



U.S. PHARMACEUTICALS
COMPLIANCE AND ETHICS CODE OF CONDUCT

Effective: January 1, 2009



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I. INTRODUCTION

Bristol-Myers Squibb Company (“BMS” or the “Company”) is committed to preserving the integrity of the U.S. healthcare system through compliance with the requirements of the federal healthcare programs and the Food and Drug Administration (“FDA”). Building and maintaining a culture of compliance and ethical behavior across the organization is a key priority for the Company and for all of its employees individually. This means complying with all applicable laws and regulations, and conducting the business of the Company with integrity, in accordance with the BMS Pledge.

Scope and Application

This U.S. Pharmaceuticals Compliance and Ethics Code of Conduct (the “Code”) summarizes various key policies, procedures, standards and guiding principles of the U.S. Pharmaceuticals group. This Code applies to all employees of the U.S. Pharmaceuticals group, as well as employees assigned to other staff functions and other business units (collectively “Employees”) and third party personnel (*e.g.* contractors, subcontractors, agents, consultants, suppliers, and vendors, collectively “Third Parties”), to the extent they are engaged in, or otherwise support the performance of, activities described in and governed by this Code. Such Employees and Third Parties are expected to know and adhere to the Code and the BMS Standards of Business Conduct and Ethics.

Employees and Third Parties are required to read, understand and comply with specific policies and related procedural documents (referred to collectively in this Code as “BMS policy”, “policies and procedures” or “procedural documents”) referenced herein or made available to them when engaging in activities which are governed by such requirements. It is expected that Employees will frequently consult the U.S. Pharmaceuticals Compliance Resource Center (“Resource Center”) on the BMS intranet at <http://onebms.bms.com/ushclcompliance> for further guidance applicable to these activities. Employees and Third Parties are expected to complete all training and relevant certification requirements in the timeframe specified.

Related Policy:

BMS Standards of Business Conduct and Ethics

II. COMPLIANCE PRINCIPLES

A. U.S. HEALTHCARE LAW COMPLIANCE

Healthcare in the United States is highly regulated. Fundamentally, the laws and regulations governing drug development, approval, labeling, promotion and pricing exist to safeguard patient safety and privacy and optimize patient healthcare outcomes, as well as to protect government programs and third-party insurers that reimburse for or purchase prescription drugs.

Compliance is not just about rules and laws. Compliance encourages ethical behavior, fosters the right values and instills a culture of integrity. Compliance empowers the Company to operate within the laws, rules, and policies that regulate the pharmaceutical industry. Operating in compliance protects the Company, employees, Third Parties, shareholders, patients and the valuable products the Company offers to its customers. Preventing, identifying and correcting non-compliance is fundamental to the Company.

Not every employee is expected to be an expert in federal and state healthcare laws and regulations, but all Employees should understand and be guided by the principles these rules seek to advance. The standards and resources of the Company's compliance and ethics program are intended to advance these principles and to provide employees with support in performing their job responsibilities.

B. GUIDING PRINCIPLES

❖ **Do not pay people to prescribe or recommend BMS products.**

We do not offer remuneration (cash or anything of value) to improperly induce or reward the purchase, prescription or recommendation of BMS products. Buying business is a violation of Company policy, this Code, and federal healthcare laws. The Federal Anti-kickback Act and similar state laws prohibit the buying of healthcare business.

❖ **Promote BMS products consistent with their approved product labeling, to an appropriate audience and in an accurate and balanced manner.**

The Federal Food, Drug and Cosmetic Act ("FDCA") requires that we promote our products in a manner that is accurate, balanced, and consistent with approved product labeling. To help ensure that the Company meets this obligation, Employees and Third Parties must only use materials for product promotion, discussions and presentations that have been approved by BMS.

❖ **Respect people's privacy.**

Compliance with privacy laws is an essential business practice. This includes protecting the privacy of the healthcare professional and the patient.

❖ **Make sure pricing information the Company provides to the government is accurate.**

The government relies on BMS pricing data to determine reimbursement and rebates for Company products. The Company must take into account all discounts, incentives, and other payments that could directly or indirectly impact pricing of Company products, when reporting pricing information.

