

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BRISTOL-MYERS SQUIBB COMPANY

I. PREAMBLE

Bristol-Myers Squibb Company (BMS) 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, BMS is entering into a Settlement Agreement with the United States. BMS will also enter into settlement agreements with various States (Related State Settlement Agreements) and BMS's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, BMS voluntarily established a worldwide compliance program (Global Compliance Program) applicable to all BMS employees in its global operations, including its United States Pharmaceuticals Group (hereafter "U.S. Pharmaceuticals Group" or "the Group"). The BMS Global Compliance Program includes, at the global level, a Chief Compliance Officer, who has the authority to report directly to the Board of Directors and the CEO, and a Corporate Compliance Council. The Global Compliance Program also includes: i) a code of conduct applicable to all employees (the "Standards of Business Conduct and Ethics"); ii) written corporate policies that set forth BMS's highest level principles, which as represented by BMS, help ensure compliance with applicable laws and regulations and promote high ethical standards; iii) educational and training initiatives, including training for all BMS employees on the Standards of Business Conduct and Ethics; iv) a corporate policy that provides for the confidential disclosure of potential compliance violations, investigation of those potential violations, and appropriate disciplinary procedures; and v) a corporate compliance audit group.

The Global Compliance Program also includes compliance programs for specific BMS business units, such as the U.S. Pharmaceuticals Group, Asia Pacific/Japan (pharmaceuticals), Europe/Middle East/Africa (pharmaceuticals), Latin America/Canada (pharmaceuticals), Global Marketing (pharmaceuticals), ConvaTec, Mead Johnson Nutritionals, Medical Imaging, and Research and Development (pharmaceuticals). Each of these programs is headed by an individual who is responsible for developing, operating, and monitoring the Global Compliance Program as it applies to the business unit. Each of these individuals also has the authority and responsibility to report compliance concerns directly to the Chief Compliance Officer, the Board of Directors, the CEO, and the applicable business unit leader. Each business unit compliance program includes written policies and procedures that are applicable to the business unit, compliance education and training initiatives, monitoring activities, and preventative and corrective actions when a compliance issue is identified.

BMS shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. BMS may modify its Compliance Program as appropriate, but, at a minimum, BMS 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 BMS under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) BMS's final Annual Report; or (2) any additional materials submitted by BMS 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 BMS 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”);
- b. all officers and directors of BMS with responsibilities relating to, or oversight for, the U.S. Pharmaceuticals Group or other employees who are engaged in, or have responsibilities that directly support the Group in, Government Pricing and Contracting Functions or Promotional and Product Services Related Functions;
- c. all employees of the U.S. Pharmaceuticals Group (a part of the Worldwide Pharmaceuticals Division) and all United States-based employees assigned to other divisions (including, but not limited to, Corporate Finance, the Law Department, the Office of Corporate Compliance, Global Labeling and Promotion Compliance, Human Resources, U.S. Pharmaceuticals Medical Affairs, Healthcare Channel Management, Global Marketing, Global Strategic Sourcing and Information Management, Global Epidemiology and Outcomes Research, and Corporate and Business Communications) who are engaged in, or have responsibilities that directly support the Group in, Government Pricing and Contracting Functions (defined below in Section II.C.3) or Promotional and Product Services Related Functions (defined below in Section II.C.4); and
- d. all contractors, subcontractors, agents, and other persons who perform Government Pricing and Contracting Functions (as defined below in Section II.C.3) or Promotional and Product Services Related Functions (as defined below in Section II.C.4) on behalf of BMS.

Notwithstanding the above, the term “Covered Persons” does not include: i) officers or employees of BMS’s Mead Johnson Nutritionals, ConvaTec, and Medical Imaging groups; Government Affairs; and Technical Operations, except to the extent that such employees begin to engage in Government Pricing and Contracting Functions or Promotional and Product Services Related Functions or they have responsibilities which directly support the Group in such Functions; ii) those employees of BMS’s Research and

Development Group except to the extent that they are engaged in Government Pricing and Contracting Functions or Promotional and Product Services Related Functions or they have responsibilities which directly support the Group in such Functions; iii) those BMS employees of Global Marketing who have not been designated to be transferred to the team in the U.S. Pharmaceuticals Group responsible for developing and implementing tactical marketing programs for pharmaceutical products that are likely to receive regulatory approval and be commercialized in the United States within one year; and iv) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes all Covered Persons whose job responsibilities relate to Government Pricing and Contracting Functions or to Promotional and Product Services Related Functions.
3. “Government Reimbursed Products” refers to U.S. Pharmaceuticals Group prescription drug products that are reimbursed by Federal health care programs. This term includes products promoted by the U.S. Pharmaceuticals Group for which BMS may not hold the New Drug Application.
4. The term “Government Pricing and Contracting Functions” refers to the collection, calculation, verification, or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8), the Medicare Program (42 U.S.C. §§ 1395-1395hhh), and other government programs (including the 340B Drug Pricing Program, codified at 42 U.S.C. § 256b (the 340B Program)) and to all other pricing, government contract, and regulatory functions relating to Government Reimbursed Products to the extent that BMS is responsible for such functions. Relevant Covered Persons engaged in Government Pricing and Contracting Functions include Covered Persons with job responsibilities relating to the calculation and reporting of Average Sales Price (ASP), Average Wholesale Price (AWP), Wholesale Acquisition Cost (WAC), Wholesale List Price, Direct Price, Average

Manufacturer Price (AMP), Best Price, the 340B Program ceiling price, and all other information reported or used in connection with Federal health care programs for Government Reimbursed Products.

