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;

20. a description of all changes to the most recently provided list of BMS's locations (including addresses) as required by Section V.A.10; 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

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 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. The Implementation Report and Annual Reports shall include a certification by the Chief Compliance Officer that:

1. he or she has reviewed the CIA in its entirety, understands the requirements described therein, and maintains a copy of the CIA for reference;

2. to the best of his or her knowledge, except as otherwise described in the applicable report, BMS is in compliance with all of the requirements of this CIA;

3. 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;

4. BMS has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

5. BMS's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for the standardized contracts and other similar documents; and 3) training materials used for purposes of Section III.C, above have been reviewed by

competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws and legal requirements. In addition, BMS's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside BMS have been reviewed by competent legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed and elevated when required, and that the materials and information when finally approved are in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws and legal 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;

6. BMS's call plans for those Government Reimbursed Products subject to the requirements of Section III.B.3.f were reviewed by U.S. Healthcare Law Compliance at least once during the Reporting Period (consistent with the requirements of Section III.B.3.f) and, for each such Government Reimbursed Product, the call plans were found to be consistent with BMS's policy objectives as referenced above in Section III.B.3.f; and

7. Each Implementation Report and Annual report shall include the certification set forth as Appendix E.

D. Designation of Information. BMS 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. BMS 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

BMS: Chief Compliance Officer
Bristol-Myers Squibb Company
345 Park Avenue
New York, NY 10154-0037
Tel (212) 546-4000
Fax (212) 605-9449

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.

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

VIII. DOCUMENT AND RECORD RETENTION

BMS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or 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 BMS prior to any release by OIG of information submitted by BMS pursuant to its obligations under this CIA and identified upon submission by BMS as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, BMS shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

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

a. a Chief Compliance Officer;

b. a CIA Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements;

h. notification of Government investigations or legal proceedings;

i. notification of communications with FDA regarding off-label matters;

j. a review of records reflecting the content of detailing sessions;

k. a review of Inquiries handled by Medical Information as required by Section III.L;

l. the FFMP in accordance with Section III.M; and

m. the IME Grants Review in accordance with Section III.N.

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 BMS fails to engage an IRO, as required in Section III.D and Appendices A-C.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day BMS fails to submit the Implementation Report or the 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 BMS fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and

Appendices B-C.

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

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of BMS 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 BMS fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to BMS, stating the specific grounds for its determination that BMS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps BMS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after BMS 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. BMS 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 BMS 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 BMS 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 BMS 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 BMS of: (a) BMS'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, BMS 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 BMS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until BMS cures, to OIG's satisfaction, the alleged breach in dispute. (BMS shall not be required to pay Stipulated Penalties if the ALJ decides BMS was in full and timely compliance with the CIA.) 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 certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that BMS 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 failure by BMS to report a Reportable Event, and take corrective action, as required in Section III.H;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by BMS constitutes an independent basis for BMS's exclusion from participation in the Federal health care programs. Upon a determination by OIG that BMS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify BMS of: (a) BMS'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.* BMS 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. BMS 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) BMS has begun to take action to cure the material breach; (ii) BMS is pursuing such action with due diligence; and (iii) BMS has provided to OIG a reasonable timetable for curing the material breach.

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

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, BMS and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of BMS;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. The undersigned BMS 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; and

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 BRISTOL-MYERS SQUIBB COMPANY

Sandra Leung
Senior Vice President, General Counsel
and Secretary
Bristol-Myers Squibb Company

9/26/07
DATE

Stephen J. Immelt, Esq.
Mitchell Lazris, Esq.
Counsel for Bristol-Myers Squibb Company

9/25/07
DATE

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

9/26/97

Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

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.

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

If BMS engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Attachment. If a new IRO is engaged, BMS shall submit the information identified in Section V.A.7 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 BMS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, BMS may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

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

2. assign individuals to design and select the samples for the applicable 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 Government Pricing and Contracting Review and each Promotional and Product Services 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 Government Pricing and Contracting Review and Promotional and Product Services Review;

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

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

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

D. IRO Independence and Objectivity.

The IRO must perform each Government Pricing and Contracting Review and each Promotional and Product Services 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 BMS.

E. IRO Removal/Termination.

1. *Provider.* If BMS terminates its IRO during the course of the engagement, BMS must submit a notice explaining its reasons to OIG no later than 30 days after termination. BMS must engage a new IRO in accordance with Paragraph A of this Appendix.

