Plans and Call Plan Review Process

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

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

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

**C. IRO Review of the Distribution of Samples of Sanofi Government Reimbursed Products**

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. Sanofi shall provide the IRO with: i) a list of Government Reimbursed Products for which Sanofi distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each Government Reimbursed Product; and iii) information about Sanofi's Policies and Procedures relating to the distribution of samples, including the Sample Distribution Plans for each Government Reimbursed Product. Sanofi shall also provide the IRO with information about the reviews of Sample Distribution Plans that Sanofi conducted during the Reporting Period as set forth in Section III.B.3.d of the CIA and any modifications to the Sample Distribution Plans made as a result of Sanofi's reviews.

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

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

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA and whether the sample was distributed by a Sanofi representative in a manner consistent with Sanofi's Sample Distribution Plan for the Government Reimbursed Product(s). To the extent that a sample was provided to an HCP or HCI by a Sanofi representative other than sales personnel, the IRO shall contact the HCP or HCI by letter. The letter shall request that

the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with a Sanofi sales representative, conversation with a Sanofi representative at headquarters, independent research, or knowledge of the HCP or HCI).

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

#### D. IRO Review of Physician Payment Listings

##### 1. Information Contained in Physician Payment Listings

For purposes of the IRO Review as set forth in this Section III.D, each annual listing of Physician Covered Recipients who received Payments (as defined in Section III.N of the CIA) from Sanofi shall be referred to as the Physician Payment Listing (Listing). For each Physician Covered Recipient, each Listing shall include the following information: i) physician's full name; ii) city and state the physician provided to Sanofi; and (iii) the aggregate value of the Payment(s) in the preceding year(s).

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

## 2. Selection of Sample for Review

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

## 3. IRO Review of Control Documents for Selected Physician Covered Recipients

For each Physician Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled Physician Covered Recipient;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Sanofi's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician Covered Recipient is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Sanofi's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Sanofi's policies).

## 4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled Physician Covered Recipient do not exist and:
  - i. no corrective action was initiated prior to the selection of the sampled Physician Covered Recipient; or
  - ii. the IRO cannot confirm that Sanofi otherwise followed its Policies and Procedures relating to the entry in the Listing for the sampled Physician Covered Recipient, including its policies and procedures relating to any Payment(s) reflected in the Listing; or
- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Sanofi's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

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

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

#### E. IRO Review of Additional Items

As set forth in Section III.E.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter

Additional Items). No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify 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 the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Sanofi's systems, processes, policies, and procedures based on its review of each Additional Item).

Sanofi may propose to the OIG that its internal audit(s) be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Sanofi's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Sanofi's planned 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 the OIG denies Sanofi's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Sanofi shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of Sanofi's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Sanofi in its internal audits.

#### F. Transactions Review Report

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

- 1) General Elements to Be Included in Report
  - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
  - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
  - c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.
- 2) Results to be Included in Report

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

(Relating to the Review of Inquiries to Medical Information)

- a) in connection with the review of Inquiries to Medical Information, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database for Medical Information; (ii) for each Inquiry for which an Inquiries Follow-Up Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Inquiry Follow-Up Review; the findings of the Compliance Officer (or

designee) as a result of the Inquiry Follow-Up Review; and any follow-up actions taken by Sanofi as a result of the Compliance Officer's (or designee's) findings; and (iii) for each Inquiry for which an Device Adulteration Review was conducted, the basis for suspecting that device adulteration may have occurred; the steps undertaken as part of the Device Adulteration Review; the findings of the Compliance Officer (or designee) as a result of the Device Adulteration Review; and any follow-up actions taken by Sanofi as a result of the Compliance Officer's (or designee's) findings;

- d) the findings and supporting rationale regarding any weaknesses in Sanofi's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in Sanofi's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Call Plan Reviews)

