

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.**

**I. PREAMBLE**

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

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

Prior to the Effective Date of this CIA (as defined below), BIPI established a voluntary compliance program applicable to all BIPI officers, managers, and employees (Compliance Program). BIPI's Compliance Program includes a Chief Ethics and Compliance Officer, an Ethics and Compliance Department, and a Compliance Committee. The Compliance Program also includes a Code of Conduct, written policies and procedures, educational and training initiatives, a disclosure program, investigation of potential compliance violations, disciplinary procedures, and regular internal auditing procedures.

BIPI shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. BIPI may modify its Compliance Program as appropriate, but, at a minimum, BIPI 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 BIPI 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, unless otherwise specified. 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) BIPI’s final Annual Report; or (2) any additional materials submitted by BIPI 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 BIPI 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) and all directors of BIPI;

b. all employees of BIPI who are: (1) based in the United States, or (2) based outside the United States and who are engaged in or who have responsibilities relating to any of the Covered Functions (as defined below in Section II.C.6); and

c. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of BIPI, 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 Covered Functions and those activities, services, or materials are not reviewed or supervised by a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include: (i) 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; or (ii) employees, contractors, subcontractors, agents, or other personnel engaged in manufacturing functions so long as they do not have responsibilities relating to any of the Covered Functions.

2. “Relevant Covered Persons” includes all Covered Persons whose job responsibilities relate to any of the Covered Functions.

3. “Government Reimbursed Products” refers to all BIPI pharmaceutical products that are marketed or sold by BIPI in the United States or pursuant to contracts with the United States that are reimbursed by Federal health care programs, except products marketed or sold by BIPI’s Consumer Health Care business.

4. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable review committees.

5. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal health care program and/or FDA requirements and distributed to HCPs and HCIs about Government Reimbursed Products, including those functions relating to any applicable review committees and to BIPI’s medical affairs function; (b) contracting with HCPs in the United States to conduct post-marketing clinical trials and other post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to government-listed compendia (such as Drugdex or other compendia of information about Government Reimbursed Products as defined below in Section III.B.3.p.)

6. The term “Covered Functions” refers to “Promotional Functions,” and “Product Related Functions”.

7. The term “Third Party Educational Activity” shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event supported by BIPI, including but not limited to, sponsorship of symposia at medical conferences.

8. The term “Third Party Personnel” shall mean personnel of the entities with which BIPI 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. BIPI represents that: (1) Third Party Personnel are employed by entities independent of BIPI; (2) BIPI 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. BIPI agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.4. Provided that BIPI complies with the requirements of Sections III.B.2, V.A.7, and V.B.4, BIPI 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.

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

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

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

1. *Compliance Officer.* Prior to the Effective Date, BIPI appointed an individual to serve as its chief compliance officer (known as its Chief Ethics and Compliance Officer or CECO) and BIPI shall maintain a CECO for the term of the CIA. The CECO 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 and with Federal health care program and FDA requirements. The CECO shall be a member of senior management of BIPI, shall report directly to the

Chairman of the Board of BIPI, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of BIPI, and shall be authorized to report on such matters to the Board of Directors at any time. The CECO shall not be or be subordinate to the General Counsel or Chief Financial Officer. The CECO shall be responsible for monitoring the day-to-day compliance activities engaged in by BIPI as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the CECO shall be limited and must not interfere with the CECO's ability to perform the duties outlined in this CIA.

BIPI shall report to OIG, in writing, any change in the identity of the CECO, or any actions or changes that would affect the CECO'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, BIPI appointed a Compliance Committee which, in conjunction with the CECO assists in the implementation and enhancement of the Compliance Program. BIPI shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the CECO and other members of senior management necessary to meet the requirements of this CIA (e.g., Sr. Vice President, Medicine & Regulatory Affairs; Sr. Vice President, Clinical Development & Medical Affairs; Vice President, Clinical Operations; Vice President, Commercial Operations; Vice President, Controlling; Vice President, Drug Regulatory Affairs; Vice President, Ethics and Compliance; Executive Director, Commercial Compliance; Executive Director, Research Development and Medicine Compliance; Sr. Vice President, Human Resources; Vice President, Associate General Counsel Operations; Senior Vice President, Managed Markets; Senior Vice President, Marketing; Vice President, Oncology; and Senior Vice President, Sales). The CECO shall chair the Compliance Committee and the Compliance Committee shall support the CECO in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the BIPI's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

BIPI 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 (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 shall, at a minimum, be responsible for the following:

a. The Board shall meet at least quarterly to review and oversee BIPI's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of the Chief Compliance Officer and compliance personnel who are "Covered Persons" under this CIA.

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 BIPI's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of BIPI's Compliance Program, including evaluating its effectiveness and receiving updates about the activities of the Chief Ethics and Compliance Officer and other compliance personnel. Based on all of these steps, the Board has concluded that, to the best of its knowledge, BIPI 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 BIPI.