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 BMS to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring BMS to engage a new IRO, OIG shall notify BMS 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, BMS may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. BMS shall

provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with BMS prior to requiring BMS to terminate the IRO. However, the final determination as to whether or not to require BMS to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B TO CIA

GOVERNMENT PRICING AND CONTRACTING REVIEW

I. Government Pricing and Contracting Review – General Description

As specified more fully below, BMS shall retain an Independent Review Organization (IRO) to perform reviews to assist BMS in assessing and evaluating its systems, processes, policies, procedures, and practices (including the controls on the systems, processes, policies, procedures, and practices) related to the requirements for (a) Average Manufacturer Price (AMP) and Best Price under the Medicaid Drug Rebate program and (b) Average Sales Price (ASP) under the Medicare Part B program. The IRO shall perform two types of engagements: 1) systems reviews of BMS's systems, processes, policies, and procedures relating to the calculation and reporting of AMP and Best Price and to the calculation and reporting of ASP for Government Reimbursed Products (collectively, the "Systems Review"); and 2) testing of a sample of transactions to assess whether BMS is calculating AMPs and ASPs for Government Reimbursed Products consistent with the policies, procedures, and methodologies developed by BMS in accordance with the requirements of the Medicaid Drug Rebate program and the Medicare Part B program, respectively (the "AMP/ASP Transactions Review"). The Systems Review and the AMP/ASP Transactions Review are referred to herein collectively as the "Government Pricing and Contracting Review."

As described more fully in Section II below, 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 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 ASP related systems, processes, policies, and procedures during the term of the CIA, the IRO shall perform an ASP Systems Review for the Reporting Period in which such changes were made in addition to conducting the ASP Systems Review for the second and fourth Reporting Periods. The IRO shall not be required to conduct an ASP Systems Review for the first Reporting Period.

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 a Medicaid Drug Pricing Systems Review for the third Reporting Period. If BMS materially changes its Medicaid Drug Pricing related systems, processes, policies, and procedures, the IRO shall perform a Medicaid Drug Pricing Systems Review for the Reporting Period in which such changes were made in addition to conducting the Medicaid Drug Pricing Systems Review for the third Reporting Period. The IRO shall

not be required to conduct a Medicaid Drug Pricing Systems Review for the first Reporting Period.

The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether the systems, processes, policies, and procedures already reported on did not materially change; and 3) an update on the systems, processes, policies, and procedures that materially changed.

The AMP/ASP Transactions Review, described more fully in Section III, shall be designed to test whether BMS is calculating AMPs and ASPs consistent with BMS's policies, procedures, and methodologies. The AMP/ASP Transactions Review shall consist of two parts, the "ASP Reported Prices Procedures" and the "AMP Reported Prices Procedures." The IRO shall conduct the AMP/ASP Transactions Review annually.

II. ASP and Medicaid Drug Pricing Systems Reviews

A. ASP Systems Review

The IRO shall review BMS's systems, processes, policies, and procedures (including the controls on the systems, processes, policies, and procedures) associated with the tracking, gathering, and accounting for all relevant data for purposes of calculating ASP as reported to the Centers for Medicare and Medicaid Services (CMS) for Government Reimbursed Products. Where practical, BMS 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 BMS pursuant to the preceding sentence. More specifically, the IRO shall review the following:

a) The systems, processes, policies, and procedures used to determine which BMS customers are included or excluded for purposes of calculating ASP;

b) The systems, processes, policies, and procedures used to determine whether and which particular transactions (e.g., discounts, rebates) are included in or excluded from ASP calculations;

c) A review of BMS's methodology for applying transactions to the ASP calculations;

d) The flow of data and information by which price, contract terms, and transactions with BMS's customers are accumulated from source

systems and entered and tracked in BMS's information systems for purposes of calculating ASP;

e) A review of BMS's inquiries to CMS regarding ASP calculations and reporting requirements, including requests for interpretation or guidance, and any responses to those inquiries; and

f) The controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, or outliers). This shall include a review of the bases upon which variations, exceptions, and outliers are identified and the follow-up activities undertaken to identify the cause of any variations.

B. Medicaid Drug Pricing Systems Review

The IRO shall review BMS's systems, processes, policies, and procedures (including the controls on the systems, processes, policies, and procedures) associated with the tracking, gathering, and accounting for all relevant data for purposes of calculating and reporting AMP and Best Price to CMS for Government Reimbursed Products. Where practical, BMS 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 BMS pursuant to the preceding sentence. More specifically, the IRO shall review the following:

a) The systems, processes, policies, and procedures used to determine which BMS customers are included or excluded for purposes of calculating AMP and Best Price;

b) The systems, policies, processes, and procedures used to determine whether and which particular transactions (e.g., discounts, rebates) are included in or excluded from AMP and Best Price determinations;

c) A review of BMS's methodology for applying transactions to the AMP and Best Price determinations;

d) The flow of data and information by which price, contract terms, and transactions with BMS customers are accumulated from the source systems and entered and tracked in BMS's information systems for purposes of determining AMP and Best Price;

e) A review of any BMS inquiries to CMS regarding AMP and Best Price determinations and reporting requirements, including requests for interpretation or guidance, and any responses to those inquiries; and

f) The controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, or outliers). This shall include a review of the bases upon which variations, exceptions, and outliers are identified and the follow-up activities undertaken to identify the cause of any variations.