5. The term “Promotional and Product Services Related Functions” includes the promotion, marketing, sales, and the development or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products. Relevant Covered Persons engaged in Promotional and Product Services Related Functions include, but are not limited to, all Covered Persons involved in detailing health care professionals (HCPs); all Covered Persons involved in contracting with HCPs for the provision of consulting or speaker services; all Covered Persons involved in promoting, marketing, or selling Government Reimbursed Products to managed care entities or pharmacy benefit managers (PBMs) or involved in contracting with managed care entities or PBMs; and all Covered Persons involved in the development or provision of promotional or medical information about Government Reimbursed Products.
6. The term “Third Party Educational Activity” shall mean any third-party activities supported by BMS involving any continuing medical education (CME), independent medical education (IME), disease awareness, or other scientific, educational, or professional program, meeting, or event, including but not limited to, sponsorship of symposia at medical conferences.
7. The term “Third Party Personnel” shall mean personnel of the entities with whom BMS has or may in the future enter into agreements to co-promote a Government Reimbursed Product in the United States or engage in joint promotional activities in the United States relating to such a product. The definition of Third Party Personnel specifically includes employees of Otsuka America Pharmaceuticals, Inc. who engage in promotional activities with BMS. BMS has represented that: 1) the Third Party Personnel are employed by other independent entities; 2) BMS does not control Third Party Personnel; and 3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. BMS 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.3, and V.B.4 related to Third Party Personnel. Provided that BMS complies with the requirements of Sections III.B.2, V.A.3, and V.B.4, BMS shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee.

1. *Compliance Officer.* Prior to the Effective Date, BMS appointed a Chief Compliance Officer and BMS shall maintain and staff the Chief Compliance Officer position during the term of the CIA. The Chief Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Chief Compliance Officer shall be a member of senior management of BMS, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of BMS, and shall be authorized to report on such matters to the Board of Directors at any time. The Chief Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by BMS as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* Prior to the Effective Date, BMS appointed a compliance committee with responsibility for BMS's Compliance Program in the United States. Consistent with the requirements of this Section III.A.2, BMS shall maintain such

a compliance committee (the “CIA Compliance Committee”) during the term of this CIA. The CIA Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior management from the Law Department, Human Resources, U.S. Pharmaceuticals Group, Finance, and Regulatory groups). The Chief Compliance Officer shall chair the CIA Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization’s risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, BMS developed, implemented, and distributed its Standards of Business Conduct and Ethics to all employees. BMS has made and shall continue to make the promotion of, and adherence to, the Standards of Business Conduct an element in evaluating the performance of all employees. In addition, BMS has developed, implemented, and distributed a U.S. Healthcare Law Compliance Code of Conduct to employees in the U.S. Pharmaceuticals Group that addresses compliance with Federal health care program and FDA requirements in sales, marketing, promotion, and the provision of information about pharmaceutical products. The Standards of Business Conduct and Ethics and the U.S. Healthcare Law Compliance Code of Conduct together shall be referred to as the “Code of Conduct” for purposes of this CIA. The Code of Conduct sets forth and shall continue to set forth, at a minimum, the following:

- a. BMS’s commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to comply with all government contracting and price reporting requirements, and to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health care program and FDA requirements;

- b. BMS's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with BMS's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of BMS's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by BMS, suspected violations of any Federal health care program and FDA requirements or of BMS's own Policies and Procedures;
- d. the possible consequences to both BMS and Covered Persons of failure to comply with Federal health care program and FDA requirements and with BMS's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and BMS'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, the Code of Conduct shall be distributed to each Covered Person and each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by BMS's Code of Conduct. This certification may be accomplished electronically. 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.

BMS 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, 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. This certification may be accomplished electronically.

2. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, BMS shall send a letter to each entity employing Third Party Personnel. The letter shall outline BMS'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 BMS's Compliance Program. BMS 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 BMS's Code of Conduct and a description of BMS's Compliance Program available to its Third Party Personnel; or (b) represent to BMS that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* Prior to the Effective Date, BMS implemented for the U.S. Pharmaceuticals Group (and for those Relevant Covered Persons supporting the Group) written Policies and Procedures regarding the operation of BMS's compliance program and its compliance with Federal health care program and FDA requirements (Policies and Procedures). These Policies and Procedures are contained in the Compliance Code of Conduct, the U.S. Healthcare Law Compliance Field Handbook (Field Handbook) and other procedural documents applicable to the Group and to other functions supporting the Group. To the extent not already accomplished, within 120 days after the Effective Date, BMS shall ensure that the Group's Policies and Procedures address or shall continue to address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. Government Pricing and Contracting Functions;
- c. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. 3729-3733);
- d. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all FDA requirements, including procedures governing the handling and/or response by

sales representatives, Medical Science Liaisons, and Medical Information to requests for information about off-label uses;

- e. appropriate mechanisms by which the Medical Information Department receives and responds to requests for information about off-label uses of BMS's products, including but not limited to, the form and content of information disseminated by Medical Information in response to such requests and the internal review process for the information disseminated;
- f. call plan development for the Group's sales representatives for those Government Reimbursed Products having a high potential for off-label use that could be driven by detailing an inappropriate audience of HCPs or institutions. For each such product, the Policies and Procedures shall require that BMS review the associated call plans and the bases upon which physician specialties and institutional provider types are included in, or excluded from, the call plans. The Policies and Procedures shall also require that BMS shall modify the call plans as necessary to ensure that BMS is promoting its 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 product meeting the requirements set forth above;
- g. consultant engagements entered into with HCPs (including, but not limited to, those engagements relating to speaker programs, speaker trainings, advisory boards, or any similar fee-for-service relationship with an HCP) and all events and expenses relating to such HCP engagements. These policies shall be designed to ensure that the consultant engagements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements;
- h. requirements that vendors, who may be retained to assist with the execution of the consultant engagements or programs referenced

above in Section III.B.3.g (including, but not limited to, the provision of meals provided to facilitate speaker programs) comply with all applicable Federal health care program and FDA requirements;

- i. services agreements (including, but not limited to, agreements relating to mailings, data purchases, and research services) or consulting agreements entered between BMS and managed care entities, PBMs, or other vendors. These Policies and Procedures shall be designed to ensure that all such agreements comply with all applicable Federal health care program and FDA requirements;
- j. sponsorship or funding of grants (including educational grants). These Policies and Procedures shall be designed to ensure that BMS's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- k. funding of or participation in, any Third Party Educational Activity as defined in Section II.C.6 above. These Policies and Procedures shall be designed to ensure that BMS'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) to the extent feasible consistent with subsection 5 below, BMS disclose its financial support of the Third Party Educational Activity and any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose BMS's financial support of the Third Party Educational Activity and any financial relationships that BMS might have with faculty, speakers, or organizers at such Activity; 3) any faculty, speakers, or organizers at the Third Party Educational Activity disclose any financial relationship with BMS; 4) any Third Party Educational Activity have an educational focus; 5) the content, organization, and operation of the Third Party Educational Activity be independent of BMS

control; 6) BMS support only Third Party Educational Activity that is non-promotional in tone/nature; and 7) BMS support of a Third Party Educational Activity be contingent on the provider's commitment to provide information at the Educational Activity that is fair, balanced, accurate and not misleading;

- l. review of promotional materials by legal and medical personnel and the review of other materials and information intended to be disseminated outside BMS in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during BMS's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program and FDA requirements;
- m. sponsorship or funding of research or related activities. These Policies and Procedures shall be designed to ensure that BMS's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- n. Policies and Procedures relating to incentive compensation for Covered Persons who are sales representatives that are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of BMS's products;
- o. disciplinary policies and procedures for violations of BMS's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

BMS represents that in calendar year 2006, it distributed the relevant portions of its Policies and Procedures, including its U.S. Healthcare Law Compliance Code of Conduct, to all individuals who were, at the time of distribution, employees of the U.S. Pharmaceuticals Group and to other Covered Persons whose job functions related to those Policies and Procedures. In addition, the Field Handbook was distributed to all sales representatives of the Group, and BMS continues to provide the Handbook to each new

sales representative of the Group. To the extent not already accomplished, within 120 days after the Effective Date, BMS shall distribute the relevant portions of its Policies and Procedures to any Covered Persons whose job functions relate to the Policies and Procedures and who did not previously receive them. Appropriate and knowledgeable staff personnel were, and shall continue to be, available to explain the Policies and Procedures.

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

C. Training and Education.

BMS represents that it provides training on a regular basis concerning a variety of topics to its employees. The training required by this CIA need not be separate and distinct from the regular training provided by BMS, but instead may be integrated fully into such regular training, so long as the training covers the topics specified below in Sections III.C.1-2. The Chief Compliance Officer shall be responsible for determining how many of the hours of BMS's regular training shall be credited toward the General and Specific Training requirements set forth below in Sections III.C.1 and 2, respectively.

1. *General Training.* In accordance with BMS's established training schedule, within 150 days after the Effective Date, BMS shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain BMS's:

- a. CIA requirements; and
- b. BMS'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 150 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.

In addition to the General Training requirements outlined above, within 150 days after the Effective Date, BMS shall notify all employees in the United States of the fact that BMS has entered a CIA with the OIG and provide an explanation of the conduct at issue in the underlying settlement and BMS's requirements and obligations under the CIA.

