CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
AVENTIS INC., AVENTIS PHARMACEUTICALS INC., SANOFI-AVENTIS U.S. INC. AND SANOFI-AVENTIS U.S. LLC

I. PREAMBLE

Aventis Inc.; Aventis Pharmaceuticals Inc.; sanofi-aventis U.S. Inc.; and sanofi-aventis U.S. LLC (hereafter referred to collectively as "API") 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). API has represented that Aventis, Inc. and Aventis Pharmaceuticals Inc. have no ongoing business operations and no employees. API has further represented that sanofi-aventis U.S. Inc. and sanofi-aventis U.S. LLC are the successors in interest to the operations of Aventis Pharmaceuticals Inc. and Aventis Inc.

Contemporaneously with this CIA, Aventis Pharmaceuticals Inc. is entering into a Settlement Agreement with the United States. Aventis Pharmaceuticals Inc. will also enter into settlement agreements with various states (Related State Settlement Agreements) and API's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, API established a voluntary compliance program applicable to its United States operations. API's United States compliance program (Compliance Program) includes the appointment of a United States Corporate Compliance Officer, a United States Compliance Committee, a United States Code of Business Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, and internal review procedures designed, as represented by API, to promote compliance with applicable laws and the promotion of high ethical standards.

API shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. API may modify its compliance

measures as appropriate, but, at a minimum, API shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by API under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). 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, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) API's final Annual Report; or (2) any additional materials submitted by API 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 API 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), all officers and directors, and all employees of API in the United States Pharmaceutical Operations group (U.S. Pharmaceutical Operations). If there are future changes in the organizational structure of API, all API employees engaged in functions other than manufacturing functions and pre-market research functions shall be considered Covered Persons; and

   b. all contractors, subcontractors, agents, and other persons who perform functions on behalf of U.S. Pharmaceutical Operations for any API product that is reimbursed by Federal health care programs (Government Reimbursed Products). This includes all persons who perform Government Pricing and Contracting Functions (as defined below in Section II.C.3) and promotion, sales, and marketing functions relating to Government Reimbursed Products.

   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. "Relevant Covered Persons" includes: 1) all Covered Persons whose job responsibilities relate to Government Pricing and Contracting Functions (as defined below in Section II.C.3); and 2) all Covered Persons whose job responsibilities relate to the promotion, sales, or marketing of Government Reimbursed Products by the Oncology Sales and Marketing Group.

3. The term "Government Pricing and Contracting Functions" refers to the collection, calculation, verification, or reporting of pricing or other information for purposes of the Medicaid Drug Rebate program (codified at 42 U.S.C. § 1396r-8), the Medicare program (42 U.S.C. §§ 1395-1395hhh), and other government programs (including the 340B Drug Pricing program, codified at 42 U.S.C. § 256B (the 340B Program).) This includes individuals whose job responsibilities include the calculation and reporting of Average Wholesale Price (AWP), Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price, and all other pricing information reported and used in connection with Federal health care programs.

4. The term "Third Party Personnel" shall mean personnel of the entities with whom API has or may in the future enter into agreements to co-promote an API product or engage in joint promotional activities relating to an API product. API has represented that: 1) the Third Party Personnel are employed by other independent entities; 2) API does not control Third Party Personnel; and 3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. API agrees to promote compliance by Third Party Personnel with Federal health care program requirements by complying with the provisions set forth below in Sections III.B.2, V.A.4, and V.B.3 related to Third Party Personnel. Provided that API complies with the requirements of Sections III.B.2, V.A.4, and V.B.3, API shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

To the extent not already accomplished, API shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Prior to the Effective Date, API appointed an individual to serve as its United States corporate compliance officer (U.S. Corporate Compliance Officer), and API shall maintain a U.S. Corporate Compliance Officer for the term of the CIA. The U.S. Corporate Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The U.S. Corporate Compliance Officer shall be a member of senior management of API, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board(s) of Directors of API, and shall be authorized to report on such matters to the Board(s) of Directors of API at any time. Beginning within 120 days after the Effective Date, and for the remainder of the term of the CIA, the U.S. Corporate Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The U.S. Corporate Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by API as well as for any reporting obligations created under this CIA.