C. Report for ASP Systems Review

For each Reporting Period for which an ASP Systems Review is performed hereunder, the IRO shall prepare a report based upon the Systems Review. This report may be (but is not required to be) combined with the report for the AMP/ASP Transactions Review described in Section III below, and shall include the following:

1. A description of the systems, processes, policies, and procedures in place to track, gather, and account for price terms, contract terms, and transactions with BMS customers that are relevant to the calculation and reporting of ASP including, but not limited to:

   a) The computer or other relevant systems (including the source systems and any other information systems, as applicable) used to track data for and to calculate and report ASP;

   b) The information input into BMS's relevant computer or other systems used to calculate ASP;

   c) The system logic or decisional rationale used to determine which customers are included or excluded for purposes of calculating ASP;

   d) The system logic or decisional rationale used to determine whether contract terms, discounts, rebates and all other relevant transactions with BMS customers are included or excluded when calculating ASP; and

   e) BMS's policies and procedures in examining system reports for variations that require critical evaluation, including the basis on which variations, exceptions, or outliers are identified, and the follow up actions taken in response.

2. A description of the documentation, information, and systems reviewed, and the personnel interviewed, if any, including a description of the following:

   a) BMS's inquiries to CMS regarding the calculation of ASP and any responses to those inquiries;

   b) BMS's systems and practices for reporting ASP to CMS as required by the Medicare Part B program; and

   c) BMS's systems and practices for reporting any adjustments to ASP or additional information related to the ASP submissions.

3. Observations, findings, and recommendations for any improvements to BMS's ASP related systems, processes, policies, and procedures, including any changes recommended in order to improve compliance with the requirements of the Medicare Part B program.

D. Report for Medicaid Drug Pricing Systems Review

For each Reporting Period for which Medicaid Drug Pricing Systems Review is performed hereunder, the IRO shall prepare a report based upon the Systems Review. This report may be (but is not required to be) combined with the report for the AMP/ASP Transactions Review described in Section III below, and shall include the following:

1. A description of the systems, processes, policies, and procedures in place to track, gather, and account for price terms, contract terms, and transactions with BMS customers that are relevant to the calculation and reporting of AMP or Best Price, including, but not limited to:

   a) The computer or other relevant systems (including the source systems and any other information systems, as applicable) used to track data for and to calculate and report AMP and Best Price;

   b) The information input into BMS's relevant computer or other systems used to calculate AMP and Best Price;

   c) The system logic or decisional rationale used to determine which customers are included or excluded for purposes of calculating AMP and Best Price;

d) The system logic or decisional rationale used to determine whether contract terms, discounts, rebates and all other relevant transactions with BMS customers are included or excluded when calculating AMP and Best Price; and

e) BMS's policies and procedures in examining system reports for variations that require critical evaluation, including the basis on which variations, exceptions, or outliers are identified, and the follow up actions taken in response.

2. A description of the documentation, information, and systems reviewed, and the personnel interviewed, if any, including a description of the following:

a) BMS's inquiries to CMS regarding the calculation of AMP and Best Price and any responses to those inquiries;

b) BMS systems and practices for reporting AMP and Best Price to CMS as required by the Medicaid Drug Rebate program; and

c) BMS's systems and practices for reporting any adjustments to AMP or Best Price or additional information relating to the submissions.

3. Observations, findings, and recommendations for any improvements to BMS's systems, processes, policies, and procedures, including any changes recommended in order to improve compliance with the requirements of the Medicaid Drug Rebate program.

III. AMP/ASP Transactions Review

A. General Description and Definitions

For each Reporting Period, the IRO shall select and review a sample of transactions from a randomly selected quarter to test whether BMS calculated and reported AMP and ASP for Government Reimbursed Products consistent with the policies, procedures, and methodologies developed by BMS in accordance with Medicaid Drug Rebate Program and Medicare program requirements, respectively. At the end of each Reporting Period, the IRO shall randomly select the quarter to be reviewed for purposes of the AMP/ASP Transactions Review. The selected quarter shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RATS-STATS" or through the use of another method of random sampling acceptable to the OIG.

For purposes of the AMP/ASP Transactions Review, the following definitions shall apply:

1. "Actual Transaction Types" are defined are defined as those transactions that are finalized at the time of the sale. As of the Effective Date, BMS had two categories of Actual Transaction Types, namely direct sales and actual discounts. Each of these categories shall be considered a universe of Actual Transaction Types from which the IRO shall draw samples as detailed below in Section III.B.1 and III.C.1. If during the term of the CIA BMS establishes additional categories of Actual Transaction Types, each of the new categories shall be considered an additional universe of transactions from which samples of Actual Transaction Types shall be selected for purposes of the AMP Reported Prices Procedures and the ASP Reported Prices Procedures. Each Transaction within the Actual Transaction Types group shall be referred to as a "Actual Transaction."