2. *Specific Training.* In accordance with BMS's established training schedule, within 150 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above.

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

- a. BMS's systems and procedures for performing Government Pricing and Contracting Functions;
- b. all applicable Federal health care program requirements relating to Government Pricing and Contracting Functions;
- c. the personal obligation of each individual involved in Government Pricing and Contracting Functions to ensure that all reported pricing and other information is accurate;
- d. the legal sanctions for violations of Federal health care program requirements; and
- e. examples of proper and improper practices related to Government Pricing and Contracting Functions.

For those Relevant Covered Persons engaged in Promotional and Product Services Related Functions, this Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional and Product Services Related Functions;
- b. all applicable FDA requirements relating to Promotional and Product Services Related Functions;
- c. all BMS policies, procedures, and other requirements applicable to Promotional and Product Services Related Functions;
- d. the personal obligation of each individual involved in Promotional and Product Services 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 and Product Services Related Functions.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 150 days after the Effective Date, whichever is later. A BMS employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to (as applicable) Government Pricing and Contracting Functions or to Promotional and Product Services Related 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 two hours of Specific Training in each subsequent Reporting Period.

In addition to agreeing to provide training that satisfies the training obligations set forth above in this Section III.C, as part of its Compliance Program BMS also routinely trains Relevant Covered Persons on the topics outlined above in Sections III.C.1-2. This additional training shall be known as "Periodic Compliance Training." BMS shall continue to provide Periodic Compliance Training to Relevant Covered Persons during

the term of this CIA. BMS shall include a description of such Periodic Compliance Training as part of its Annual Reports, but BMS shall not be required to formally track the Periodic Compliance Training for each Relevant Covered Person.

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

4. *Qualifications of Trainer.* The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, BMS trainers and/or outside consultant trainers selected by BMS or it may be satisfied through relevant, accredited continuing education programs provided the programs cover the topics outlined above in Sections III.C.1-2. Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements.

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

6. *Computer-based Training.* BMS may provide the training required under this CIA through appropriate computer-based training approaches. If BMS 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 BMS chooses to provide computer-based General or Specific Training, all applicable requirements to provide a number of “hours” of training in this Section III.C may be met with respect to computer-based training by providing the required number of “normative” hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, BMS 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 BMS in assessing and evaluating its Government Pricing and Contracting Functions and its Promotional and Product Services Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by BMS shall have expertise in the applicable requirements of the Medicaid Drug Rebate Program, the Medicare Program, and other applicable Federal health care program and FDA requirements as may be appropriate to the specific Review for which it is retained. Each IRO shall assess, along with BMS, 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.

The IRO(s) shall conduct two types of reviews. The first review shall assess BMS’s systems, processes, policies, procedures, and practices relating to the Government Pricing and Contracting Functions (Government Pricing and Contracting Review). The second review shall assess BMS’s systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions (Promotional and Product Services Review). Collectively, both of the IRO reviews shall be referred to as “Reviews”.

b. *Frequency and Brief Description of Reviews.*

1) *Government Pricing and Contracting Review.* As set forth more fully in Appendix B, the Government Pricing and Contracting Review shall consist of two components - a Systems Review and a Transactions Review. The Systems Review shall be comprised of two components (the “ASP

Systems Review” and the “Medicaid Drug Pricing Systems Review”). If there are no material changes in BMS’s Medicaid Drug Pricing related systems, processes, policies, and procedures during the term of the CIA, the IRO shall perform the Medicaid Drug Pricing Systems Review for the third Reporting Period. If there are no material changes in BMS’s ASP related systems, processes, policies and procedures during the term of the CIA, the IRO shall perform the ASP Systems Review for the second and fourth Reporting Periods. If BMS materially changes its systems, processes, policies, and procedures relating to the Medicaid Drug Pricing or ASP, the IRO shall perform a Government Pricing and Contracting Systems Review for the Reporting Period in which such changes were made in addition to conducting the Review for Reporting Periods specified above, however, the IRO shall not be required to conduct a Systems Review for the first Reporting Period. The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

The Government Pricing and Contracting Review shall be an assessment of BMS’s systems, processes, policies and practices relating to the tracking, gathering, and accounting for all relevant data for purposes of properly calculating and reporting ASP, AMP, and Best Price and a review of a sample of certain pricing transactions.

2) *Promotional and Product Services Review.* As set forth more fully in Appendix C, the Promotional and Product Services Review shall consist of two components - a Systems Review and a Transactions Review. If there are no material changes in BMS’s systems, processes, policies, and practices relating to Promotional and Product Services Related Functions, the Promotional and Product Services Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If BMS materially changes its systems, processes, policies, and practices relating to

Promotional and Product Services Related Functions, 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. The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

In connection with the Systems Review, the IRO shall review BMS's systems, processes, policies, and practices relating to Promotional and Product Services Related Functions. In connection with the Transactions Review, the IRO shall review samples of specified Promotional and Product Services related transactions.

c. Retention of Records. The IRO and BMS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and BMS) related to the reviews. The IRO and BMS shall retain and make these records available consistent with Section VIII below.