- f) a list of the Government Reimbursed Products promoted by Sanofi during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each Government Reimbursed Product which was promoted during the Reporting Period: i) a description of the criteria used by Sanofi in developing or reviewing the Call Plans and for including or excluding specified types of HCPs or HCIs from the Call Plans; ii) a description of the review conducted by Sanofi of the Call Plans and an indication of whether Sanofi reviewed the Call Plans as required by Section III.B.3.c of the CIA; iii) a description of all instances for each Call Plan in which it appears that the HCPs and HCIs included on the Call Plan are inconsistent with Sanofi's criteria relating to the Call Plan and/or Sanofi's Policies and Procedures; and iv) a description of all instances in which it appears that Sanofi failed to follow its criteria or Policies and

Procedures relating to Call Plans or the review of the Call Plans;

- h) the findings and supporting rationale regarding any weaknesses in Sanofi's systems, processes, policies, procedures, and practices relating to Sanofi's Call Plans or the review of the Call Plans, if any;
- i) 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 Call Plans or the review of the Call Plans;

(Relating to the Sampling Event Reviews)

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

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

(Relating to the Physician Payment Listing Reviews)

- n) a description of the entries in the Listing for each Physician Covered Recipient sampled and a description of Control Documents reviewed in connection with each selected Physician Covered Recipient;
- o) for each sampled Physician Covered Recipient, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Sanofi policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the Physician Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Sanofi's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) disciplinary action was undertaken in those instances in which Sanofi policies were not followed;
- p) for each sampled Physician Covered Recipient unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled Physician Covered Recipient, including a description of the circumstances requiring corrective action and the nature of the corrective action;

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

(Relating to the Review of Additional Items)

- r) for each Additional Item reviewed, a description of the review conducted;
- s) for each Additional Item reviewed, the IRO's findings based on its review;
- t) 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, if any; and
- u) 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.

## **Appendix C to CIA for Sanofi**

### **IRO Reviews of Sanofi's CARE Systems and Transactions**

#### **I. General Description of the Compliance Assessment Risk Evaluation Process**

Prior to Effective Date of the CIA, Sanofi US implemented a Compliance Assessment Risk Evaluation (CARE) process. Sanofi US represents that it designed the CARE process to perform a risk analysis to prioritize the risks associated with various activities related to marketing, sales, and promotion and other interactions with HCPs/HCIs in connection with Government Reimbursed Products. The Sanofi North America Compliance Department performs CARE on an annual basis. The analysis includes risks associated with various Federal health care laws and FDA requirements. CARE drives the Sanofi annual compliance audit plan (Compliance Audit Plan), which is reviewed and approved by the Compliance Committee (Compliance Committee). Throughout the term of this CIA, the Compliance Committee shall provide oversight over CARE through quarterly meetings.

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

#### **A. Overview.**

Sanofi represents that it established the following process:

Sanofi represents that the primary purpose of the CARE process is to prioritize the risk of various activities identified by the Sanofi North America Compliance Department associated with various marketing, sales and promotional activities and other interactions with HCP/HCIs within Sanofi. Input regarding the risks associated with these activities is gathered through four distinct components of the process:

1. **Baseline Activity Risk** - Represents the overall government and industry-wide compliance risks associated with relevant healthcare and transparency laws. This information is gathered by administering a survey to various individuals both internal (Compliance, Legal, Regulatory, Commercial, etc.) and external to Sanofi whose industry and government expertise provides credible input on the risks associated with each activity identified. The survey includes an annual risk assessment of activities related to each Government Reimbursed Product. The survey will include

input from disciplines within each Business Unit representing all of the commercial brands.

2. **Audit History** - Represents the risks to Sanofi associated with each activity identified as documented in previous internal audits raising U.S. compliance issues, compliance audits, and monitoring reviews. Audit history will also include any external reviews of compliance-related activity done by consultants, IRO or any other external organization. Information regarding previous auditing and monitoring ratings is collected by the Compliance Department.
3. **Spend Risk** - Represents the risks associated with the relative proportion of promotional spend associated with each particular activity identified. Information regarding forecasted spend associated with each activity is gathered from various financial representatives within Sanofi across all Government Reimbursed Products.
4. **Product Risk** - Represents the risks associated with various factors that might be relevant throughout the life cycle for each Government Reimbursed Product. Input regarding certain risks associated with each specific Government Reimbursed Product is gathered by sending a survey to each Business Unit leadership (and delegates) and associated product attorneys.