C. PHARMACEUTICAL INDUSTRY STANDARDS AND GUIDANCE

The P/RMA Code and OIG Compliance Program Guidance for Pharmaceutical Manufacturers set forth key principles on which industry compliance programs are based. These principles are fundamental to the U.S. Pharmaceuticals compliance and ethics program and are embodied in our Company's Standards of Business Conduct and Ethics, this Code, and procedural documents.

❖ **OIG Compliance Guidance**

The Office of Inspector General for the U.S. Department of Health and Human Services ("OIG") is responsible for maintaining the integrity of the federal healthcare programs, including Medicare and Medicaid. Its **Compliance Program Guidance for Pharmaceutical Manufacturers** (the "OIG Compliance Guidance") focuses on establishing and maintaining an effective compliance program; the integrity of pricing information provided to the government to establish payment amounts; industry relationships with healthcare professionals, particularly related to practices that have the potential to corrupt physician judgment (kickbacks); and compliance with the laws regulating drug samples. The OIG Compliance Guidance provides the foundation for the U.S. Pharmaceuticals compliance program.

❖ **P/RMA Code**

The Pharmaceutical Research and Manufacturers of America ("P/RMA") represents research-based pharmaceutical and biotechnology companies. Its **Code on Interactions with Healthcare Professionals** ("the P/RMA Code") reinforces our intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine. BMS adheres to the P/RMA Code.

Related Policies:

BMS-CP-043, Interactions with Healthcare Professionals

USP-POL-0013, Government Price Reporting

BMS-CP-016, Privacy

III. PRINCIPAL ACTIVITIES SUBJECT TO U.S. HEALTHCARE LAWS AND REGULATIONS

A. PRODUCT ADVERTISING AND PROMOTION

1. Overview

The primary focus of all Company promotional interactions with healthcare professionals is the communication of accurate and balanced product information that is consistent with approved product labeling. Every aspect of BMS drug advertising and promotion in the U.S. is governed by the FDCA, related regulations, and by FDA, which administers the FDCA and its regulations. The Company is held to FDA's objective standards in making safety and efficacy claims about BMS products. FDA approval determines what can be included in product labeling, and product labeling is the framework for what can be said in BMS advertising and promotion. All promotional statements must be consistent with approved product labeling.

Healthcare professionals may prescribe, recommend, or purchase products for uses that are not addressed in approved product labeling because FDA does not regulate the practice of medicine. BMS, however, may only promote products for approved uses. Promotion to healthcare professionals for unapproved uses, or to a category of healthcare professionals who do not treat patients for whom a product is labeled (for example, promoting a product to pediatricians that is not approved for use in children) will be viewed by government regulators as illegal "off-label promotion."

FDA recognizes that there is often scientifically and medically sound product information that is outside product labeling. This information may be valuable to healthcare professionals and often is best known and understood by the pharmaceutical companies that have developed the products. Because companies may only promote their products consistent with product labeling, FDA has created regulatory provisions that permit companies to disclose off-label information in specific and limited situations that FDA considers to be *bona fide* scientific exchange. For example, companies may respond to questions from healthcare professionals about information that is outside product labeling, but only if the questions are unsolicited and the answers are scientific, balanced, non-misleading and responsive to the specific request. The Company may not engage in tactics that solicit or prompt such questions or broaden the initial question asked.

2. Promotional Materials

All materials used in advertising and promotion of a product must be approved in accordance with the procedural documents that define the promotional material review and approval process. Other materials are subject to pertinent policies or procedures setting forth appropriate standards of review. Employees and Third Parties who support U.S. Pharmaceuticals in creating or approving promotional or informational materials must be familiar with and adhere to all review and content requirements. Employees and others speaking on behalf of the Company, including but not limited to sales representatives, Medical Science Liaisons ("MSLs"), and BMS contracted speakers, may only use materials that have received every level of required approval.

Requirements governing the use of product information and product names include the following:

- 1) Material that contains or suggests the name of or a claim for a BMS product cannot be disseminated outside of the Company unless the material has received every level of required approval. This approval may consist of approval of a template or a type of material, such as business communications from Account Executives in the Managed Markets arena. In all cases, any requirements applicable to the template or type of material must be followed.
- 2) Material developed by a managed care organization, as well as anything published in medical literature, available on the Internet, or derived from any other source cannot be used by any person speaking or promoting on behalf of the Company, unless the material has received BMS approval.
- 3) Approved materials that are altered, abbreviated or in any other way modified (including highlighting) are considered unapproved materials.
- 4) Expired or rescinded material must not be used.