2. "Smoothed Transaction Types" are defined as those transaction types that are available on a lagged basis. As of the Effective Date, BMS had two categories of Smoothed Transaction Types, namely indirect sales and adjustments or discounts available on a lagged basis. Each of these categories shall be considered a universe of Smoothed Transaction Types from which the IRO shall draw samples as detailed below in Sections III.B.1 and III.C.1. If during the term of the CIA BMS establishes additional categories of Smoothed Transaction Types, each of those new categories shall be considered an additional universe of transactions from which samples of Smoothed Transaction Types shall be selected for purposes of the AMP Reported Prices Procedures and the ASP Reported Prices Procedures. Each Transaction within the Smoothed Transaction Types group shall be referred to as a "Smoothed Transaction."

The Actual Transaction Types and Smoothed Transaction Types shall be referred to hereafter as "Transaction Types".

B. AMP Reported Prices Procedures

1. Grouping and Testing of Transaction Types.

For each Reporting Period, the IRO shall review a sample of transactions to test whether BMS calculated and reported AMP for Government Reimbursed Products in accordance with its policies, procedures, and methodologies (AMP Reported Prices Procedures). The IRO shall conduct its AMP Reported Prices Procedures by selecting and testing samples from

each universe of the applicable Transaction Types, as grouped by BMS, for the selected quarter of the Reporting Period.

a) Actual Transactions

For each universe of Actual Transaction Types, the IRO shall select a probe sample and shall test for the following attributes:

i) Whether the Actual Transactions are supported by source documents; and

ii) Whether BMS included or excluded each Actual Transaction in the AMP calculation in accordance with its policies, procedures, and methodologies.

b) Smoothed Transactions

For each universe of Smoothed Transaction Types, the IRO shall select a probe sample and shall test for the following attributes:

i) Whether the Smoothed Transaction amounts were calculated in accordance with BMS's policies, procedures, and methodologies, and were supported by relevant commercial arrangements or other source documentation; and

ii) Whether the Smoothed Transactions were included in or excluded from the AMP calculation in accordance with BMS's policies, procedures, and methodologies.

2. Additional Investigation of Transactions

The IRO shall test a probe sample of 30 Transactions from each universe of Transactions Types for the selected quarter. If the IRO finds a net dollar error rate of 5% or more of the total sample size in any probe sample, BMS and the IRO shall hold an interim conference with the OIG to discuss the IRO's preliminary findings. The IRO shall present its findings, BMS shall present its management response, and the OIG shall review and consider the information provided by the IRO and BMS. In its discretion, and following consultations with BMS and the IRO, the OIG shall determine whether an Additional Investigation shall be required. For any required Additional Investigation, the IRO shall review additional documentation and/or conduct additional interviews with appropriate personnel as

necessary to identify the root cause of the net dollar error rate of 5% or more.

Upon completion of the probe reviews and any Additional Investigation, for each universe of Transaction Types, the IRO shall report to the OIG its final findings, if any, for these probe samples.

In its discretion, the OIG will determine and notify BMS (based on discussions with the IRO and BMS, the results of the probe reviews, and findings based on any Additional Investigation) whether the testing of a statistically valid random sample of additional Transactions from the applicable universe shall be required. After consultation with the IRO and BMS, the OIG will, in its discretion, determine the size of the statistically valid random sample.

The probe samples shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RATS-STATS" or through the use of another method of random sampling acceptable to the OIG.

C. ASP Reported Prices Procedures

1. Grouping and Testing of Transactions Types

For each Reporting Period, the IRO shall review a sample of transactions to test whether BMS calculated and reported ASPs for Government Reimbursed Products in accordance with its policies, procedures, and methodologies (ASP Reported Prices Procedures). The IRO shall conduct its ASP Reported Prices Procedures by selecting and testing samples from each universe of the applicable Transaction Types, as grouped by BMS, for the selected quarter of the Reporting Period.

a) Actual Transactions

For each universe of Actual Transaction Types, the IRO shall select a probe sample and shall test for the following attributes:

i) Whether the Actual Transactions are supported by source documentation; and

ii) Whether BMS included or excluded each Actual Transaction in the ASP calculation in accordance with its policies, procedures, and methodologies.

b) Smoothed Transactions

For each universe of Smoothed Transaction Types, the IRO shall select a probe sample and shall test for the following attributes:

i) Whether the Smoothed Transaction amounts were calculated in accordance with BMS's policies, procedures, and methodologies, and were supported by relevant commercial arrangements or other source documentation; and

ii) Whether the Smoothed Transactions were included in or excluded from the ASP calculation in accordance with BMS's policies, procedures, and methodologies.