The information gathered through these four components each contribute to an overall numeric score (Risk Rating) that is assigned to each risk activity included in the process. In addition, the process allows further insight into the relative Risk Ratings of each specific Company Product included in the model.

#### B. Final Output.

A summary of the outputs is generated in ranked form. The Sanofi North America Compliance Department evaluates the top prioritized risk activities against the remaining risk activities to assess whether any adjustments need to be made in order to align with company priorities and/or government commitments to develop the final top risk activities (Final Risk Activities). All changes to the original ranked form will be captured in an assumptions document and kept by the Sanofi North America Compliance Department. The Final Risk Activities will help guide the Compliance Audit Plan for the subsequent year. The Compliance Audit Plan is subject to adjustments throughout the year and any changes will also be captured in an assumptions document.

## II. IRO CARE Review, General Description

A. As specified more fully below, Sanofi shall retain an IRO to assist Sanofi in assessing and evaluating its systems, processes, policies, procedures, and practices relating to the CARE process to identify the risks associated with marketing and promotion of Government Reimbursed Products.

The CARE Review shall consist of two components - a systems review (CARE Systems Review) and a transactions review (CARE Transactions Review) as described more fully below. Sanofi may engage, at its discretion, a single IRO to perform both components of the CARE Review provided that the entity has the necessary expertise and capabilities to perform both.

B. If there are no material changes in Sanofi's systems, processes, policies, and procedures relating to the CARE process, the IRO shall perform the CARE Systems Review for the first and third Reporting Periods. If Sanofi materially changes its systems, processes, policies, and procedures relating to the CARE process, the IRO shall perform a CARE Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Systems Review for the first and third Reporting Periods. The additional CARE 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 CARE Transactions Review for the second through fifth Reporting Periods of the CIA.

## III. CARE Systems Review

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

1. A review of the systems and processes by which Sanofi identifies and evaluates risk through its CARE process, including the sources of information (e.g., the individual personnel, departments or functional areas, and/or any systems) used to determine the Final Risk Activities that are used to develop the Compliance Audit Plans; the types of underlying data and information that are considered or evaluated during the development of the Baseline Activity Risk, Audit History Risk, Spend Risk, and Product Risk; and the timing for performing the components of CARE;
2. An assessment of whether, in conducting CARE: i) additional or different sources of information; ii) additional or different types of

data or information; and iii) additional or different timing cycles should be utilized;

3. A review of the experience and background of the individuals responsible for conducting CARE and compiling the data for CARE and an assessment of the completeness and appropriateness of the training, policies, procedures, standard operating procedures, and guidance such individuals receive;
4. An assessment of how the Compliance Audit Plan is developed to address the Final Risk Activities identified by CARE and how the Compliance Audit Plan is monitored;
5. An assessment of whether and how Final Risk Activities are audited as part of the Compliance Audit Plan; and
6. An assessment of whether CARE should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific products reviewed.

B. The IRO shall prepare a report based upon each CARE Systems Review performed (CARE System Review Report). The CARE Systems Review Report will include the IRO's findings, recommendations, observations, and comments on items 1-6 above and, to the extent not otherwise addressed, an assessment of the following: (i) whether the CARE Process identifies and prioritizes relevant risks; (ii) whether the Compliance Audit Plan incorporates all Final Risk Activities; (iii) whether sufficient controls exist to ensure that all Final Risk Activities are audited; (iv) whether and how Final Risk Activities are audited as part of the Compliance Audit Plan; and (v) how monitoring Final Risk Activities (and any findings from the monitoring) affects the CARE process and the Compliance Audit Plan for the following year.