BIPI 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 BIPI 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 BIPI 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: President and Chief Executive Officer; Senior

Vice President, Marketing; Senior Vice President, Sales; Senior Vice President, Medicine & Regulatory; Senior Vice President, Clinical Development & Medical Affairs; Vice President, Regulatory Affairs; Senior Vice President, Managed Markets; Vice President, Commercial Operations; Vice President, Clinical Operations; and to the extent that there are organizational changes at BIPI and any new or different business unit performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other executives, vice-presidents, and/or leaders/heads of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit.

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 BIPI policies, 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 BIPI 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, BIPI developed, implemented, and distributed a written code of conduct to all Covered Persons who are BIPI employees. This code is known as BIPI’s Code of Conduct and Corporate Integrity (Code of Conduct). BIPI makes, and shall continue to make, 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 90 days after the Effective Date, shall be revised to address or include the following:

- a. BIPI'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 the Covered Functions;
- b. BIPI'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 BIPI's own Policies and Procedures;
- c. BIPI's requirement that all Covered Persons shall be expected to report to the CECO, or other appropriate individual designated by BIPI, suspected violations of any Federal health care program requirements, FDA requirements, or of BIPI's own Policies and Procedures;
- d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and BIPI's Policies and Procedures; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and BIPI's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, 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 BIPI'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.

BIPI shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized.



Each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* Within 120 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, BIPI shall send a letter, either in hard copy or electronic form, to each entity employing Third Party Personnel. The letter shall outline BIPI's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of BIPI's Compliance Program. BIPI 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 BIPI's Code of Conduct and a description of BIPI's Compliance Program available to its Third Party Personnel; or (b) represent to BIPI 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 BIPI shall implement written policies and procedures regarding the operation of the Compliance Program and BIPI's compliance with Federal health care program and FDA requirements (Policies and Procedures). 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 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. appropriate ways to conduct Product 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;

- d. the materials and information that may be distributed by BIPI sales representatives about Government Reimbursed Products and the manner in which BIPI sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives refer all requests for information about non-FDA approved (“off-label”) uses of Government Reimbursed Products to Medical & Technical Information (“MTI”) or its agents;
- e. the materials and information that may be distributed by MTI and the mechanisms through, and manner in which, MTI or its agents receives and responds to requests for information from an HCP or another individual or entity about off-label uses of BIPI’s Government Reimbursed Products; the form and content of information disseminated by BIPI in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that MTI or its agents develop a database (“Inquiries Database”) to track all requests for information about BIPI’s products that are made to MTI. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about BIPI’s products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting HCP, health care institution (HCI), or other individual or entity; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label use for the product; 6) nature/form of the response from BIPI (including a record of the materials provided to the HCP or HCI in response to the request); and 7) the name of the BIPI representative who called on or interacted with the HCP, customer, or HCI, if known;

- f. the manner and circumstances under which medical personnel from Field Based Medicine interact with or participate in

meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the Field Based Medicine personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Government Reimbursed Products;

- g. the development, implementation, and review of call plans for sales representatives who promote and sell Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that BIPI review the call plans for the 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 BIPI modify the call plans as necessary to ensure that BIPI is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program 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;
- h. the development, implementation, and review of plans for the distribution of samples of 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 from BIPI. The Policies and Procedures shall also require that BIPI modify the Sample Distribution Plans as necessary to ensure that BIPI is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;
- i. 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 arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;

- j. 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 and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- k. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that BIPI's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- l. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.7 above. These Policies and Procedures shall be designed to ensure that BIPI's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements;

The Policies and Procedures shall require that: 1) BIPI disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection III.B.3.1.4 below, any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose BIPI'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 BIPI; 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 BIPI's control; 5) BIPI supports only Third Party Educational Activity that is non-promotional in tone/nature; and 6) BIPI'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;

- m. review of promotional materials and information intended to be disseminated outside BIPI by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during BIPI'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 and FDA requirements. The Policies and Procedures shall require that: 1) applicable review committees review all promotional materials 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 materials for review) shall be documented and referred for appropriate follow-up;
- n. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Procedures shall be designed to ensure that BIPI's funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;
- o. compensation (including through salaries, bonuses, or other means) for Relevant Covered Persons who are sales representatives. These Policies and Procedures shall: 1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of BIPI's Government Reimbursed

Products; and 2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate off-label promotion of Government Reimbursed Products;

- p. the submission of information about any Government Reimbursed Product to any government-listed 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 BIPI’s discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia);
- q. sponsorship of post-marketing clinical trials, post-marketing investigator-initiated studies (IISs), and other post-marketing studies (collectively “Research”) by BIPI, 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;
- r. 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 between the author and BIPI, 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; and
- s. disciplinary policies and procedures for violations of BIPI’s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

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), BIPI 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 made available to all Covered Persons.

### C. Training and Education.

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

- a. CIA requirements; and
- b. BIPI's Compliance Program (including the Code of 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.

Notwithstanding the above, BIPI shall not be required to provide General Training to personnel who perform only site services or engineering functions (e.g., food services, facilities, ground maintenance, and security functions.)

2. *Specific Training.* BIPI shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training shall be known as Specific Training.