2. *IRO Review Reports.* The IRO(s) shall prepare a report based upon each Review performed in accordance with Section III.D.1 above. The information and contents to be included in the report for each Review are described in Appendices B and C, which are incorporated by reference.

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

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

E. Disclosure Program.

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

The Disclosure Program shall continue to emphasize a nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be

conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, BMS shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

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

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

- i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
- ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:

- i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
- ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

- b. "Screened Persons" include:
 - i. prospective and current owners of BMS (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading);
 - ii. prospective and current officers and directors of BMS;
 - iii. prospective and current employees of BMS; and
 - iv. prospective and current contractors and agents of BMS who are Covered Persons.

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

- a. BMS shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.
- b. BMS shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. BMS shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

3. *Removal Requirement.* If BMS has actual notice that a Screened Person has become an Ineligible Person, BMS shall remove such Screened Person from responsibility for, or involvement with, BMS's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If BMS has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, BMS shall take all appropriate actions to ensure that the responsibilities of that Screened 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 by senior management at United States corporate headquarters, BMS shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to BMS conducted or brought by a governmental entity or its agents involving an allegation that BMS 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. BMS shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Reportable Events.*

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

- i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of prescription drugs for which penalties or exclusion may be authorized; or
- ii. the filing of a bankruptcy petition by BMS.

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

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

- i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;
- ii. a description of BMS's actions taken to correct the Reportable Event; and
- iii. any further steps BMS plans to take to address the Reportable Event and prevent it from recurring.
- iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities 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 BMS and the FDA that materially discusses BMS's or a Covered

Person's actual or potential unlawful or improper promotion of BMS's products (including any improper dissemination of information about off-label indications), BMS shall provide a copy of the report, correspondence, or communication to the OIG. BMS 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. Review of Records Reflecting the Content of Detailing Sessions.

For each Reporting Period, BMS shall obtain non-BMS records (e.g., Verbatims or similar records) generated by an independent entity (Survey Entity) reflecting the purported content and subject matter of detailing interactions between Group sales representatives and HCPs for up to three Covered Products (as defined below). In order to satisfy its obligations under this Section III.J, BMS may propose that it obtain an alternative type of survey record (e.g. message recall studies) rather than the records of the detailing sessions. The OIG will consider BMS's proposal, and after considering BMS's proposal shall, in its discretion, identify the type of survey records to be obtained.

For each Covered Product, BMS shall contract with the Survey Entity to conduct inquiries into the content and subject matter of the detailing interactions. The OIG shall select and notify the Survey Entity of a one week period within every other quarter of the Reporting Period for which the surveys shall be conducted beginning in the second full quarter after the Effective Date. For each Covered Product, BMS shall obtain records reflecting the purported content and subject matter of detailing sessions during the identified week in all regions across the United States.

Prior to the start of the second Reporting Period and every Reporting Period thereafter, based on the information provided and other information known to it, and after consultation with BMS, the OIG shall select up to three Government Reimbursed Products to be the basis for the review outlined in this Section III.J. These identified products shall be known as the "Covered Products." The parties have already identified the Covered Products for the first Reporting Period.

BMS shall review the records obtained from the Survey Entity and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of the Covered Products. BMS shall make findings based on its review (Off-Label Findings) and shall take any

responsive action it deems necessary. If necessary for purposes of its review, BMS shall endeavor to gather additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report, BMS shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of BMS's Off-Label Findings, and a description of the action(s), if any, BMS took in response to the Off-Label Findings.

K. Drug Price Reporting Requirements.

1. *General Statement of Purpose and Intent.* On a quarterly basis, BMS shall report to the entities identified below in Section III.K.2.c certain ASP and AMP pricing information, as specified below in Sections III.K.2.a and b (collectively referred to as the "Pricing Information"). In particular, BMS shall report an ASP for each of the "ASP Covered Products" and an AMP for each of the "AMP Covered Products" described in Appendix D. The ASP Pricing Information shall be provided subject to the confidentiality provisions set forth in the Related State Settlement Agreements or as otherwise required by law.
2. *Specific Reporting Requirements.*
 - a. Average Sales Price Defined. For purposes of this CIA, "Average Sales Price" or "ASP" is defined to have the meaning of, and will be calculated in accordance with the requirements for Average Sales Price as defined 42 U.S.C. § 1395w-3a and all applicable regulations and written directives. BMS shall report under this CIA the same ASPs for the same formulations of the ASP Covered Products that it reports to CMS for purposes of the Medicare Part B program. The ASPs shall be calculated in the same way that BMS calculates ASPs for Medicare purposes and they shall be reported under this CIA in the same electronic format used to report ASPs to CMS.
 - b. Average Manufacturer Price Defined. For purposes of this CIA, "Average Manufacturer Price," or "AMP," is defined to have the meaning of, and will be calculated in accordance with the requirements for Average Manufacturer Price as defined in 42 U.S.C. § 1396r-8(k)(1) and in all applicable regulations,

written directives, and guidance, including the Medicaid Program Drug Rebate Agreement. BMS shall report under this CIA the same AMPs for the same formulations of the AMP Covered Products that it reports to CMS on a quarterly basis for each AMP Covered Product, along with any retroactive AMP adjustments that BMS reports to CMS. The AMPs shall be calculated in the same way that BMS calculates the AMPs for Medicaid purposes, and they shall be reported under this CIA in the same electronic format used to report this information to CMS under the Medicaid Drug Rebate Program.