API shall report to OIG, in writing, any changes in the identity or position description of the U.S. Corporate Compliance Officer, or any actions or changes that would affect the U.S. Corporate Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, API appointed a United States compliance committee for its United States operations (U.S. Compliance Committee). The U.S. Compliance Committee includes and shall, at a minimum, continue to include the U.S. Corporate Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., the President/CEO and senior executives of relevant departments, such as U.S. Scientific and Medical Affairs, U.S. Market Access and Business Development, U.S. Legal, U.S. Quality and Compliance, U.S. Pharmaceutical Operations, U.S. Human Resources). The U.S. Corporate Compliance Officer shall continue to chair the U.S. Compliance Committee

and the U.S. Compliance Committee shall support the U.S. Corporate Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, API established a United States code of business conduct (known as its "U.S. Code of Business Conduct"). To the extent not already accomplished, within 90 days after the Effective Date, API shall distribute the U.S. Code of Business Conduct to all Covered Persons. API shall make the promotion of, and adherence to, the U.S. Code of Business Conduct an element in evaluating the performance of all employees. The U.S. Code of Business Conduct shall, at a minimum, set forth:

a. API's commitment to full compliance with all Federal health care program requirements, including the commitment to comply with all requirements relating to Government Pricing and Contracting Functions, and to promote, sell, and market Government Reimbursed Products (as defined above in Section II.C.1.b) in accordance with Federal health care program requirements;

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

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

d. the possible consequences to both API and Covered Persons of failure to comply with Federal health care program requirements and

with API's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and API's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by API's U.S. Code of Business Conduct. New Covered Persons shall receive the U.S. Code of Business Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

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

2. *Third Party Personnel.*

Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, API shall send a letter to each entity employing Third Party Personnel. The letter shall outline API's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of API's Compliance Program. API shall attach a copy of its U.S. Code of Business Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of API's U.S. Code of Business Conduct and a description of API's Compliance Program available to its Third Party Personnel; or (b) represent to API 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, API shall implement written policies and procedures regarding the operation of API's Compliance Program and its compliance

with Federal health care program requirements (Policies and Procedures). At a minimum, the Policies and Procedures shall address:

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

b. Government Pricing and Contracting Functions;

c. the promotion, sales, and marketing of API products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b; and

d. disciplinary policies and procedures for violations of API's Policies and Procedures, including policies relating to Federal health care programs requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. These Policies and Procedures may be made available through the publishing of the Policies and Procedures on API's intranet site.

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

C. Training and Education.

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

a. CIA requirements; and

b. API's U.S. Compliance Program (including the U.S. Code of Business Conduct and the Policies and Procedures as they pertain to general compliance issues).

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.

To the extent that General Training provided to Covered Persons during the 180 days immediately prior to the Effective Date of this CIA satisfies the requirements of Section III.C.1.b above, the OIG shall credit the training toward the requirements of Section III.C.1.b for the first Reporting Period. API may satisfy the remaining General Training obligations in Section III.C.1.a for the Covered Persons who received the training described above by notifying them in writing or in electronic format of the fact that API entered a CIA and providing an explanation of API's requirements and obligations under the CIA.

To the extent that a Covered Person is on a leave of absence during the entire period when the required General Training is offered, the Covered Person shall receive the training within 30 days of the conclusion of the leave of absence.

2. *Specific Training.* To the extent not already accomplished, within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of specific training (Specific Training) in addition to the General Training required above.

For those Relevant Covered Persons engaged in Government Pricing and Contracting Functions, this Specific Training shall include a discussion of:

a. API's systems and procedures for performing Government Pricing and Contracting Functions;

b. all applicable Federal health care program requirements relating to Government Pricing and Contracting Functions;

c. the personal obligation of each individual involved in Government Pricing and Contracting Functions to ensure that all pricing and other information reported is accurate;

d. the legal sanctions for violations of Federal health care program requirements; and

e. examples of proper and improper practices related to Government Pricing and Contracting Functions.

For those Relevant Covered Persons in the Oncology Sales and Marketing groups whose job responsibilities relate to the promotion, sales, or marketing of Government Reimbursed Products, this Specific Training shall include a discussion of:

a. all applicable Federal health care program requirements relating to the promotion, sales, and marketing of Government Reimbursed Products;

b. Policies and Procedures and other requirements applicable to promotion, sales, and marketing of Government Reimbursed Products;

c. the personal obligation of each individual involved in the promotion, sales, or marketing of Government Reimbursed Products to comply with applicable legal requirements;

d. the legal sanctions for violations of the Federal health care program requirements; and

e. examples of proper and improper practices related to the promotion, sales, and marketing of Government Reimbursed Products.