2. Additional Investigation of Transactions

The IRO shall test a probe sample of 30 Transactions from each universe of Transactions Types for the selected quarter. In the event the IRO finds a net dollar error rate of 5% or more of the total sample size in any probe sample, BMS and the IRO shall hold an interim conference with the OIG to discuss the IRO's preliminary findings. The IRO shall present its findings, BMS shall present its management response, and the OIG shall review and consider the information provided by the IRO and BMS. In its discretion, and following consultations with BMS and the IRO, the OIG shall determine whether an Additional Investigation shall be required. For any required Additional Investigation, the IRO shall review additional documentation and/or conduct additional interviews with appropriate personnel as necessary to identify the root cause of the net dollar error rate of 5% or more.

Upon completion of the probe reviews and any Additional Investigation, for each universe of Transaction Types, the IRO shall report to the OIG its final findings, if any, for these probe samples.

In its discretion, the OIG will determine and notify BMS (based on discussions with the IRO and BMS, the results of the probe reviews, and findings based on any Additional Investigation) whether the testing of a statistically valid random sample of additional Transactions from the applicable universe shall be required. After consultation with the IRO and BMS, the OIG will, in its discretion, determine the size of the statistically valid random sample.

The probe samples shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RATS-STATS" or through the use of another method of random sampling acceptable to the OIG.

D. AMP/ASP Transactions Review Report

1. General Requirements

The IRO shall prepare a report annually based upon each ASP/AMP Transactions Review performed. The report shall contain the following general elements pertaining to both the AMP Reported Prices Procedures and the ASP Reported Prices Procedures:

a) Testing Objective – a clear statement of the objective(s) intended to be achieved by each engagement;

b) Testing Protocol – a detailed narrative description of (i) the procedures performed; (ii) the sampling units; and (iii) the universe from which the sample was selected; and

c) Sources of Data – a full description of documentation and/or other relevant information relied upon by the IRO when performing the testing.

The IRO shall also include the following information in each ASP/AMP Transactions Review Report:

2. AMP Reported Prices Procedures

a) For each universe of Transaction Types tested, the IRO shall state its findings and supporting evidence as to whether the Transaction Types tested satisfied the corresponding testing criteria outlined above in Section III.B.1;

b) For each universe of Transaction Types tested, the IRO shall state the net dollar error rate discovered;

c) For each universe of Transaction Types for which the OIG determined that an Additional Investigation was required, the IRO shall state its findings and supporting evidence;

d) For each universe of Transaction Types for which the IRO conducted testing on a full statistically valid sample, the IRO shall state its findings and supporting evidence; and

e) The IRO shall report any recommendations for changes to BMS's policies, procedures, and/or methodologies to correct or address any weaknesses or deficiencies uncovered during the AMP Reported Prices Procedures.

3. ASP Reported Prices Procedures

a) For each universe of Transaction Types tested, the IRO shall state its findings and supporting evidence as to whether the Transaction Types tested satisfied the corresponding testing criteria outlined above in Section III.C.1;

b) For each universe of Transaction Type tested, the IRO shall state the net dollar error rate discovered;

c) For each universe of Transaction Type(s) for which the OIG determined that an Additional Investigation was required, the IRO shall state its findings and supporting evidence;

d) For each universe of Transaction Type(s) for which the IRO conducted testing on a full statistically valid sample, the IRO shall state its findings and supporting evidence; and

e) The IRO shall report any recommendations for changes to BMS's policies, procedures, and/or methodologies to correct or address any weaknesses or deficiencies uncovered during the ASP Reported Prices Procedures.

Appendix C to CIA for Bristol-Myers Squibb Company
Promotional and Product Services Review

I. Promotional and Product Services Review, General Description

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

If there are no material changes in BMS's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If BMS materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services 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 Promotional and Product Services Transactions Review for each Reporting Period of the CIA.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of BMS's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Promotional and Product Services Related Functions. Where practical, BMS 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 BMS pursuant to the preceding sentence.