- c. Reporting Obligations for ASP Covered Products and AMP Covered Products. Except as otherwise noted below, within 35 days after the last day of each calendar quarter, BMS shall report, in accordance with Sections III.K.2.a and b above, the ASPs for the ASP Covered Products and the AMPs (and prior-quarter AMP adjustments) for the AMP Covered Products. BMS shall make these reports to: 1) the Medicaid programs of each of the States that have entered into a Related State Settlement Agreement with BMS; and 2) to a commercial drug price reporting service (such as First Data Bank, Inc.) designated by any State that has entered into a Related State Settlement Agreement and has received BMS's ASPs and AMPs thereunder. If appropriate to reflect changes in the sources from which the State Medicaid programs receive their Pricing Information, BMS agrees that, upon the receipt of a written request by any of the States that have entered into a Related State Settlement Agreement, it will report the Pricing Information to a drug price reporting source other than, and in addition to, the drug price reporting service originally designated by the State, subject to the confidentiality provisions referenced in Section III.K.2.e. The Pricing Information shall be reported to the commercial drug price reporting service solely for the purposes of reporting pricing information to the Medicaid programs of those States that entered Related State Settlement Agreements and the ASP Pricing Information shall

be subject to the confidentiality provisions referenced in Section III.K.2.e.

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

- d. Certification Requirement. BMS shall certify that the ASPs and AMPs reported hereunder are calculated in accordance with requirements of the Medicare and Medicaid programs as they relate to ASP and AMP. Said certifications shall be made in the form attached hereto as Appendix E, and shall include an acknowledgment that the ASPs, AMPs, and prior-quarter AMP adjustments reported under this CIA were reported to CMS and are the same prices that were reported to CMS. BMS agrees that this certification by an appropriate employee or agent of BMS constitutes a certification by BMS.

- e. Confidentiality of Reported Pricing Information. BMS represents that it considers the ASP Pricing Information it reports under this Section III.K to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of BMS. The Related State Settlement Agreements will contain certain confidentiality provisions governing the treatment of the reported ASP Pricing Information. BMS will enter good faith negotiations with the commercial drug prices reporting service(s) to reach a mutually acceptable confidentiality agreement to govern the handling of ASP Pricing Information reported by BMS to the commercial drug price reporting service. Among other provisions, such confidentiality agreement shall: a) permit the commercial drug price reporting service to disclose BMS's ASP Pricing Information only to the

Medicaid programs of those States that have entered into a Related State Settlement Agreement with BMS and the disclosure shall be made pursuant to the terms of the Related State Settlement Agreement; and b) require BMS's ASP Pricing Information to otherwise be kept strictly confidential.

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

L. Medical Information.

1. *Policies and Procedures*.

BMS has established a Medical Information Department to undertake various responsibilities, including responding to requests for off-label information about BMS products. BMS has in place, and shall continue to maintain, Policies and Procedures addressing the discussion and dissemination of information about non-FDA approved uses of products (off-label information). These Policies and Procedures provide, among other things, that Covered Persons may not directly or indirectly solicit, encourage, or promote unapproved uses of a product to HCPs. Further, under these Policies and Procedures, when a U.S. Pharmaceuticals Group sales representative receives an inquiry about an unapproved use of a product (Inquiry), he/she is required to document the Inquiry in a Medical Information Request Form (MIRF). After documenting the Inquiry, the sales representative is required to submit such Inquiry to the Medical Information Department rather than responding to the Inquiry himself or herself, except as permitted by BMS policy. BMS Policies and Procedures include mechanisms by which the Medical Information Department or Medical Science Liaisons receive and respond to requests for off-label information about BMS products, including but not limited to, the form and content of information disseminated in response to such requests and the internal review process for the information disseminated.

2. *Monitoring.*

BMS shall continue its process of documenting all unsolicited off-label inquiries received by Group sales representatives through an MIRF. The MIRF is submitted to Medical Information (electronically or in paper form) for response; the 800 number for Medical Information is also offered to an HCP in the event there is an urgent need for the requested medical information. The MIRF includes the HCP's name, address, designation, and signature; the urgency of the request and, concomitantly, the delivery mode requested by the HCP for the response (*i.e.*, written, telephone, or in person); a detailed, written description of the request including the topic; and the name of the sales representative who received the request from the HCP. The MIRF is submitted by a sales representative to Medical Information.