New Relevant Covered Persons shall receive this 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. An employee of API who has completed the Specific Training shall review a new Relevant Covered Person's work and the work of a Relevant Covered Person returning from a leave of absence, to the extent that the work relates to (as applicable) Government Pricing and Contracting

Functions or to the promotion, sales, and marketing of Government Reimbursed Products until such time as the applicable Relevant Covered Person completes his or her applicable Specific Training.

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

To the extent that Specific Training provided to Relevant Covered Persons during the 180 days immediately prior to the Effective Date of this CIA satisfies the requirements set forth above in this Section III.C.2 above, the OIG shall credit the training toward the Specific Training requirements for the first Reporting Period.

To the extent that a Relevant Covered Person is on a leave of absence during the entire period when the required Specific Training is offered, the Relevant Covered Person shall receive the training within 30 days of the conclusion of the leave of absence.

3. *Certification.* Each individual who is required to attend General or Specific Training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The U.S. Corporate Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the General or Specific Training shall be knowledgeable about the subject area of their training.

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

6. *Computer-based Training.* API may provide the General and Specific Training required under this CIA through appropriate computer-based training approaches. If API chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or to provide additional information to the individuals receiving such training. In addition, if API chooses to provide computer based General or Specific Training, all applicable

requirements to provide a number of "hours" of training in this Section III.C. may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, API 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 API in assessing and evaluating the obligations pursuant to this CIA. The applicable requirements relating to the IRO are outlined in Attachment A, which is incorporated by reference.

Each IRO engaged by API shall have expertise in auditing and in applicable Federal health care program requirements (including the requirements of the Medicaid Drug Rebate program and the Medicare Part B program as they relate to AMP and ASP, respectively). Each IRO shall assess, along with API, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

b. *Types and Frequency of Reviews.* The IRO shall conduct two types of reviews. Both of the reviews shall be focused on: (a) the AMP for the AMP Covered Products, as defined in Attachment C, and (b) the ASP for the ASP Covered Products as defined in Attachment C.

First, as set forth more fully in Attachment B, the IRO shall perform an AMP/ASP Systems Review (Systems Review) that shall address API's systems, processes, policies, and practices associated with tracking, gathering, and accounting for all relevant data for purposes of calculating AMPs and ASPs in accordance with the requirements of the Medicaid Drug Rebate program and the Medicare Part B program, respectively. Second, as set forth more fully in Attachment B, the IRO shall conduct an AMP/ASP Transactions Review

(Transactions Review) that shall address and analyze API's systems, policies, and practices with regard to specific transactions affecting the calculation of AMPs and ASPs for purposes of the Medicaid Drug Rebate program and the Medicare Part B program, respectively.

If there are no material changes in API's AMP/ASP related systems, processes, policies, and practices during the term of this CIA, the IRO shall perform the AMP/ASP Systems Review for the second and fourth Reporting Periods. If API materially changes the systems, processes, policies, and practices, then the IRO shall perform an AMP/ASP Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the second and fourth Reporting Periods. The IRO shall not be required to conduct an AMP/ASP Systems Review for the first Reporting Period.

The AMP/ASP Transactions Review shall be performed annually. However, for the first Reporting Period only, as set forth more fully in Appendix B, the time period covered by the Transactions Review will be the last two quarters of the Reporting Period. For the second and all subsequent Reporting Periods, the Transactions Review shall cover the entire Reporting Period. The IRO shall perform all components of each review.

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

2. *Review Reports*. The IRO shall prepare a report based upon each Systems Review and each Transactions Review performed. These reports shall be known as the Systems Review Report and the Transactions Review Report, respectively. Information to be included in the Systems Review Reports and the Transactions Review Reports (collectively "Reports") is described in Attachment B.

3. *Validation Review*. In the event OIG has reason to believe that: (a) API's Systems Review or Transaction Review (collectively "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 Systems and/or Transactions Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). API 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 API's final Annual Report shall be initiated no later than one year after API's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify API 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, API may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. API agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with API 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 API a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Prior to the Effective Date, API established a disclosure program that includes a mechanism (a toll-free compliance telephone line known as the "Helpline") to enable individuals to disclose, to the U.S. Corporate Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with API's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law (Disclosure Program). API shall maintain the Disclosure Program throughout the term of this CIA. API shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy,

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

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

F. Ineligible Persons.

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

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

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

c. "Screened Persons" includes prospective and current owners of API (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), and current and prospective officers, directors, and employees of API. Screened Persons also includes all prospective and current contractors and agents of API who are Covered Persons.

