

## **2012 Annual Description of Comprehensive Compliance Program Pursuant to California Health and Safety Codes §§ 119400-119402**

### **A. Introduction**

On April 1, 2012, and in compliance with the annual declaration requirement under California Health and Safety Code §§119400 - 119402, Bristol-Myers Squibb Company (BMS) made its 2012 declaration for the twelve (12) month period covering January 1, 2011 through December 31, 2011.

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 Office of Compliance and Ethics 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. Corporate Compliance Council – BMS has a Compliance and Ethics Council that advises the Chief Compliance and Ethics Officer on compliance-related activities and issues for the purposes of assessing compliance risks, helping to prevent compliance violations from occurring and, ensuring appropriate responses to compliance violations that may occur. The members of the Compliance and Ethics Council are high-level personnel from multiple business units and functions across the company.

## 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 Standards of Business Conduct and Ethics (SBCE) and in the US Pharmaceuticals Compliance and Ethics Code of Conduct (USPCECOC). The SBCE and the USPCECOC require BMS employees to obey all laws, act in an ethical manner and make business decisions that are consistent with BMS policy.

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 distributes 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. Although BMS has created systems to support the specific annual dollar spending limit requirement of the CCP, and has monitored promotional spend to the extent of limiting individual healthcare professional participation in promotional programs, BMS has nonetheless been unable to track with specificity the value of "all promotional or other items" permitted by the PhRMA Code provided to a California medical or other healthcare professional during the 2011 calendar year, nor expenditures made by the Company from other than the US Pharmaceuticals Division, which other division expenditures

are represented by good faith estimates. BMS is, however, in the process of finalizing plans to establish additional tracking and monitoring mechanisms. These system changes will take time to implement. BMS fully endorses the *PhRMA* Code and is abiding 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 BMS SBCE. 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 training on the USCECOC. In addition, examples of our compliance education and training programs include: the OIG Guidance; the *PhRMA* Code; promotional compliance; 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 the Office of 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, the Office of 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, which may arise due to obligations pursuant to a Corporate Integrity Agreement with the OIG, 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 July 1, 2005 (as revised most recently on April 1, 2012).

This Description is effective as of April 1, 2012. 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.