Within 120 days after the Effective Date, each Relevant Covered Person engaged in Promotional Functions or Product Related Functions 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 Functions and to Product Related Functions;
- b. all applicable FDA requirements relating to Promotional Functions and to Product Related Functions;
- c. all BIPI Policies and Procedures and other requirements applicable to Promotional Functions and Product Related Functions;
- d. the personal obligation of each individual involved in Promotional Functions and Product Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Promotional Functions and Product 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. A BIPI employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to any of the Covered Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

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

3. *Board Member Training.* Within 120 days after the Effective Date, BIPI shall provide at least two hours of training to each member of the Board of Directors, in



addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

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

4. *Certification.* Each Covered Person 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 CECO (or designee) shall retain these certifications, along with all course materials. These shall be made available to OIG, upon request.

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 and FDA requirements.

6. *Update of Training.* BIPI shall review its 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 monitoring and audits or the IRO Reviews, and any other relevant information.

7. *Computer-based Training.* BIPI may provide the training required under this CIA through appropriate computer-based training approaches. If BIPI 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. In addition, if BIPI chooses to provide computer-based General or Specific Training, all applicable requirements to provide a number of “hours” or 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, BIPI 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 BIPI in assessing and evaluating its Covered Functions. More specifically, the IRO(s) shall conduct reviews that assess BIPI’s systems, processes, policies, procedures, and practices relating to the Covered Functions (IRO Reviews).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by BIPI shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with BIPI, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

b. *Frequency and Brief Description of Reviews.*

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

The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

In addition, each Transactions Review shall also include a review of up to three additional areas or practices of BIPI 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 Reporting Period, the OIG will consult with BIPI and may consider internal audit work conducted by BIPI, the Government Reimbursed Product portfolio, the nature and scope of BIPI’s promotional practices and arrangements with HCPs and HCIs, and other information known to it.

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

The OIG shall notify BIPI of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or BIPI 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 BIPI shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and BIPI) 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 and B.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any of BIPI’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). BIPI 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 BIPI's final Annual Report shall be initiated no later than one year after BIPI's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify BIPI 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, BIPI 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. BIPI 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 IRO Review issues with BIPI 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 BIPI a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

#### E. Disclosure Program.

Prior to the BIPI Effective Date, BIPI established a Disclosure Program that includes a mechanism (the toll free Ethics and Compliance Helpline) to enable individuals to disclose, to the CECO or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with BIPI's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. BIPI shall maintain such a Disclosure Program throughout the term of the CIA. BIPI publicizes, and shall continue to appropriately publicize, the existence of the Disclosure Program and the Ethics and Compliance Helpline (e.g., via periodic e-mails to employees, by posting the information in prominent common areas, or through references in the Code of Conduct and during training.)

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

BIPI 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.

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 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 List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

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

- a. as part of the hiring or contracting process, BIPI shall require all prospective and current Covered Persons to disclose whether they are Ineligible Persons and shall screen potential Covered Persons against the Exclusion Lists prior to engaging their services.
- b. BIPI shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. BIPI shall 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.F affects BIPI's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. BIPI understands that items or services furnished by excluded persons are not payable by Federal health care programs and that BIPI may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether BIPI meets the requirements of Section III.F.

3. *Removal Requirement.* If BIPI has actual notice that a Covered Person has become an Ineligible Person, BIPI shall remove such Covered Person from responsibility for, or involvement with, BIPI'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 BIPI 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, BIPI 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.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, BIPI shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to BIPI conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that BIPI 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. BIPI 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. 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 criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to BIPI);
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

d. the filing of a bankruptcy petition by BIPI.

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

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

3. *Reportable Events under Sections III.H.1.a-c.* For Reportable Events under Sections III.H.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 or FDA authorities implicated;
- b. a description of BIPI's actions taken to correct the Reportable Event; and
- c. any further steps BIPI plans to take to address the Reportable Event and prevent it from recurring.

BIPI shall not be required to report as a Reportable Event any ongoing investigation or legal proceeding by a governmental agency or its agents previously disclosed under Section III.G.

4. *Reportable Events under Section III.H.1.d.* For Reportable Events under Section III.H.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.

I. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between BIPI and the FDA that materially discusses BIPI's or a Covered Person's actual or potential unlawful or improper promotion of BIPI's products (including any improper dissemination of information about off-label indications), BIPI shall provide a copy of the report, correspondence, or communication to the OIG. BIPI shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and



shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales representatives' interactions 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 off-label 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, BIPI 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 BIPI approved materials and may not directly or indirectly promote the product for off-label uses.) BIPI shall maintain a centralized electronic system through which all speaker programs are administered. 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 BIPI. BIPI shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, BIPI 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. BIPI shall require the completion of monitoring forms by sales representatives or other BIPI personnel regarding whether a speaker program complied with BIPI requirements, and in the event of non-compliance, BIPI shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, BIPI shall institute a Speaker Monitoring Program under which BIPI compliance personnel or other appropriately trained personnel who are independent from the functional area being monitored (Monitoring Personnel)

shall attend speaker programs during each Reporting Period and conduct live audits of 75 of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and BIPI representative activities during the program to assess whether the programs were conducted in a manner consistent with BIPI's Policies and Procedures. BIPI 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, Monitoring Personnel shall conduct observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with BIPI'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 BIPI compliance personnel both on a risk-based targeting approach and on a sampling approach, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, BIPI compliance personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the BIPI 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 BIPI policy; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the sales representative.