2. *Screening Requirements.* API shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements:

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

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

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

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

3. *Removal Requirement.* If API has actual notice that a Screened Person has become an Ineligible Person, API shall remove such Screened Person from responsibility for, or involvement with, API's business operations related to the Federal

health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened 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 Screened Person is reinstated into participation in the Federal health care programs.

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

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at United States corporate headquarters, API shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to API conducted or brought by a governmental entity or its agents involving an allegation that API 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. API 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.

H. Reporting.

1. *Reportable Events.*

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

i. 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; or

ii. the filing of a bankruptcy petition by API.

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

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

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

ii. a description of API's actions taken to correct the Reportable Event; and

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

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

I. Drug Price Reporting Requirements.

1. *General Statement of Purpose and Intent.* On a quarterly basis, API shall report to the entities identified below in Section III.I.2.c certain pricing information, as specified below in Sections III.I.2.a and b (collectively referred to as the "Pricing Information"). In particular, API will report an ASP, as defined in Section III.I.2.a below, for the "ASP Covered Products" described in Attachment C, and API will also report an AMP, as defined in Section III.I.2.b below, for the "AMP Covered Products" described in Attachment C. The Pricing Information shall be provided subject to the confidentiality provisions and conditions set forth herein, in the Related State Settlement Agreements, in any commercial drug price reporting service confidentiality agreements as referenced in Section III.I.2.e below, or as otherwise required by law.

2. *Specific Reporting Requirements.*

a. Average Sales Price Defined. For purposes of this CIA, "Average Sales Price" or "ASP" is defined to have the meaning of, and will be calculated in accordance with, the requirements for Average Sales Price as defined in 42 U.S.C. § 1395w-3a and all applicable requirements of the Medicare Part B program. API shall report under this CIA the same ASPs for the same formulations of the ASP Covered Products that it reports to CMS on a quarterly basis for purposes of the Medicare Part B program. The ASPs shall be reported under this CIA in the same electronic format used to report ASPs to CMS.

b. Average Manufacturer Price Defined. For purposes of this CIA, "Average Manufacturer Price," or "AMP," is defined to have the meaning of, and will be calculated in accordance with, the requirements for Average Manufacturer Price as defined in 42 U.S.C. § 1396r-8(k)(1) and all applicable requirements of the Medicaid Drug Rebate program. API shall report, under this CIA, the same AMPs for the same formulations of the AMP Covered Products that it reports to CMS on a quarterly basis, along with any retroactive AMP adjustments that API reports to CMS for purposes of the Medicaid Drug Rebate program. The AMPs shall be reported under this CIA in the same electronic format used to report AMPs to CMS.

c. Reporting Obligations for ASP Covered Products and AMP Covered Products. Except as otherwise noted below, within 35 days after the last day of each calendar quarter, API shall report, in accordance with Sections III.I.2.a and b above, the ASPs for the ASP Covered Products and the AMPs (and prior-quarter AMP adjustments) for the AMP Covered Products that API reported for the applicable calendar quarter to CMS pursuant to the Medicare Part B and Medicaid Drug Rebate programs, respectively. API shall make these reports to: 1) the Medicaid programs of

those States that have entered into a Related State Settlement Agreement with API (Settlement States); and 2) to a commercial drug price reporting service (such as First DataBank, Inc.) designated by any Settlement State that has received API's ASPs and AMPs pursuant to a Related State Settlement Agreement. If appropriate to reflect changes in the sources from which the State Medicaid programs receive their Pricing Information, API agrees that, upon the receipt of a written request by any of the Settlement States, it will report the required information to a drug price reporting source other than, and in addition to, the drug price reporting service originally designated by the Settlement State, subject to the confidentiality provisions referenced in Section III.I.2.e relating to Pricing Information. The Pricing Information shall be reported to the commercial drug price reporting service solely for the purposes of reporting pricing information to the Medicaid programs of Settlement States and the Pricing Information shall be subject to the confidentiality provisions referenced in Section III.I.2.e.