Materials created and approved for use in promotion, must be balanced and complete, which means that efficacy information must be balanced with appropriate safety and relevant risk information. For each of the Company's products discussed, Employees must have available a copy of the current prescribing information.

Employees may not solicit, accept or agree to accept any kind of compensation (monetary or in-kind) for the distribution and sale of the Company's products or promotional materials from any party other than BMS. For example, BMS employees may not sell BMS promotional materials or samples over the Internet or through any other medium.

Related Policy:

USP-DIR-0009, Promotional Material Review and Approval

3. Promotional Activities: The Role of Field Sales and the Sales Call, the In-Office Program and the Speaker Program

Government regulators view any product-related or product-supporting activity or program in which the structure, content, speaker list and/or invitation list are subject to the control of BMS as promotional. Any Employee or Third Party engaging in a promotional activity must do so in accordance with the applicable compliance principles.

A. The Role of Field Sales and the Sales Call

The sales call is the cornerstone of sales representatives' activities. It must be carried out in compliance with the requirements of the FDCA and the Anti-kickback Act, as embodied in this Code and applicable procedural documents. When conducting a sales call or initiating *any* discussion about Company products, the sales representative must use only current BMS approved materials, present complete and accurate information, consistent with the current approved product labeling and present a fair balance between claims of effectiveness and information about safety and tolerability. Sales representatives must review safety and risk information that is relevant to the

product attributes discussed during each sales presentation. They must base product comparisons exclusively on approved materials. Sales representatives may not solicit or prompt off-label questions under any circumstances and may respond to requests for medical information only as directed by their management in accordance with Company policy and training. Sales representatives must direct promotional activities to appropriate audiences *e.g.*, those healthcare professionals and entities who would reasonably be expected to prescribe, recommend or purchase products for their labeled indication. The Company does not “buy business”- employees must not reward prescribing or access or improperly induce customers to prescribe, purchase or recommend the Company’s products.

Related Policy:

USP-POL-0012, Call Planning

B. The In-Office Program

An in-office program is an informational program or presentation delivered by a BMS sales representative to an appropriate target audience of healthcare professionals at their office. An in-office program should offer the healthcare professionals and appropriate clinical team an educational opportunity to learn about a BMS product or related disease area. This type of presentation is sometimes facilitated by a meal. See the section below entitled “Meals” for additional information.

All Employees and Third Parties engaging in in-office promotion must consult and comply with relevant requirements contained in applicable procedural documents. In particular, a sales representative may not invite an MSL to attend or participate in an in-office program to be delivered by the sales representative.

C. The Speaker Program

BMS engages healthcare professionals as speakers to provide approved information to customers about BMS products and related disease areas. Speakers are selected because they are qualified to discuss BMS products based on standard, objective criteria, and attendees are invited because they can benefit from the information presented. (Please see the section below entitled “Fee for Service Engagements: Consultants and Speakers”). Both the FDCA and the Anti-kickback Act apply to the arrangements involved with speaker programs. Thus, speakers as agents of BMS are subject to the FDA rules and regulations with respect to promoting products consistent with labeling and other requirements. These requirements are contained in the BMS Speaker Standards, a copy of which is attached to every speaker agreement. A contracted speaker may respond to an off-label question only in accordance with the BMS Speaker Standards, and only if the question is unsolicited or unprompted. BMS does not engage speakers to influence their prescribing decisions.

Please see the section entitled “Meals” for additional guidance.

Related Policies:

USP-POL-0002, Fee-for-Service Engagements with Healthcare Professionals

USP-DIR-0002-1, Speakers

4. Promotional Activities: Exhibits and Displays

Exhibits and displays offer an opportunity for BMS to provide approved product information to clinical decision makers about BMS products. As with other forms of product promotion, exhibits and displays must conform to FDA regulations and guidelines governing product promotion and must be consistent with approved product labeling. Exhibits are also subject to federal and state laws and regulations and other standards governing interactions with healthcare professionals, including the P/RMA Code.

All exhibit or display requests that involve a fee must be submitted in writing and approval must be received prior to exhibiting. Sales representatives must follow and submit requests in accordance with the applicable procedure. Payment for an exhibit or display must represent reasonable value for the exhibit space as determined by applicable policy and required approval.