#### IV. CARE Transactions Review

A. At least thirty (30) days prior to the end of the second through fifth Reporting Periods, Sanofi shall submit to OIG a list of all Final Risk Activities for the prior Reporting Period. For example, at the end of the second Reporting Period, Sanofi shall submit to OIG a list of all Final Risk Activities for the first Reporting Period. Prior to the end of each of the second through fifth Reporting Periods, OIG shall select up to 5 Final Risk Activities (Selected Final Risk Activities) to be reviewed in connection with

the CARE Transactions Review (in accordance with the steps set forth below). If the OIG does not select the Selected Final Risk Activities to be reviewed, the IRO shall select the Selected Final Risk Activities to be reviewed.

B. For the second through the fifth Reporting Periods, the IRO shall conduct a review of: (i) the CARE process that led to the identification of the Selected Final Risk Activity; (ii) documents and materials related to the development of the Compliance Audit Plan for the Selected Final Risk Activity; and (iii) documents relating to monitoring the Compliance Audit Plan for the Selected Final Risk Activity. The IRO shall also identify and assess the responses to any audit findings that resulted from the audit of the Selected Final Risk Activity as part of the Compliance Audit Plan (e.g. changes to training, appropriate disciplinary action(s), or changes to practices). The IRO shall also interview the individual(s) responsible for compiling the data and conducting CARE and the individual(s) responsible for the implementation of the risk monitoring and mitigation activities specified in the Compliance Audit Plan.

The objectives of the IRO CARE Transaction Review shall be to: (i) understand the processes followed by Sanofi in conducting CARE and identifying Final Risk Activities; (ii) determine for the Selected Final Risk Activity whether an appropriate Compliance Audit Plan was developed; (iii) determine whether CARE could be enhanced, revised, or refined for the Selected Final Risk Activity and (iv) assess Sanofi's implementation of the Compliance Audit Plan for the Selected Final Risk Activity and the monitoring of the Compliance Audit Plan.

C. The IRO will prepare a report based on each CARE Transactions Review performed (CARE Transaction Review Report). The Transactions Review Report shall include the following:

1. an identification of the Selected Final Risk Activity and a description of the documents and information reviewed in connection with each Selected Risk Activity;
2. for each Selected Final Risk Activity, a description of: i) the CARE process followed in developing the Selected Final Risk Activity and the Compliance Audit Plan; and ii) the types of identified risks associated with the Selected Risk Activity;
3. for each Selected Final Risk Activity, whether Sanofi followed its CARE process policies and procedures in selecting the Selected Final Risk Activity and developing the Compliance Audit Plan;

4. an assessment of whether an appropriate Compliance Audit Plan was developed and implemented for the Selected Final Risk Activity;
5. for each Selected Final Risk Activity, a description of the expertise of those people responsible for developing and implementing the Care process and development and implementation of the Compliance Audit Plan;
6. for each Selected Final Risk Activity and related Compliance Audit Plan, a description of the planned audit of that activity under the Compliance Audit Plan, whether the audit occurred, whether the audit complied with Sanofi's policies and procedures, and a description of any deficiencies;
7. for each Selected Final Risk Activity, a description and assessment of the response(s) Sanofi took for any audit findings resulting from the audit of the Selected Final Risk Activity as part of the Compliance Audit Plan (e.g. changes to training, appropriate disciplinary action(s), or changes to practices);
8. for each Selected Final Risk Activity a description of: (i) any recommendations made by the IRO regarding the Compliance Audit Plan or any monitoring activities; (ii) whether, and in what manner, Sanofi implemented the recommendations from the IRO; and (iii) if Sanofi did not implement the IRO recommendations, a description of the rationale for Sanofi's decision not to implement the recommendations; and
9. the IRO's findings and supporting rationale regarding any weaknesses or deficiencies in Sanofi's systems, processes, policies, procedures, and practices relating to the CARE process and Compliance Audit Plan, if any; and 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 the CARE process and Compliance Audit Plan.