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

3. *Records Reviews.* As a component of the FFMP, BIPI 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, BIPI shall develop and implement a plan for conducting Records Reviews associated with

at least three Government Reimbursed Products and a sampling of the representatives promoting those products in every separate region. The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about BIPI's products provided by BIPI, upon request by the OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, BIPI shall select the three products to be reviewed.

These Records Reviews shall include the monitoring and review of: 1) records and 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, sample distribution records, and expense reports); 2) requests for medical information about, or inquiries relating to, Government Reimbursed Products; 3) tutorials and preceptorships; 4) 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.* 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 Ethics and Compliance Department for review and follow-up as appropriate. In the event that a potential violation of BIPI's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, BIPI 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.H 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 Ethics and Compliance Department.

BIPI 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, BIPI also shall provide the OIG with 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 BIPI took as a result of such determinations. BIPI shall make the Observation reports for all other Observations available to the OIG upon request.

K. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 120 days after the Effective Date BIPI shall develop and implement a monitoring program for the following types of activities: 1) consultant arrangement activities; 2) research-related activities; 3) publication activities; and 4) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that BIPI engages U.S.-based HCPs or HCIs for services that relate to Promotional Functions or to Product Related Functions other than for speaker programs, research-related activities, or publication activities (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. BIPI 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 BIPI.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI 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. BIPI's 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 BIPI Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI 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 BIPI compliance personnel.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI 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, BIPI received the work product generated by the Consultant.

Within 120 days after the Effective Date, BIPI shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 40 Consultant arrangements with HCPs. More specifically, Monitoring Personnel shall review 20 advisory board arrangements and 20 other types of Consultant arrangements. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. 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 BIPI'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 Ethics and Compliance Department for review and follow-up as appropriate.

2. *Research-Related Activities.* To the extent that BIPI engages U.S.-based HCPs or HCIs to conduct post-marketing studies (including post-marketing clinical studies), or post-marketing IISs related to Government Reimbursed Products, such HCPs and HCIs shall be referred to collectively as "Researchers". BIPI shall require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid, and compliance obligations for the Researchers. Researchers shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by BIPI.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI shall establish an annual budgeting plan for Researchers that identifies the business or scientific need for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. BIPI 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 Research arrangements and related events are used for legitimate purposes in accordance with BIPI Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI shall establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in this process (or elsewhere, as appropriate) and shall be subject to review and approval by BIPI compliance personnel.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI shall amend its policies and procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was engaged.

Within 120 days after the Effective Date, BIPI shall establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher Program Audits) of at least 20 Researcher arrangements with HCPs or HCIs. The Researcher Monitoring Program shall review Researcher arrangements both on a risk-based targeting approach and on a sampling approach. Monitoring Personnel conducting the Researcher Program Audits shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were supported by BIPI and performed by the Researchers in a manner consistent with BIPI's Policies and Procedures. Results from the Researcher Program Audits, including identification of potential violations of policies, shall be compiled and reported to the Ethics and Compliance Department for review and follow-up as appropriate.

3. *Publication Activities.* To the extent that BIPI engages U.S.-based HCPs or 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. BIPI shall require all Authors to enter written agreements describing the scope of work to be performed, the fees to be paid in connection with the Publication Activities, and compliance obligations of the Authors. Authors shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by BIPI.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI 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 Plan shall also identify the budgeted amounts to be spent on Publication Activities. BIPI’s 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 BIPI Policies and Procedures.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI 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 for 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 BIPI compliance personnel.

Within 120 days after the Effective Date, BIPI 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. Monitoring Personnel conducting the Publication Monitoring Program 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 BIPI’s Policies and Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of policies, shall

be compiled and reported to the Ethics and Compliance Department for review and follow-up as appropriate.

4. *Medical Education Grant Activities.* To the extent not already accomplished, within 120 days after the Effective Date, BIPI shall establish a Grants Management System as the exclusive mechanism through which requestors may seek or be awarded grants for independent medical education activities.

The Grants Management System shall ensure that the BIPI sales and marketing departments have no involvement in, or influence over, the review and approval of medical education grants. To the extent not already accomplished, within 120 days after the Effective Date, BIPI shall develop a system for grant submission and processing by a centralized office which is not part of the sales or marketing division. BIPI shall continue the medical education grant 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.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 medical education grants. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. 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 BIPI'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 Ethics and Compliance Department for review and follow-up as appropriate.

5. *Follow Up Reviews and Reporting.* In the event that a potential violation of BIPI'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, BIPI 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.H 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 Ethics and Compliance Department.