At medical congresses, the Marketing Department may sponsor commercial exhibits. The Marketing Departments must follow applicable procedures and receive the required approval for the content of and payment for exhibits at medical congresses.

For non-promotional exhibits and displays sponsored by Medical Affairs, please refer to the Medical Affairs Section C.

5. Promotional Activities: Prescription Drug Samples

FDA recognizes that drug samples can play an important role in healthcare. They may be delivered by a sales representative or sent directly to a licensed prescriber by mail or common carrier. Under the FDCA and the Prescription Drug Marketing Act (“PDMA”), there are special rules that apply to the labeling and distribution of sample packaging and to sample programs.

Samples are made available only to licensed prescribers so that prescribers develop an understanding of the potential value of BMS products to particular patients. They are NOT provided for the prescribers’ personal, staff, or family use, nor are they provided as a charitable donation, or for billing to state, federal or private healthcare programs on behalf of the patients. All Employees and Third Parties are prohibited from selling samples or offering them for resale.

BMS and its business partners label every sample package to meet the requirement that samples clearly and legibly identify their lot number, expiration date, storage requirements and are clearly labeled as “not for resale.” Sample packages, therefore, must not be broken apart or compromised in any way. All sample quantities provided to prescribers must be completely and accurately recorded with the prescriber’s signature confirming the request for and receipt of samples. Samples must be stored in such a way as to maintain product quality.

Related Policy:

USP-POL-0018, Prescription Drug Samples

B. APPROPRIATE INTERACTIONS WITH HEALTHCARE PROFESSIONALS, CUSTOMERS, THIRD PARTIES AND COMPETITORS.

Interactions between BMS employees and healthcare professionals, customers, and/or other Third Parties should always focus on the communication of accurate, complete and balanced BMS product information and relevant scientific information. These interactions must be designed to enhance the practice of medicine and to benefit patients. The Company does not approve or permit practices that may be perceived as attempting to buy business, and sanctions only those practices intended to facilitate appropriate information-focused interactions.

1. Meals, Educational Items, Travel, Entertainment and Healthcare Professionals

Meals

U.S. Pharmaceuticals permits the provision of modest meals to healthcare professionals solely to facilitate the appropriate interaction between the employee providing the meal and the healthcare professional. In accordance with applicable policies and procedures, meals may only be provided to healthcare professionals in connection with an informational in-office presentation, a business discussion or an informational discussion, including a speaker program, a consultant meeting, or speaker training session. The focus of such interactions should remain on the substance and quality of the presentation, information provided and/or meeting content, not on the meal or venue.

Meals may only be provided to an appropriate target audience as defined by U.S. Pharmaceuticals procedural documents, and may be provided only on an occasional basis and at a suitable venue. Meals must be of modest value as judged by local standards, and the cost of a meal, per person, may not exceed U.S. Pharmaceuticals meal limits. Any meals offered in connection with informational presentations made by field sales representatives or their immediate managers must also be limited to in-office or in-hospital settings. The full names, titles and affiliations of all attendees must be captured. Meals for spouses or guests accompanying healthcare professionals may NOT be provided.

Employees are required to follow all applicable Company procedural documents or stricter federal, state or institutional requirements if they apply.

Related Policies:

USP-POL-0007, Meals, Educational Items, Travel and Healthcare Professionals

USP-DIR-0007-1, Meals and Healthcare Professionals

Educational Items Provided to Healthcare Professionals

Where permitted by law, BMS may occasionally offer healthcare professionals items designed primarily for the education of patients or healthcare professionals. Such items must be approved by BMS, must not have value to healthcare professionals outside of his or her professional

responsibilities, must not be of substantial value (*i.e.* the retail value may not appear to be in excess of \$100) and must not be offered on more than an occasional basis, even if each individual item is appropriate.

Non-educational and reminder items (*e.g.*, pens and pads) must not be offered to healthcare professionals or members of their staff, even if they are of nominal value and/or accompanied by patient or physician educational materials. This prohibition applies to all interactions with healthcare professionals including but not limited to advisory boards, speaker trainings, medical congresses, conferences and exhibits and displays.