Specifically, the IRO shall review BMS's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions associated with the following (hereafter "Reviewed Policies and Procedures"):

1) BMS's systems, policies, processes, and procedures applicable to the manner in which BMS representatives (including sales representatives and/or Medical Science Liaisons (MSLs)) handle requests or inquiries relating to information about non-FDA-approved (*i.e.,* off-label) uses of BMS products and the dissemination of materials relating to off-label uses of products. This review includes:

a) the manner in which sales representatives and/or the Medical Information Department receive and respond to requests for information about off-label uses;
b) the form and content of information disseminated by Medical Information;
c) BMS's internal review process for the information disseminated by Medical Information;
d) BMS's systems, processes, and procedures (including its TRECnet Database) to track requests for information about off-label uses of products and responses to those requests;
e) the manner in which BMS collects and supports information reported in its TRECnet database;
f) the processes and procedures by which the Chief Compliance Officer (and other appropriate individuals within BMS) identify situations in which it appears that improper off-label promotion may have occurred; and
g) BMS's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion;

2) BMS's policies and procedures applicable to the manner and circumstances under which Medical Information personnel (including MSLs) participate in meetings or events with physicians, pharmacists, or other health care professionals (collectively "HCPs")

(either alone or with sales representatives) and the role of the Medical Information personnel at such meetings or events;

3) BMS's systems, policies, processes, and procedures relating to the retention of HCPs as consultants (*e.g.,* as members of advisory boards or focus groups, or as speakers.) This shall include a review of:

a) the criteria used to determine whether, how many, and under what circumstances (including the venue for the performance of any services) BMS will enter such consultant arrangements and the business rationale for entering such arrangements;

b) the processes and criteria used to identify and select HCPs with whom BMS enters consultant arrangements, including the role played by sales representatives in the process (if any). This includes a review of BMS's internal review and approval process for such arrangements, and the circumstances under which there may be exceptions to the process;

c) BMS's tracking or monitoring of the services provided or the work performed by consultants (including the receipt of the consultants' work product, if any);

d) BMS's policies and procedures related to circumstances, if any, under which the HCP or the HCP's agent is required to disclose the existence of the consultant arrangement in place between BMS and the HCP;

e) the uses made of work product received from consultants, if any;

f) BMS's processes for establishing the amounts paid to HCPs who are consultants and the reasons or justifications for any differentials in the amounts paid to different HCPs;

g) the criteria used to determine under what circumstances entertainment, travel, lodging, meals, and/or other items or reimbursements are provided to consultants, and BMS's processes for establishing the amounts paid or reimbursed for such items;

h) whether and in what manner BMS tracks or monitors the prescribing habits or product use of individuals or entities with whom it enters consultant arrangements, if any; and

i) the budget funding source within BMS (*e.g.*, department or division) for the consultant arrangements;

4) BMS's systems, policies, processes, and procedures relating to BMS's internal review and approval of promotional materials disseminated by BMS;

5) BMS's systems, policies, processes, and procedures for tracking expenditures (individual and aggregate) associated with the Reviewed Policies and Procedures referenced in Section II.A.3, above;

6) BMS's policies, processes, and procedures relating to disciplinary actions that BMS may undertake in the event a Covered Person violates a BMS policy or procedure relating to Promotional and Product Services Related Functions;

7) BMS's systems, policies, processes and procedures relating to incentive compensation for 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 BMS's 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; and

8) BMS's systems, processes, policies, and procedures relating to the development and review of call plans for BMS's sales forces. This shall include a review of the basis upon which specified medical specialties are included in, or excluded from, the call plans based on their expected utilization of the BMS products for FDA-approved uses or non-FDA-approved uses.

B. Promotional and Product Services 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 BMS's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-8 above, including a general description of BMS'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 BMS;

4) a detailed description of any system used to track and respond to requests for information about BMS's products received by Medical Information;

5) a description of BMS's systems, policies, processes, and procedures for tracking any expenditures associated with the Reviewed Policies and Procedures referenced in Section II.A.3, above;

6) a general description of BMS's disciplinary measures applicable for a failure to comply with its policies and procedures relating to Promotional and Product Services Related Functions;

7) a detailed description of BMS's incentive compensation system for 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 BMS may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

8) findings and supporting rationale regarding any weaknesses in BMS's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

9) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

Prior to the IRO's submission of the report to the OIG, BMS shall be provided with a copy of the report and an opportunity to respond to each comment made by the IRO. Provided it does not delay the timely filing of the Annual Reports, any responses by BMS may be included in the IRO report submitted to the OIG. Otherwise, any responses by BMS to the IRO's findings may be submitted separately to the OIG following the Annual Report submission.

III. Promotional and Product Services Transaction Review

The Compliance Department annually conducts audits relating to activities and work of the U.S. Pharmaceuticals Group. For example, the Compliance Department has conducted audits of promotional programs and consultant programs conducted in certain therapeutic areas, and it has conducted audits of BMS's grants process. BMS expects to continue such audits on a calendar year basis during the term of the CIA. At its option, BMS may provide a detailed description of its planned annual audits to the OIG 60 days prior to the beginning of each new calendar year. BMS may propose to the OIG that its planned internal audits be substituted for a portion of the Promotional and Product Services Transactions Review outlined below in this Section III for the applicable Reporting Period.