For each unsolicited request received about a BMS product through the MIRF or 800 number, BMS has developed, and shall continue to maintain, a database (*e.g.*, TRECnet) that includes the following items of information: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, MIRF, phone); 3) name and signature of the requesting HCP; 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 indication for the product; 6) nature/form of the response from BMS (including a record of the materials provided in response to the request); and 7) the name of the sales representative who called on or interacted with the HCP, if applicable.

On a quarterly basis, BMS shall conduct a U.S. Pharmaceuticals Group sales representative-submitted off-label inquiry analysis (Off-Label Inquiry Analysis). In order to conduct its Off-Label Inquiry Analysis, Medical Information shall compile and conduct an initial analysis, by therapeutic area, and shall provide a quarterly report to the Chief Compliance Officer and General Counsel about Inquiries submitted to Medical Information about the respective BMS product(s). The quarterly report shall contain information for each therapeutic area and shall report requested information for each product in each therapeutic area. Each quarterly report for a BMS product shall identify the ten (10) sales representatives for each therapeutic area (*i.e.*, CV/Metabolics, Neuroscience, Virology, Oncology, ImmunoScience) with the largest number of requests for medical information.

The requests and resulting responses for the sales representatives appearing on the quarterly report as set forth above will be further analyzed and reviewed by the

Chief Compliance Officer and the General Counsel (or their designees) in consultation with Medical Information, to determine whether there are indicia of off-label promotion. If there is evidence of off-label promotion by a sales representative, the matter will be referred for a formal investigation in accordance with BMS's Policies and Procedures for the handling of investigations (Off-Label Review). As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Chief Compliance Officer shall disclose Reportable Events pursuant to Section III.H above, if applicable.

On at least a semi-annual basis, the Chief Compliance Officer shall review the Medical Information Department's Policies and Procedures relating to the handling of Inquiries concerning off-label uses of BMS's products and shall provide a report on the results of such review to the CIA Compliance Committee.

BMS shall maintain a record of the steps undertaken during each Off-Label Inquiry Analysis, including a general description of the records reviewed. As part of the Off-Label Review process, BMS shall maintain a record of the identities of individuals interviewed, the steps undertaken during the Review, and the records reviewed. The Annual Reports to the OIG shall include a summary of the Off-Label Inquiry Analyses conducted during the applicable Reporting Period. In addition, any findings made during any Off-Label Reviews and any corrective action taken shall be recorded in the files of the Compliance Department and summarized in the Annual Reports. BMS shall make its records relating to its Off-Label Inquiry Analyses and any Off-Label Reviews available to the OIG upon request.

M. Field Force Monitoring

The BMS Compliance Department has developed a Field Force Monitoring Program (FFMP) to evaluate and monitor US Pharmaceuticals Group sales representatives' interactions with HCPs. The FFMP is a formalized process designed to directly observe the appropriateness of sales representative interactions with HCPs and to identify potential off-label promotional activities. BMS compliance personnel conduct direct field observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with BMS compliance Policies and Procedures. These direct field observations are full day ride-alongs with sales representatives and are referred to as Compliance Monitor Observations (CMO). Each

CMO consists of directly observing all meetings between a sales representative and HCPs during the workday. The CMOs are scheduled throughout the year, are randomly selected by BMS compliance personnel, include each therapeutic area and actively promoted brand, and are conducted across the United States. At the completion of each CMO, BMS compliance personnel prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the BMS compliance professional;
- 3) the date and duration of the CMO;
- 4) the product(s) promoted during the CMO;
- 5) an overall assessment of compliance with BMS compliance policy; and
- 6) the identification of any potential off-label promotional activity by the sales representative.

BMS shall continue its FFMP during the term of this CIA. Specifically, BMS compliance personnel shall conduct at least thirty (30) full day CMOs during each Reporting Period. The number of inspections conducted for each therapeutic area and brand shall be proportional in number to the size of each therapeutic area and brand, and shall be conducted across the United States. BMS shall include a summary of FFMP and the results of the FFMP as part of each Annual Report.

In the event that a compliance issue, including potential off-label promotion, is identified during a CMO, BMS will investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Chief Compliance Officer shall disclose Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during a CMO and any corrective action shall be recorded in the files of the Compliance Department.

As part of each Annual Report, BMS shall provide the OIG with copies of the CMO report in any instances in which it was determined that improper promotion occurred and a description of the action(s) that BMS took as a result of such determinations. BMS shall make the CMO reports for all other CMOs available to the OIG upon request.

N. Independent Medical Education and Grants Review

BMS represents that the Group has in place and shall maintain Policies and Procedures relating to the sponsorship of Third Party Educational Activities, including IME activities, and to the use of grants or charitable contributions to support other third party activities, such as patient education or other health related activities. BMS further represents that the Policies and Procedures are designed to ensure that BMS support for these activities will comply with all applicable Federal health care program requirements (including the Federal anti-kickback statute) and FDA requirements (including the FDA's "Guidance on Industry Supported Scientific and Educational Activities"), and that BMS support of such activities will be transparent.