Related Policies:

USP-POL-0007, Meals, Educational Items, Travel and Healthcare Professionals

USP-DIR 0007-2, Educational Items and Healthcare Professionals

Travel

BMS may pay reasonable travel-related expenses (airfare, lodging, and meal expenses) for contracted healthcare professionals only if they are consultants traveling to and from a BMS consultant engagement or advisory board meeting, speakers traveling to and from speaker programs, or trainees traveling to and from a speaker training meeting. BMS does not pay travel-related expenses for spouses or guests. All travel for consultants is governed by the BMS-CP-057, *Travel*.

Related Policies:

USP-POL-0002, Fee-for-Service Engagements with Healthcare Professionals

USP-POL-0007, Meals, Educational Items, Travel and Healthcare Professionals

BMS-CP-057, Travel

Entertainment

To ensure the appropriate focus on educational and informational exchange and to avoid the appearance of impropriety, the Company should not provide **any** entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the items; (2) whether the company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.

Related Policies:

USP-POL-0002, Fee-for-Service Engagements with Healthcare Professionals

USP-POL-0007, Meals, Educational Items, Travel and Healthcare Professionals

2. Fee-for-Service Engagements: Consultants and Speakers

BMS enters into contracts with healthcare professionals who are medical and/or scientific experts. BMS may engage a healthcare professional to meet a valid business or scientific need by providing advice about a product or disease state, training an internal audience or creating needed materials. BMS may also engage healthcare professionals as speakers to provide approved information to our customers about BMS products and related disease areas. Speakers are deemed by FDA to be acting in a promotional capacity and are a subset of consultants. Regardless of whether healthcare professionals are engaged to advise the Company or speak on its behalf, it is very important that the Company respects the line that these healthcare professionals draw between their business relationship with the Company and their delivery of patient care, so that they are free to make medical decisions in the best interests of their patients.

Payments (or anything else of value) to healthcare professionals and others in a position to influence the purchase, recommendation, or prescription of BMS products can raise potentially serious legal issues. While reasonable payments for genuine consulting services are legally permissible, sham or token consulting arrangements must not be used to permit inappropriate payments or evade the restrictions that apply to interactions with healthcare professionals who are not consultants or speakers. BMS may enter into relationships with healthcare professionals to provide advisory or speaker services to the Company only when there are legitimate services being provided that are of real value to the Company and that fulfill a clearly identified need of the Company, and only when the parties have entered into a written agreement that reflects a fair market value payment for such services set in advance.

Healthcare professionals may never be engaged as consultants or speakers as a “reward” for past or present business or as an inducement for future business. Return on investment analyses and other tracking for business generation may not be conducted in connection with consultant arrangements or in connection with the retention of a speaker.

BMS requires its consultants and speakers to verify that they are not debarred or excluded from doing business with any government healthcare programs, that they will disclose their financial relationship with BMS to their employer and/or any institution with which they are affiliated, and that they will not enter into such arrangements with BMS when prohibited from doing so.

Healthcare professionals who are members of a committee that sets formularies or develops clinical guidelines and who also serve as speakers or consultants for BMS are required to disclose to the committee the existence and nature of their relationship with BMS for at least two years beyond the termination of any speaker or consultant arrangement, and to follow the procedures set forth by the committee of which they are a member. Further, all consultants and speakers must agree to read and abide by the BMS Standards of Business Conduct and Ethics and this Code.

Related Policies:

USP-POL-0002, Fee-for-Service Engagements with Healthcare Professionals

USP-DIR-0002-1, Speakers

USP-DIR-0002-2, Consultants

USP-DIR-0002-3, Managed Care Advisory Boards

USP-DIR-0002-4, Tracking Prescribing Behaviors of Healthcare Professionals by Field Sales Representatives

3. Relationships with Managed Care Customers

Interactions with managed care and trade (wholesalers and distributors) customers raise special concerns due to the potential complexity of business relationships with such customers and the combination of public and private payers with which both BMS and managed care and trade customers conduct business. Company interactions with managed care and trade customers include (a) encouraging access to and appropriate utilization of BMS products through (i) communication of accurate, complete, balanced and Company-approved scientific and relevant product information, and (ii) by offering properly disclosed product pricing terms; (b) offering appropriate information or healthcare quality products and services to managed care and trade customers; and (c) participating in appropriate collaborative activities with managed care and trade customers.