If the OIG agrees to permit certain of BMS's internal audit work for a given Reporting Period to be substituted for a portion of the Promotional and Product Services Transaction 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 of at least 20% of the sampling units reviewed by BMS in its internal audits.

The OIG retains sole discretion over whether to allow BMS's internal audit work to be substituted for a portion of the Promotional and Product Services Transactions Review. In making its decision, the OIG agrees to consider, among other factors, the nature and scope of BMS's planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and BMS's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies BMS's request to permit BMS's internal audit work to be substituted for a portion of the Promotional and Product Services Review in a given Reporting Period, BMS shall engage the IRO to perform the Review as outlined below in this Section III.

A. Promotional and Product Services Transactions Review

1) Background on Policies and BMS Activities

BMS has developed policies and procedures relating to programs with HCPs that may be initiated by the Group's sales representatives and/or home office personnel. These programs include the following, which shall be collectively referred to hereafter as the "Reviewed Activities":

a) In-office and out-of-office informational programs initiated by sales representatives (including meals associated with the programs);
b) Speaker programs;
c) Speaker training programs;
d) Consultant arrangements other than the retention of HCPs as speakers (*e.g.,* for advisory boards*)*;
e) The provision of gifts to HCPs; and
f) Promotional activities involving exhibits, displays, and medical congresses.

2) Description of Reviewed Activities Control Documents and Selection of Samples for Review

Reviewed Activities Control Documents shall include all documents or electronic records (collectively "documents") associated with each set of Reviewed Activities. These documents include, but are not limited to, all documents submitted by sales representatives or headquarters personnel to request approval for the Reviewed Activity; business rationale or justification forms; written contracts relating to the Reviewed Activity; all documents relating to the occurrence of the Reviewed Activity (*e.g.,* attendance rosters, receipts); and all documents reflecting any work product generated in connection with the Reviewed Activity.

For each Reporting Period, the OIG, in its discretion, shall select three of the Reviewed Activities listed above in Section III.A.1 to be reviewed for purposes of the Transactions Review. The OIG shall make its selection at the conclusion of the Reporting Period after consultation with BMS. After making its selection, the OIG shall notify BMS about which three Reviewed Activities shall be reviewed as part of the Transactions Review. In turn, the IRO shall review all Control Documents associated with 30 randomly selected occurrences of each selected type of Reviewed Activities. (For example, if the OIG selected Speaker Programs, Consultant Arrangements, and Gifts as the three Reviewed Activities for a

particular Reporting Period, the IRO would randomly select 30 Speaker Programs, 30 Consultant Arrangements, and 30 Gifts and would review all Control Documents associated with each of the selected Programs, Arrangements, and Gifts.)

3) IRO Review of Selected Control Documents

For each sample of Reviewed Activities, the IRO shall review the Control Documents associated with each selected sample to evaluate the following:

a) Whether all required Control Documents exist in appropriate files in accordance with BMS's policies;

b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in BMS's policies; and

c) Whether the Control Documents reflect that BMS's policies were followed in connection with the underlying activities (*e.g.*, all required written approvals for the activity were obtained in accordance with BMS's policies.)

4) Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

a) All required Control Documents relating to a Reviewed Activity do not exist and:
   i. no corrective action was initiated prior to the selection of the Reviewed Activities by the OIG; or
   ii. the IRO cannot confirm that BMS otherwise followed its policies and procedures relating to the Reviewed Activity.

b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with BMS'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 BMS has initiated corrective action prior to the selection of the Reviewed Activities by the OIG, or if a Control Document does not exist but the IRO can determine that BMS

otherwise followed its policies and procedures with regard to the Reviewed Activity, 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 Reviewed Activities 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.

B. IRO Review of BMS's Call Plan Assessments

The IRO shall conduct a review and assessment of BMS's review of its call plans 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 health care institutions (HCIs) as set forth in Section III.B.3.f of the CIA. Such products shall be referred to hereafter as "High Risk Products". BMS shall provide the IRO with: i) a list of the High Risk Products promoted by BMS during the Reporting Period and a description of how BMS identified the High Risk Products as such; ii) information about the FDA-approved uses for such products; and iii) the call plans for each High Risk Product. BMS shall also provide the IRO with information about the reviews of call plans for the High Risk Products that BMS conducted during the Reporting Period and any modifications to the call plans made as a result of BMS's reviews.

For each call plan, the IRO shall select a sample of 30 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 BMS in conducting its review and/or modification of the call plan in order to determine whether BMS followed its policy as outlined in Section III.B.3.f of the CIA in reviewing and/or 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 BMS's policy as outlined in Section III.B.3.f of the CIA. The IRO shall also note any instances in which it appears that BMS failed to follow its policy as outlined in Section III.B.3.f of the CIA.

C. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services 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 Promotional and Product Services Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Promotional and Product Services Review Report:

a) a description of each type of sample unit reviewed for each Reviewed Activity, including the number of each type of sample units reviewed (*e.g.,* Control Documents associated with each of the various types of Reviewed Activities) and an identification of the types of Control Documents reviewed for each type of sample unit;

b) for each sample unit, 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 BMS policy; (iii) each Control Document reflects that BMS's policies were followed in connection with the underlying activity reflected in the document (*e.g.*, all required approvals were obtained); and (iv) any disciplinary action was undertaken in those instances in which BMS policies were not followed;

c) for each sample 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 IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action;

d) if any Material Errors are discovered in the 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;

e) a list of the High Risk Products promoted by BMS during the Reporting Period, a description of how BMS identified the High Risk Product as such, and a summary of the FDA-approved uses for such products;

f) for each High Risk Product, i) a description of the criteria used by BMS for including or excluding specified types of HCPs or HCIs from the call plans for such product; ii) a description of the review conducted by BMS of the call plans and an indication of whether BMS reviewed the call plans as required by Section III.B.3.f; iii) a description of any instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with BMS's policy as outlined in Section III.B.3.f of the CIA; and iv) a description of any instances in which it appears that BMS failed to follow its policy as outlined in Section III.B.3.f of the CIA; and

g) recommendations, if any, for changes in BMS's systems, processes, policies, and procedures to correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to either Reviewed Activities or call plans. The report shall include findings and supporting rationale for all such recommendations.

APPENDIX D

DESCRIPTION OF ASP AND AMP COVERED PRODUCTS

The products described in this Appendix D are the "ASP Covered Products" and the "AMP Covered Products" for purposes of the requirements of Section III.K of the CIA and Appendix B thereto.

"ASP Covered Products" are all BMS products for which BMS reports an Average Sales Price (ASP) for Medicare Part B covered drugs to the Centers for Medicare & Medicaid Services (CMS) pursuant to 42 U.S.C. § 1395w-3a and other applicable requirements of the Medicare Part B program.

"AMP Covered Products" are all Medicaid "covered outpatient drugs" as defined in 42 U.S.C. § 1396r-8 (k)(2), (k)(3) and (k)(4); that is, all BMS products for which BMS reports an Average Manufacturer Price (AMP) to CMS pursuant to the requirements of the Medicaid Drug Rebate program.

Appendix E to CIA for Bristol-Myers Squibb Company

Certification

In accordance with the Corporate Integrity Agreement (CIA) entered between BMS and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information, and belief:

1) BMS has in place policies and procedures describing in all material respects the methods for performing Government Pricing and Contracting Functions (as defined in Section II.C.4 of the CIA) (hereafter "Government Price Reporting Policies and Procedures");

2) the Government Price Reporting Policies and Procedures have been designed to ensure compliance with BMS' price reporting obligations under the Medicare Part B Program and the Medicaid Drug Rebate Program;

3) BMS' Government Price Reporting Policies and Procedures were followed in all material respects in connection with the calculation of Average Manufacturer Prices (AMPs) for BMS's AMP Covered Products (as defined in Appendix D of the CIA) and in connection with the calculation of Average Sales Prices (ASPs) for BMS's ASP Covered Products (as defined in Appendix D) for: [specifically identify the applicable quarters];

4) The ASPs and AMPs that were reported for the ASP Covered Products and the AMP Covered Products in accordance with Section III.K of the CIA were the same ASPs and AMPs that were reported to the Centers for Medicare and Medicaid Services for purposes of the Medicare Part B Program and the Medicaid Drug Rebate Program, respectively;

5) In accordance with Section III.K of the CIA, the ASPs for the ASP Covered Products for the quarters specified above were: 1) calculated in accordance with the definitions and requirements of the Medicare Program, and 2) reported to the Medicaid Programs of those States that entered into a Related State Settlement Agreement with BMS and to any commercial drug price reporting service(s) as required by Section III.K.2.c of the CIA;

6) In accordance with Section III.K of the CIA, the AMPs and prior-quarter AMP adjustments for the AMP Covered Products for the quarters specified above were: 1) calculated in accordance with definitions and requirements of the Medicaid Program; and 2) reported to the Medicaid Programs of those States that entered into a Related State

Settlement Agreement with BMS and to any commercial drug price reporting service(s) as required by Section III.K.2.c of the CIA;

7) I hereby certify that the statements made in connection with the submission of ASPs and AMPs and in this Certification are true, complete, and current and are made in good faith. I understand that the ASPs and AMPs reported or made available to the State Medicaid programs of those States that executed Related State Settlement Agreements with BMS may be used in the administration of the Medicaid programs of those States and/or may be used by those States for Medicaid reimbursement purposes.

_____

Signature

_____

Name of CEO, CFO, or Authorizing Official
(as defined in 42 C.F.R. § 414.804(a)(6))

_____

Date