With regard to grants, the Policies and Procedures prohibit the use of grants as a price concession, reward to customers, or inducement to prescribe, recommend, or purchase pharmaceutical products. With regard to IME, the Policies and Procedures provide that IME must be objective, unbiased, balanced and scientifically rigorous and not subject to BMS influence or control. In addition, the Policies and Procedures prohibit the consideration and approval of grant requests from being conditioned in any way upon the prescribing, purchasing, or recommending of BMS's products.

The Policies and Procedures require that all requests for support for IME be made through an online application available through a grants website. All requests for support for IME are included in a database that captures and tracks all support for IME. The Policies and Procedures do not permit the involvement of sales representatives in the submission or consideration of grant requests, including grants to support IME. Rather, sales representatives are required to refer all inquiries concerning grant requests to a toll free number and/or the grants website. Representatives are specifically trained to acknowledge that they have no role in grant consideration or approval process. The determination to provide BMS support for an IME activity is determined solely by the Grants function in the Medical Affairs Department, with subsequent Law Department review. All support for IME requires a signed agreement with the provider of the IME.

BMS shall perform quarterly reviews to determine whether grants to support IME were approved and handled consistent with the Policies and Procedures. In order to conduct such review, BMS compliance personnel shall select a sample of ten grants each quarter and review documentation collected, tracked, and maintained with regard to approved IME grants. The sample shall be randomly selected and shall represent all

therapeutic areas. The review shall include an assessment of the processes and procedures used to approve the grant (including justification of the amount thereof) or sponsorship of the IME and shall include test steps to verify the following for each grant reviewed:

- a. that the agreement to fund the grant is in writing;
- b. that the grant is documented and that records of the grant are collected, tracked, and maintained;
- c. that the funding of the grant was made in accordance with the internal review and approval process set forth in the Policies and Procedures, including that necessary approvals were obtained and documented and that records were appropriately maintained;
- d. that consistent with its Policies and Procedures, BMS did not control the content, selection of speakers, presenters and/or moderators for the IME activity;
- e. that effective responses are being implemented when violations of Federal anti-kickback statute and/or FDA sponsorships requirements are discovered, including disciplinary action and reporting of the conduct (including disclosing Reportable Events pursuant to Section III.H above);
- f. that the Group does not track or monitor the prescribing habits or product use of entities in connection with their receipt of grants.

In addition, in connection with the quarterly review referenced above, compliance personnel shall review the IME process to insure that with respect to a sample of IME activities funded by the Group during the Reporting Period, BMS confirmed that the activities funded actually occurred and that the funds were used as stated or reflected in the grant application or request. The quarterly review referenced above and the review described in the preceding sentence shall be referred to hereafter collectively as the "IME Grants Review."

BMS shall maintain a record of each IME Grants Review, including a description of the process by which BMS conducted the IME Grants Review, a description of each grant reviewed, and a description of BMS' findings with regard to each grant reviewed. Each Annual Report shall include a description and summary of the IME Grants Review conducted during the applicable Reporting Period, BMS's findings with regard to each grant reviewed, and any corrective action taken. BMS shall make its records relating to its IME Grants Reviews available to the OIG upon request.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, BMS changes locations or sells, closes, purchases, or establishes a new business unit or location related to the Government Pricing and Contracting Functions, or to Promotional and Product Services Related Functions, BMS shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider or supplier number, and the name and address of any corresponding contractor that issued the number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 180 days after the Effective Date, BMS 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 Chief Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;
2. the names and positions of the members of the CIA Compliance Committee required by Section III.A;
3. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to BMS's letter;
4. to the extent not already provided to the OIG, a copy of all Policies and Procedures required by Section III.B.3;
5. 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);

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

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request;

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

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

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

10. a list of all of BMS'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 or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which BMS currently submits claims (if applicable); and

11. the certifications required by Section V.C.

B. Annual Reports. BMS shall submit to OIG annually a report with respect to the status of, and findings regarding, BMS'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 Chief Compliance Officer and any change in the membership of the CIA Compliance Committee described in Section III.A;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements) and copies of any compliance-related Policies and Procedures;
3. 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);
4. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each entity employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to BMS's letter;
5. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
 - b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
7. BMS's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

8. a summary and description of any and all current and prior engagements and agreements between BMS and the IRO, if different from what was submitted as part of the Implementation Report;
9. a certification from the IRO regarding its professional independence and objectivity with respect to BMS;
10. 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;
11. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;
12. any changes to the process by which BMS fulfills the requirements of Section III.F regarding Ineligible Persons;
13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by BMS in response to the screening and removal obligations set forth in Section III.F;
14. 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;
15. a summary describing any 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. all information required by Section III.J;
17. all information required by Sections III.L;
18. all information required by Section III.M;
19. all information required by Section III.N;