BMS may occasionally require certain services and may seek to enter into arrangements to purchase valid services from managed care customers for fair market value. In accordance with the applicable policy, negotiations for purchased services or other deliverables must be conducted separately from any discussions with managed care customers regarding the decision about the purchase or placement of a BMS product on formulary. Any such arrangements must be commercially reasonable arrangements. Payments to managed care customers cannot be linked to any volume of referrals or business generated. BMS does not enter into sham or token arrangements with managed care customers to avoid the provision of product rebates or discounts or to justify otherwise inappropriate payments.

Related Policies:

USP-POL-0010, Interactions with Managed Care and Trade Customers

USP-DIR-0010-1, Services Agreements

4. Business Alliances: Joint Ventures, Partnerships and Other Relationships

BMS enters into business alliances, including joint ventures, co-promotion, co-marketing, and co-licensing agreements, with other pharmaceutical companies. BMS works with its alliance partners to create standards and controls that promote compliance with the U.S. healthcare laws. BMS makes its Standards of Business Conduct and Ethics and this Code, and a description of its compliance program (the “BMS Standards”) available to its alliance partners, and expects that its alliance partners will make the BMS Standards available to their employees or that its alliance partners will comply with standards that are substantially comparable to BMS Standards.

Each product subject to a business alliance will have specific business rules and processes. These processes govern, among other things, approval of promotional materials, fee-for-service engagements (such as consultants and speakers), exhibits and display opportunities, sales calls, samples programs and other promotional activities. In the absence of a specific business alliance policy or procedure, BMS Employees must follow relevant BMS policies and procedures. BMS Employees may not use business partners to work around BMS policies and procedures.

5. BMS Third Party Vendor Engagements

BMS retains Third Party vendors to assist with the performance of certain activities. These vendors must comply with all applicable federal healthcare program and FDA requirements. Any BMS Employee who is responsible for such vendor's activities must ensure that the vendor has been provided with a copy of relevant BMS policies and procedures. Employees and Third Party vendors should understand that Third Parties, in performing services on behalf of the Company, must adhere to the same high standards to which the Company itself is bound. Further, all such vendors shall agree to read and abide by the BMS Standards of Business Conduct and Ethics and this Code. Employees who are concerned that a vendor is not conducting its activities in compliance with BMS policies and procedures should report compliance concerns to their manager or the Law Department.

6. Interactions with Government Employees

Employees may interact with healthcare professionals with responsibilities at federal government institutions, like the Veterans Administration Facilities, the Department of Defense, and state institutions such as state hospitals and psychiatric and correctional facilities. In addition to the general industry standards for interactions with healthcare professionals, federal and state ethics laws introduce higher standards that apply to healthcare professionals who have responsibilities at government institutions or are government employees. Although many of the governmental ethics laws were not drafted for or targeted specifically at the pharmaceutical industry, they are rules of broad application and govern BMS interactions with these government employees. BMS strictly prohibits improper interactions with government employees that may have the intent, or may take on the appearance, of expecting to influence the official's judgment or decisions.

7. Interactions with Competitors

At no time may an Employee unfairly criticize a competitor or its product(s). At no time may a BMS employee engage in any practice aimed at improperly interfering with a competitor's current or prospective business relationships. Except for certain activities undertaken pursuant to a business alliance, at no time may an Employee discuss matters related to business (*e.g.*, prices, discounts, market strategies) or enter into any agreement or understanding regarding such matters, directly or indirectly, with any employee or agent of a competitor, nor may an Employee do anything that might give the appearance of such an agreement or understanding. Communications and actions on business matters pursuant to a business alliance may be undertaken only in accordance with specific rules and processes with respect to such business alliance. Always consult with the Law Department before undertaking any such activities.

C. MEDICAL AFFAIRS, MEDICAL INFORMATION, THE DEVELOPMENT OF SCIENTIFIC INFORMATION ABOUT OUR PRODUCTS, CHARITABLE DONATIONS AND OTHER CORPORATE GIVING AND IME GRANTS

1. USP Medical Affairs

Pharmaceutical companies are commercial organizations that, in their development of products, act as scientific research and medical organizations. USP Medical Affairs is the branch of the Company's Research & Development organization charged with developing and providing unbiased, scientifically accurate and balanced information about products marketed by U.S. Pharmaceuticals in order to guide their development, and to support their safe and appropriate use. USP Medical Affairs is also responsible for developing information about our products to respond to healthcare professionals' unsolicited questions about product uses or other information that may not be consistent with product labeling. Respect for the boundary between the objectives of the USP Medical Affairs organization and the objectives of the commercial arm of the Company supports the Company's credibility in the medical community and with government authorities.

