

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