BIPI 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, BIPI 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 BIPI's requirements or Policies and Procedures, and a description of the action(s) that BIPI took as a result of such determinations. BIPI shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

#### L. Reporting of Physician Payments.

1. *Reporting of Payment Information.* Quarterly Reporting: On or before June 1, 2013, BIPI shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.L.2) directly or indirectly from BIPI during the first quarter of 2013 and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter, BIPI shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

Annual Reporting: On or before March 31, 2014, and 90 days after the end of each subsequent calendar year, BIPI shall post on its website a report of the cumulative value of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from BIPI during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.L shall include a complete list of all individual physicians or Related Entities to whom or which BIPI made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii)

city and state that the physician has provided to BIPI for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

## 2. *Definitions and Miscellaneous Provisions.*

(i) BIPI shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. BIPI shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.L affects the responsibility of BIPI 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 physicians or Related Entity.

(ii) For purposes of Section III.L.1, “Payments” is defined to include all “payments or other transfers of value” as that term is defined in §1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) and any regulations promulgated thereunder. The term Payments includes, by way of example, the types of payments or other transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom BIPI would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by BIPI or by a vendor retained by BIPI to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iii) For purposes of its annual and quarterly 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 § 1128G(c)(E) of the Affordable Care Act and any subsequent regulations promulgated thereunder, BIPI may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(iv) The term “Payments” does not include transfers of value or other items that are not included in or are excluded from the definition of “payment or other transfers of value” as set forth in § 1128G(e)(10) under Section 6002 of the

Affordable Care Act and any regulations promulgated thereunder.

(v) For purposes of this Section III.L, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

M. Other Transparency/Disclosure Initiatives.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI will post on its company website the following information with respect to both grants and charitable contributions to U.S.-based HCPs and HCIs: 1) the ultimate recipient organization’s name, to the extent known by BIPI; 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. BIPI shall continue to post (and provide updates to) the above-described information about grants and charitable contributions throughout the term of this CIA. BIPI shall notify the OIG in writing at least 60 days prior to any change in the substance of its 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, BIPI will require all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with BIPI that may be externally imposed on the Consultants based on their affiliation with formulary or P&T committees or committees associated with the development of treatment protocols or standards. BIPI shall continue this requirement throughout the term of this CIA. BIPI represents that within 120 days after the Effective Date, BIPI shall, if necessary, amend its policies relating to Consultants to explicitly state that BIPI requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with BIPI that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 150 days following the Effective Date, BIPI shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. BIPI shall continue these disclosure requirements throughout the term of this CIA.

To the extent not already accomplished, within 120 days after the Effective Date, BIPI will require all Authors of biomedical manuscripts to fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with BIPI and to disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 120 days after the Effective Date, BIPI, if necessary, shall amend its policies relating to Authors to explicitly state BIPI's requirement about full disclosure by Authors consistent with the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts with Authors and in any new contracts with Authors entered into after 120 days following the Effective Date, BIPI shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with BIPI, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

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

To the extent not already accomplished, within 120 days after the Effective Date, BIPI shall post or make available information on its company website about postmarketing commitments (PMCs). The BIPI website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing BIPI studies, and information about the nature and status of FDA post-marketing commitments. BIPI shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

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

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, BIPI changes locations or closes a business unit or location related to or engaged in any of the Covered Functions, BIPI 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, BIPI purchases or establishes a new business unit or location related to or engaged in any of the Covered Functions, BIPI 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 BIPI. 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 BIPI 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 or Location. In the event that, after the Effective Date, BIPI proposes to sell any or all of its business units or locations that are subject to this CIA, BIPI shall notify OIG of the proposed sale at no later than five days after the sale is publicly disclosed by BIPI. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, 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, BIPI 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 CECO required by Section III.A.1, and a summary of other noncompliance job responsibilities the CECO 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 BIPI'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 certification, 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.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' response to BIPI'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 shall be available to OIG, upon request.

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; (d) a summary and description of any and all current and prior engagements and agreements between BIPI and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to BIPI;

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

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

13. a certification from the CECO that, if required under Section III.L and to the best of his/her knowledge, information regarding Payments has been posted on BIPI's website as required by Section III.L;

14. a list of all of BIPI's locations (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 BIPI currently submits claims (if applicable);

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

16. the certifications required by Section V.C.

B. Annual Reports. BIPI shall submit to OIG annually a report with respect to the status of, and findings regarding, BIPI'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 CECO 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. the number of individuals required to review BIPI'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);
4. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' response to BIPI's letter;
5. 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);
6. 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, the 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 shall be available to OIG, upon request.

7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;
8. BIPI's response to the reports prepared pursuant to the reviews outlined in Section III.D, along with corrective action plan(s) related to any issues raised by the reports;



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

10. certifications from the IRO regarding its professional independence and objectivity with respect to BIPI;

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

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

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

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

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

16. a summary of the FFMP and the results of the FFMP required by Section III.J, 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 BIPI took as a result of such determinations;

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

18. a certification from the CECO that to the best of his/her knowledge, information regarding Payments has been posted on BIPI's website as required by Section III.L;

19. a description of all changes to the most recently provided list of BIPI's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers; and

20. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

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

2. Chief Ethics and Compliance Officer: In each Implementation Report and Annual Report, BIPI shall include the following individual certification by the CECO:

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

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

3. BIPI'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 and FDA requirements. In addition, BIPI's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside BIPI have been reviewed

by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by BIPI 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 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

4. BIPI's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.g) and, for each product the call plans were found to be consistent with BIPI's policy objectives as referenced above in Section III.B.3.g.