The first report of ASPs and AMPs hereunder shall be made to each Settlement State, and to the commercial drug price reporting service (such as First DataBank, Inc.) designated by any Settlement State, within 35 days after the end of the first full calendar quarter following the Effective Date of that State's Related State Settlement Agreement.

d. Certification Requirement. API shall certify that the ASPs and AMPs reported hereunder are calculated in accordance with requirements of the Medicare Part B and Medicaid Drug Rebate programs as they relate to ASP and AMP and the definitions set forth in Section III.I.2.a-b above. Said certifications shall be made in the form attached hereto as Attachment D, and shall include an acknowledgment that the ASPs, AMPs, and prior-quarter AMP adjustments were reported to CMS and are the same prices that were reported to CMS. API agrees that this certification by the employee or agent of API constitutes a certification by API.

e. Confidentiality of Reported Pricing Information. API represents that it contends that the Pricing Information it reports under this Section III.I is confidential commercial or financial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of API. The Related State Settlement Agreements will contain certain confidentiality provisions governing the treatment of Pricing Information. API will enter good faith negotiations with the commercial drug prices reporting service(s) to reach a mutually acceptable confidentiality agreement to govern the handling of Pricing Information reported by API to the commercial drug price reporting service. Among other provisions, such confidentiality agreement shall: a) permit the commercial drug price reporting service to disclose API's Pricing Information only to the Medicaid programs of Settlement States that have entered into a subscription agreement with the commercial drug price reporting service and the disclosure shall be made pursuant to the terms of the Related State Settlement Agreement; and b) require API's Pricing Information to otherwise be kept strictly confidential or, in the case of AMP Pricing Information, to be kept confidential until CMS makes such Pricing Information publicly available.

f. Document Retention. API shall retain all supporting work papers and documentation relating to the ASPs of its ASP Covered Products and the AMPs of its AMP Covered Products for the longer of six years after the Effective Date of this CIA or as otherwise required by law, and shall make such documentation available for inspection by the OIG or its duly authorized representative(s) in accordance with the provisions set forth in Sections VII and VIII.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, API changes locations or sells, closes, purchases, or establishes a new business unit or location engaged in Government Pricing and Contracting Functions or in the promotion, sales, or marketing of Government Reimbursed Products, API shall notify OIG of this fact as soon as possible, but no later

than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider or supplier number, and any corresponding contractor's name and address that issued each Federal health care program provider or supplier number. Each new business unit or location meeting the criteria set forth in this Section IV shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, API shall submit a written report to OIG summarizing the status of the 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 U.S. Corporate Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the U.S. Corporate Compliance Officer may have;

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

3. a copy of API's U.S. Code of Business Conduct required by Section III.B.1;

4. with regard to the entities employing Third Party Personnel: (a) a copy of the letter (including all attachments) required by Section III.B.2 to be sent to each entity employing the Third Party Personnel; (b) a list and description of all existing co-promotion or other agreements between API and the entities employing Third Party Personnel; and (c) a description of the entities' response to API's letter;

5. a copy of all Policies and Procedures required by Section III.B.3;

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

7. 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;

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 shall be available to OIG, upon request.

8. a description of the Disclosure Program required by Section III.E;

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between API and the IRO; and (d) the proposed start and completion dates of the Systems and Transaction Reviews;

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

11. a description of the process by which API fulfills the requirements of Section III.F regarding Ineligible Persons;

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

13. a list of all of API's United States locations (including locations and mailing addresses); the corresponding name under which each United States location is doing business; the corresponding phone numbers and fax numbers; each such United States location's Federal healthcare program provider or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which API currently submits claims (if applicable);

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

15. the certifications required by Section V.C.

B. Annual Reports. API shall submit to OIG annually a report with respect to the status of, and findings regarding, API'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 U.S. Corporate Compliance Officer and any change in the membership of the U.S. Compliance Committee described in Section III.A;

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

3. with regard to the entities employing Third Party Personnel: (a) a copy of the letter (including all attachments) required by Section III.B.2 to be sent to each entity employing the Third Party Personnel; (b) a list and description of all existing co-promotion or other agreements between API and the entities employing Third Party Personnel; and (c) a description of the entities' response to API's letter;

4. 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 contractor policy) and copies of any compliance-related Policies and Procedures;

5. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

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 shall be available to OIG, upon request.