

2018 Annual Description of Comprehensive Compliance Program Pursuant to California Health and Safety Codes §§ 119400-119402

A. Introduction

On or before April 1, 2018, and in compliance with the annual declaration requirement under California Health and Safety Code §§119400 - 119402, Bristol-Myers Squibb Company (BMS) made its 2018 declaration for the twelve (12) month period covering January 1, 2017 through December 31, 2017.

As part of the Bristol-Myers Squibb Company Mission and Commitment, we have committed, "...to act on our belief that the priceless ingredient of every product is the integrity of its maker." BMS recognizes that compliance is central to good business practices, and that with the support of senior management, BMS employees at all levels should play an active role in the company's compliance activities. BMS has a strong commitment to establishing and maintaining an effective compliance program that promotes ethical business conduct. To help put this commitment into action, the company has established a comprehensive compliance program (CCP) structured around the seven elements outlined in the April 2003 "*Compliance Program Guidance for Pharmaceutical Manufacturers*," published by the United States Department of Health and Human Services, Office of Inspector General (OIG Guidance).

BMS's CCP is designed to prevent and detect violations of law or company policy. It is BMS's policy that all employees must comply with applicable laws and regulations, as well as with company policies. However, as acknowledged by the OIG Guidance, implementing a CCP cannot guarantee that improper employee conduct will be eliminated in its entirety. If BMS becomes aware of violations of law or company policy, the matter will be investigated and, if appropriate, disciplinary action will be taken and corrective measures will be implemented to prevent future violations.

Below is an overview of BMS's CCP. As described by the OIG Guidance, this program was designed to fit BMS's unique compliance needs. BMS continuously assesses the effectiveness of its CCP to enable it to implement necessary adjustments or refinements.

B. Overview of CCP

1. Leadership and Structure

a. **Compliance Officer** – BMS has a Chief Compliance and Ethics Officer who can exercise independent judgment and effectuate change within the company. The Chief Compliance and Ethics Officer has overall responsibility for the BMS Compliance and Ethics department and the compliance program at BMS. The Chief Compliance and Ethics Officer provides regular reports to the Audit Committee of the BMS Board of Directors, and to BMS senior management, on the status of the compliance program.

b. **Compliance Committees** – BMS has established local Compliance Committees, co-chaired by the local President / General Manager and the local Compliance Officer, in every market in which BMS does business directly, including the U.S. The mission of these committees is to: (1) continuously assess and improve in-market execution of the BMS

compliance program, based on identified risks and opportunities; (2) ensure a culture of compliance; and (3) align on compliance program accountabilities and resourcing. The leaders of all business and key support functions in each market sit on the local Compliance Committee, including in the U.S.

2. Written Standards

The BMS CCP includes a system of Corporate Policies that set forth the Company's highest level principles, to ensure compliance with applicable laws and regulations, and support good business practices. The Company's most important Corporate Policies are included in the BMS Principles of Integrity ("Principles") and in the US Pharmaceuticals Compliance Policy Portal and companion mobile application. The Principles and the Policy Portal/Policy Application require BMS employees to obey all laws, act in an ethical manner and make business decisions that are consistent with BMS policy guidance.

The OIG Guidance addresses several areas of potential risk for pharmaceutical manufacturers and suggests that companies develop compliance policies in these areas: data integrity pertaining to government reimbursement practices; kickbacks or other illegal remuneration; and distribution of drug samples. BMS has implemented written standards addressing each of these areas.

In addition, with respect to business activity in California, BMS has established "a specific annual dollar limit on gifts, promotional materials, or items or activities that [BMS] may give or otherwise provide to an individual medical or healthcare professional." This annual dollar limit is \$2,500 and primarily reflects dollars expended in association with programs designed to inform prescribing medical and other healthcare professionals about BMS products and the disease states these products help treat. BMS will evaluate this limit on an annual basis and make any necessary adjustments consistent with any operational or practical issues related to compliance with the statute. It is important to note that this annual dollar limit is an *upper limit*. It is not a representation of the *average* value of promotional materials, educational items or activities that BMS, a global biopharmaceutical company with many different divisions, medicines, and sales forces, may provide annually to a typical individual medical or healthcare professional. That *average* value would be a lower amount. Beginning in January 2009, and in line with the Pharmaceutical Research and Manufacturers of America (*PhRMA*) "Code on Interactions with Healthcare Professionals", BMS no longer distributed non-educational items, such as pens, mugs and other "reminder" items to healthcare professionals.