2. Field Medical Representatives: Medical Science Liaisons

USP Medical Affairs employs scientists, pharmacists, physicians and other healthcare professionals as MSLs. The primary role of the MSL is the communication of complex scientific and medical information to ensure the safe and appropriate use of BMS products. Consistent with applicable policies, MSLs may be engaged as speakers in Company promotional programs. MSLs do not report to Sales and Marketing and do not take direction from these Departments. MSL compensation is not based on sales of individual products.

MSLs, like all BMS employees, must comply with the requirements of the FDCA. Any statements that MSLs make about BMS products must be consistent with the product labeling, except that, in order to meet the medical information needs of healthcare professionals, MSLs may respond to unsolicited requests for medical information and discuss information that is outside of the product labeling, as long as they state that the information is outside of the product labeling, answer only the specific request made, and do not expand the discussion. Information provided to healthcare professionals in response to their unsolicited requests must be accurate, complete, and balanced, and documented in accordance with applicable procedures. Any materials MSLs use must have received every level of required approval according to BMS policies and procedures.

3. Medical Information Requests

Consistent with guidance from FDA, the Company may respond to unsolicited requests for off-label or pre-approval information in a non-promotional manner. The Medical Information Department receives requests from healthcare professionals about BMS products and related issues. This Department provides timely, accurate, and up-to-date medical information to support the appropriate use of BMS products. To ensure that questions answered by the Medical Information Department are truly unsolicited, and that responses are accurate, complete, and of scientific value, BMS has policies and procedures governing the content and manner of responses to requests for off-label or pre-approval information.

Related Policy:

USP-POL-0016, The Handling of Unsolicited Requests for Medical Information by Field Based Representatives
GMA-POL-GBL-11.01, BMS Responses to Requests for Medical Information

4. Medical Congress Activities

Medical congresses are primarily a means to facilitate scientific exchange among healthcare professionals. All information provided to healthcare professionals by BMS at medical congresses and all interactions with healthcare professionals must be consistent with product labeling, except in the context of congress presentations by scientific or medical personnel in which the Company is permitted to provide appropriate, high quality scientific information about BMS products or disease states. Any congress activities must be orderly and consistent with BMS policies, applicable legal requirements and industry standards.

BMS employees must receive management approval prior to attending a medical congress. Activities at medical congresses are subject to all applicable BMS policies and procedures governing interactions with healthcare professionals, including approved educational items and meals; standards governing conduct in exhibit booths, receptions, and business meetings; and procedures for handling or forwarding requests for off-label or pre-approval information.

Every aspect of BMS promotional and medical exhibits at medical congresses, including design, location, appearance, and content, must receive, in advance, required approval according to BMS policies and procedures. Decisions to make payment in connection with any medical congress must be made according to BMS policies and procedures.

5. Investigator-Sponsored Trials

BMS conducts research through its Research & Development organization. Under the auspices of the USP Medical Affairs department, BMS also may provide financial support and investigational drug product for high quality scientific research initiated and conducted by outside investigators (Investigator Sponsored Trial or “IST”). It is essential that such research be supported in strict accordance with applicable Company policies and applicable procedures, so as to avoid any concern that research funding is awarded as an inducement to prescribe BMS products. BMS may never enter into an agreement to fund an IST with a healthcare professional as a “reward” for past or present business nor as an inducement for future business.

It is also essential that applicable policies and procedures be followed to avoid any concern that the purpose of a trial is to increase use of a product, or finally that the research is constructed to encourage broader off-label use of a Company product in a commercial context (*e.g.*, seeding trials). Thus, for those ISTs in which BMS is not considered the legal or regulatory “sponsor” under FDA regulations, the studies must meet high standards of scientific and clinical merit and not be duplicative of existing studies. Medical Affairs, Research & Development, and MSL employee interactions with healthcare professionals who seek support from BMS for scientific research are subject to specific BMS policies and procedures that limit such employees’ involvement in proposals for ISTs to ensuring protection of patients and ensuring that the trial design is adequate to yield meaningful and valid scientific results. Employees of the commercial organization (*e.g.*, sales or marketing employees) may play no role in the discussion of IST proposals or decisions awarding support to ISTs.