D. Designation of Information. BIPI 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. BIPI 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

**BIPI:** Alessandra Hawthorne  
Chief Ethics and Compliance Officer  
900 Ridgebury Road  
Ridgefield, CT 06887-0368  
Telephone: 203.798.5597  
Facsimile: 203.791.6260

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, BIPI 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 BIPI's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of BIPI's locations for the purpose of verifying and evaluating: (a) BIPI's compliance with the terms of this CIA; and (b) BIPI'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 BIPI 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 BIPI'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. BIPI shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. BIPI's employees may elect to be interviewed with or without a representative of BIPI present.

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

BIPI 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 BIPI prior to any release by OIG of information submitted by BIPI pursuant to its obligations under this CIA and identified upon submission by BIPI as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, BIPI shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

BIPI 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, BIPI 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 BIPI fails to establish and implement any of the following obligations as described in Section III:

- a. a Chief Ethics and Compliance Officer;
- b. a Compliance Committee;
- c. the Board of Directors compliance obligations, including the resolution from the Board;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons, Relevant Covered Persons, and Board Members;

- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. reporting of Reportable Events;
- k. notification of written communications with FDA as required by Section III.I;
- l. a program for FFMP as required by Section III.J;
- m. a program for Monitoring Non-Promotional Activities as required by Section III.K; and
- n. posting of any Payments as required by Section III.L.

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 BIPI fails to engage and use an IRO as required in Section III.D and Appendices A-B.

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

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of BIPI 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 BIPI fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to BIPI stating the specific grounds for its determination that BIPI has failed to comply fully and adequately with the CIA obligation(s) at issue and steps BIPI shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after BIPI 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. BIPI 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 BIPI 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 BIPI 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 BIPI 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 BIPI of: (a) BIPI'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, BIPI 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 BIPI elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until BIPI 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 BIPI 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 BIPI to report a Reportable Event and take corrective action as required in Section III.H;
- c. a failure to engage and use an IRO in accordance with Section III.D and Appendices A-B;
- 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 BIPI constitutes an independent basis for BIPI's exclusion from participation in the Federal health care programs. Upon a determination by OIG that BIPI has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify BIPI of: (a) BIPI'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.* BIPI 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. BIPI 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) BIPI has begun to take action to cure the material breach; (ii) BIPI is pursuing such action with due diligence; and (iii) BIPI has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, BIPI fails to satisfy the requirements of Section X.D.3, OIG may exclude BIPI from participation in the Federal health care programs. OIG shall notify BIPI in writing of its determination to exclude BIPI (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 BIPI’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, BIPI 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 BIPI 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, BIPI 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 BIPI was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. BIPI 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 BIPI to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless BIPI 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 BIPI 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) BIPI had begun to take action to cure the material breach within that period; (ii) BIPI has pursued and is pursuing such action with due diligence; and (iii) BIPI provided to OIG within that period a reasonable timetable for curing the material breach and BIPI 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 BIPI, only after a DAB decision in favor of OIG. BIPI's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude BIPI 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 BIPI 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. BIPI 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 BIPI, BIPI 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**

BIPI and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of BIPI;
- 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 BIPI signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.**

/Gregory Behar/

10-22-12

GREGORY BEHAR  
President and Chief Executive Officer  
Boehringer Ingelheim Pharmaceuticals, Inc.

DATE

/Alessandra N. Hawthorne/

10-22-12

ALESSANDRA N. HAWTHORNE  
Chief Ethics and Compliance Officer  
Boehringer Ingelheim Pharmaceuticals, Inc.

DATE

/J. Sedwick Sollers III/

10-22-12

J. SEDWICK SOLLERS III  
King & Spalding LLP  
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/Mark A. Jensen/

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ELIZABETH S. WHITE  
King & Spalding LLP  
Counsel for Boehringer Ingelheim Pharmaceuticals, Inc.

DATE



## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement

1. BIPI shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information set forth in Section V.A.10 of the CIA, OIG will notify BIPI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, BIPI may continue to engage the IRO.

2. If BIPI 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, BIPI 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 written notice of the identity of the selected IRO, OIG will notify BIPI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, BIPI may continue to engage the IRO.

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional Functions and Product Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which BIPI products are reimbursed;

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

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

C. IRO Responsibilities.

The IRO shall:

1. perform each component of the IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program 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, policy, or regulation, 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 Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the IRO Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and BIPI.

E. IRO Removal/Termination.

1. *BIPI and IRO.* If BIPI terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, BIPI 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. BIPI must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the prior 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 BIPI to engage a new IRO in accordance with Paragraph A of this Appendix. BIPI must engage a new IRO within 60 days of termination of the prior IRO.

Prior to requiring BIPI to engage a new IRO, OIG shall notify BIPI 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, BIPI 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 BIPI prior to requiring BIPI to terminate the IRO. However, the final determination as to whether or not to require BIPI to engage a new IRO shall be made at the sole discretion of OIG.