Based upon historical data, BMS anticipates very few medical or healthcare professionals will approach or reach the annual upper limit. BMS has created systems to support compliance with the specific annual dollar spending limit requirement of the CCP, and has monitored promotional spend to the extent of limiting dollars expended on individual healthcare professionals in association with their attendance at promotional programs. (BMS uses good faith estimates of such spending with respect to certain types of expenditures and certain classes of recipients.) BMS does not define "promotional materials" to include documents that are used to educate and inform healthcare professionals about its products. BMS continues to take measures to enhance its ability to track and monitor all expenditures involving healthcare professionals and continues to fully

endorse the *PhRMA* Code and abide by its recommendations.

3. Education and Training

Educating and training our employees on their ethical obligations and legal requirements pursuant to applicable healthcare laws is a prominent element of BMS's CCP. All BMS employees in the US have received training on the Principles. In addition, all BMS employees in the US Pharmaceuticals division or who support the US Pharmaceuticals division with respect to promotional and product services or government pricing and contracting have received appropriate training. Compliance education and training programs incorporate: the OIG Guidance; the *PhRMA* Code; anti-kickback laws; the federal False Claims Act; promotional compliance including the Food, Drug and Cosmetic Act; privacy; and conflicts of interest. BMS also regularly reviews and revises its education and training programs, as well as identifies any new areas of education and training that may have become necessary.

4. Internal Lines of Communication

BMS encourages open communication between Compliance and Ethics and all employees. BMS maintains a Helpline through which BMS employees may report potential compliance incidents, or seek guidance on compliance questions, that include, but are not limited to: violations of laws, regulations, or company policy; crimes; fraud; accounting matters; wholesaler inventory level issues; unethical behavior; and employment-related issues. Employees may make these reports with anonymity, confidentiality, and without fear of retaliation or other negative consequences, except in the unusual circumstance in which disclosure of the identity of the employee may be required by law. In addition, Compliance and Ethics maintains an internal website on which a broad scope of compliance-related information can be found.

5. Auditing and Monitoring

BMS's CCP includes monitoring and auditing that evaluate whether there are policies and procedures addressing risk areas, whether the policies and procedures have been implemented and communicated, and whether the policies and procedures were followed. The areas for monitoring and audit are reviewed and updated to reflect evolving compliance concerns, new regulatory requirements, or circumstances identifying a new risk area. The results of auditing and monitoring activities may be used as a basis for adapting and improving existing compliance policies, procedures and training.

6. Responding to Potential Violations

When BMS believes that an employee has violated a law or company policy, it investigates the matter and takes appropriate disciplinary action in order to address the violation and prevent future violations. The consequences for violations of company policy, including those identified in our CCP, include disciplinary action up to and including termination of employment.

7. Corrective Action Procedures

The BMS CCP is designed, implemented and enforced with the goal of preventing and detecting unlawful and unethical behavior. However, as recognized in the OIG Guidance, no compliance program, including BMS's CCP, can completely eliminate the possibility that individual employees are engaging in conduct that would be considered improper. Therefore, BMS continuously assesses the effectiveness of its CCP to enable it to implement necessary adjustments or refinements to the program.

As described above, BMS strives to put ethical principles into practice, with policies and practices that fully embody responsibility, integrity and decency. BMS views its CCP as a reflection of this overall commitment, demonstrating responsiveness to evolving concerns and compliance risks.

California Health and Safety Codes §§ 119400 -119402 require BMS to "...make its Comprehensive Compliance Program [CCP] . . . available to the public." For the purpose of satisfying that requirement, this description provides an overview of BMS's CCP as of April 1, 2018.

BMS will assess its CCP at least annually, for the purpose of declaring compliance with California Health and Safety Codes §§ 119400-119402.

A copy of this Description of BMS's CCP may be obtained by calling the toll-free number 1-800-348-5526.