## **Appendix B to CIA Promotional and Product Services Review**

### **I. Promotional and Product Services Review, General Description**

As specified more fully below, BIPI shall retain an Independent Review Organization (IRO) to perform reviews to assist BIPI in assessing and evaluating its systems, processes, policies, procedures, and practices related to BIPI's Promotional Functions and Product Related Functions (IRO Review). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. BIPI may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in BIPI's systems, processes, policies, and procedures relating to Promotional Functions and Product Related Functions (collectively "Covered Functions"), the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If BIPI materially changes its systems, processes, policies, and procedures relating to the Covered 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 fourth 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 BIPI's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain aspects of the Covered Functions. Where practical, BIPI 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 BIPI pursuant to the preceding sentence.

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

1) BIPI's systems, policies, processes, and procedures applicable to the manner in which BIPI sales representatives and/or MTI personnel and MTI agents handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (*i.e.*, off-label) uses) and the dissemination of materials relating to off-label uses of products. This review includes:

- a) the manner in which BIPI sales representatives handle requests for information about off-label uses of Government Reimbursed Products (e.g., by referring all such requests to MTI);
- b) the manner in which MTI personnel and MTI agents handle and respond to requests for information about off-label uses of Government Reimbursed Products (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 physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions ("HCIs") by BIPI;
- d) BIPI's systems, processes, and procedures (including the Inquiries Database) to track requests for information about off-label uses of products submitted to MTI and its agents and responses to those requests;
- e) the manner in which BIPI collects and supports information reported in any systems used to track and respond to requests for product information, including its Inquiries Database;
- f) the processes and procedures by which MTI and its agents, the CECO, or other appropriate individuals or their designees within BIPI identify situations in which it appears that off-label or other improper promotion may have occurred; and
- g) BIPI's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

- 2) BIPI's policies and procedures applicable to the manner and circumstances under which its medical personnel (including personnel from Field Based Medicine) 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 personnel at such meetings or events;
- 3) BIPI's systems, policies, processes, and procedures relating to BIPI's internal review and approval of information and materials related to Government Reimbursed Products disseminated to HCPs or HCIs by BIPI;
- 4) BIPI's systems, policies, processes and procedures relating to incentive compensation for Relevant Covered Persons who are sales representatives, 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 promotion, sales, and 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 BIPI establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;
- 5) BIPI's systems, processes, policies, and procedures relating to the development and review of call plans (as defined in Section III.B.3.g) 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 or non-FDA-approved uses;
- 6) BIPI's systems, processes, policies, and procedures relating to the development, implementation, and review of Sample Distribution Plans for 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 from BIPI;
- 7) BIPI'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) BIPI's systems, processes, policies, and procedures relating to non-speaker related consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, mentorships, ad hoc advisory activities, and any other financial engagements or arrangements with an HCP or HCI, if any) and all events and expenses relating to such engagements or arrangements.

## 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 BIPI's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-8 above, including a general description of BIPI'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.1-8 above are made known or disseminated within BIPI;
- 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 BIPI's incentive compensation system for Relevant Covered Persons who are sales representatives, 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 BIPI may establish compensation differently for individual Government Reimbursed Products, the IRO shall report separately on each such type of compensation arrangement;
- 6) findings and supporting rationale regarding any weaknesses in BIPI'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 Transaction Review

As described more fully below in Sections III.A-D, the Transactions Review shall include: (1) a review of BIPI's call plans and BIPI's call plan review process; (2) a review of Sampling Events as defined below in Section III.B; (3) a review of records relating to a sample of the Payments that are reported by BIPI pursuant to Section III.L of the CIA; and (4) a review of up to three additional items identified by the OIG in accordance with Section III.D.1.b of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

#### A. IRO Review of BIPI's Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of BIPI's review of its call plans for Government Reimbursed Products as set forth in Section III.B.3.g of the CIA. BIPI shall provide the IRO with: i) a list of Government Reimbursed Products promoted by BIPI during the Reporting Period; ii) information about the FDA-approved uses for each BIPI Government Reimbursed Product; and iii) the call plans for each Government Reimbursed Product. BIPI shall also provide the IRO with information about the reviews of call plans that BIPI conducted during the Reporting Period and any modifications to the call plans made as a result of BIPI'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 BIPI in conducting its review and/or modification of the call plan in order to determine whether BIPI 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 and HCIs on a particular call plan are inconsistent with BIPI's criteria relating to the call plan and/or BIPI's Policies and Procedures. The IRO shall also note any instances in which it appears that BIPI failed to follow its criteria or Policies and Procedures.

#### B. IRO Review of the Distribution of Samples of BIPI Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs. BIPI shall provide the IRO with: i) a list of Government Reimbursed Products for which BIPI distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each BIPI

Government Reimbursed Product; and iii) information about BIPI's policies and procedures relating to the distribution of samples of each type of Government Reimbursed Product, including BIPI's Sample Distribution Plan showing which type samples may be distributed by sales representatives to HCPs and HCIs of particular medical specialties or types of clinical practices. BIPI shall also provide the IRO with information about the reviews of Sample Distribution Plans that BIPI conducted during the Reporting Period as set forth in Section III.B.3.g of the CIA and any modifications to the distribution plans made as a result of BIPI's reviews.

For each Government Reimbursed Product for which BIPI distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which BIPI 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: i) the quantity, dosage, and form of the BIPI Government Reimbursed Product provided to the HCP or HCI; ii) the identity and type of medical specialty or clinical practice of the HCP or HCI; iii) which individual BIPI sales representative or department (e.g., the Medicine and Regulatory division) provided the sample to the HCP or HCI; iv) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to the Medicine and Regulatory division); and v) the manner and mechanism through which the request was fulfilled (e.g., sales representative distribution or direct shipment).

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 BIPI representative in a manner consistent with BIPI's sample distribution policy for the Government Reimbursed Product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by a BIPI representative other than a sales representative, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: i) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; ii) verify that he/she/it requested the samples provided during the Sampling Event; iii) explain or confirm its type of medical specialty or clinical practice; and iv) identify the basis for requesting the sample (e.g., conversations with a BIPI sales representative, conversation with a representative of BIPI's Medicine and Regulatory division, independent research or knowledge of the HCP or HCI, *etc.*)

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 BIPI 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 BIPI failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event.

### C. IRO Review of Physician Payment Listings

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

As set forth in Section III.L of the CIA, BIPI shall post quarterly and annual listings of physicians and Related Entities who received Payments, as defined in the CIA, directly or indirectly from BIPI during the prior calendar year or quarter as applicable. For purposes of the IRO review as set forth in this Section III.C, each annual listing shall be referred to as the “Physician Payment Listing” or “Listing.” For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician’s full name; ii) name of Related Entity (if applicable); iii) city and state of the physician’s practice or the Related Entity; and iv) the aggregate value of the Payment(s) in the preceding year.

For purposes of this IRO review, the term “Control Documents” shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for the sampled physician and/or Related Entity. 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 sales representatives 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 Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment 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 Reporting Period, of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or

Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in 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 Physicians and/or Related Entities

For each physician and/or Related Entity 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 and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in BIPI's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that BIPI'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 BIPI'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 and/or Related Entity do not exist and:
  - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
  - ii. the IRO cannot confirm that BIPI otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, 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 BIPI'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 BIPI has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that BIPI otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, 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.

#### D. IRO Review of Additional Items

As set forth in Section III.D.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 150 days prior to the end of the applicable Reporting Period, the OIG shall notify BIPI 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 BIPI 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 BIPI's systems, processes, policies, and procedures based on its review of each Additional Item.)

BIPI may propose to the OIG that its internal audit(s) and/or review conducted as part of the Field Force Monitoring Program (FFMP) described in Section III.J of the CIA or the Non-Promotional Monitoring Program described in Section III.K, be partially substituted 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 BIPI's monitoring activities and 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 BIPI's planned monitoring activities and internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and BIPI's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies BIPI'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, BIPI shall engage the IRO to perform the Review as outlined in this Section III.D.

If the OIG agrees to permit certain of BIPI's monitoring activities or 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 BIPI in its internal audits.

#### E. 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 Call Plan Reviews)

- a) a list of the Government Reimbursed Products promoted by BIPI during the Reporting Period and a summary of the FDA-approved uses for such Government Reimbursed Products;

- b) for each BIPI Government Reimbursed Product: i) a description of the criteria used by BIPI 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 BIPI of the call plans and an indication of whether BIPI reviewed the call plans as required by Section III.B.3.g 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 BIPI's criteria relating to the call plan and/or BIPI's Policies and Procedures; and iv) a description of all instances in which it appears that BIPI failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;
- c) the findings and supporting rationale regarding any weaknesses in BIPI's systems, processes, policies, procedures, and practices relating to BIPI's call plans or the review of the call plans, if any;
- d) recommendations, if any, for changes in BIPI'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)

- e) for each BIPI Government Reimbursed Product distributed during the Reporting Period: i) a description of Sample Distribution Plan (including whether sales representatives may provide samples of the Government Reimbursed 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 were not consistent with the uses of the Government Reimbursed Product approved by the FDA. This description shall include a description of the process followed by BIPI 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 BIPI failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event;

- f) the findings and supporting rationale regarding any weaknesses in BIPI's systems, processes, policies, procedures, and practices relating to BIPI's distribution of samples of BIPI Government Reimbursed Products, if any;
- g) recommendations, if any, for changes in BIPI'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)

- h) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- i) for each sampled physician or Related Entity, 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 BIPI policy; iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; iv) each Control Document reflects that BIPI's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and v) any disciplinary action that was undertaken in those instances in which BIPI policies were not followed;
- j) for each sampled physician or Related Entity 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 physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- k) 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)

- l) for each Additional Item reviewed, a description of the review conducted;
- m) for each Additional Item reviewed, the IRO's findings based on its review;
- n) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in BIPI's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- o) for each Additional Item reviewed, recommendations, if any, for changes in BIPI's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.