Related Policy:

GMA-DIR-USP-202.01, Medical Science Liaison (MSL) Role in BMS-Supported Investigator Sponsored Trials (ISTs)

6. Adverse Events

BMS's mission is to extend and enhance human life by providing the highest quality pharmaceutical products, and current and accurate information about its products. Prompt reporting of all adverse events and medical events enables BMS to monitor the safety profile of all products and meet corporate regulatory reporting requirements. All employees have the obligation to report all adverse events and medical events of which they become aware. An adverse event is any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product, whether or not a causal relationship with the use of the product is demonstrated. A medical event can be any unfavorable or unintended sign (including abnormal laboratory finding), symptom or illness temporally associated with use of a medicinal product whether or not related to the medicinal product. BMS requires pregnancy and overdoses to be reported as an adverse event. An adverse event must be reported even if it is listed in the product label or package insert and even if the healthcare professional or other reporter indicates that he or she has already reported or intends to report the event. Failure to report adverse events could result in undue risk to patients or study subjects. Reporting of adverse events is also required under FDA and international regulations.

Employees must report all adverse events regarding BMS products to the Company within 24 hours or one business day after they become aware of the event. U.S. employees should call 1-866-232-2557 (1-866-AECALLS).

Related Policy:

BMS-CP-044, Reporting Spontaneous Adverse Events and Medical Events

7. Publication of Clinical Trial Results and Other Scientific Publications

BMS is committed to communicating timely and accurate information about clinical trials that the Company initiates for its investigational compounds and marketed products, consistent with the BMS publication plan for the product. BMS has adopted the voluntary principles issued by P/RMA on the conduct of clinical trials and the communication of clinical trial results. Consistent with these principles, the Company will continue to report clinical trial results in an objective, accurate, balanced, and complete manner regardless of outcome.

The BMS Corporate Policy on Publications and related procedural documents apply to publications about products marketed by U.S. Pharmaceuticals. Responsibility for such publications resides with U.S. Pharmaceuticals Medical Affairs, and not with the commercial organization. Any BMS funding or involvement in a publication must be disclosed in the publication. BMS scientific publications may not be influenced by commercial objectives, and reprints may only be distributed to healthcare professionals or others outside the Company as directed by the Home Office.

Related Policies:

BMS-CP-049, Scientific Publications

BMS-CD-049, Scientific Publications
GMA-POL-GBL-16.01, Scientific Publications

8. Charitable Donations and Other Corporate Giving

The BMS Pledge includes a promise of “conscientious citizenship,” including support for worthwhile causes. In addition to the activities of the Bristol-Myers Squibb Foundation and the Company’s Corporate Philanthropy department, U.S. Pharmaceuticals supports the Company Pledge through Charitable Donations and Other Corporate Giving.

Charitable Giving includes both Charitable Donations and Other Corporate Giving. Charitable Donations are donations made to charitable organizations in support of the general mission or activities of these non-profit 501 (c) (3) organizations. Through Other Corporate Giving, U.S. Pharmaceuticals may also support specific activities of healthcare-related organizations and entities *e.g.* corporate memberships in professional medical associations, corporate sponsorships of disease-awareness events, fellowships and other corporate support of third party efforts to improve public health, disease treatment and or patient access. All requests for such funding are reviewed for compliance with relevant legal and industry requirements. All these requests must also comply with BMS policies and procedures for the submission, review, determination and processing of charitable donations requests or requests for other corporate giving. All external requests for support begin with an application through the BMS grants website.

The responsibility for the management, review and determination of funding of requests is allocated to the U.S. Primary Oversight and Review Committee (“PROC”). BMS funds must never be used to induce or reward the use, prescription, or recommendation of BMS products. Return on investment analyses and other tracking for business generation may not be conducted in connection with charitable contributions, other corporate giving or grant support.

Related Policies

BMS-CP-041, Charitable Giving

BMS-CD-041a, Charitable Giving

USP-DIR-0011, Charitable Donations and Other Corporate Giving

9. Independent Medical Education (“IME”) Grants

Through the provision of Independent Medical Education grants (“IME grants”), BMS also supports a variety of third-party medical education and scientific programs including continuing medical education. IME is a subset of grant-funded activities. IME programs must be objective, unbiased, and scientifically rigorous. They may not focus on particular BMS products and may not be promotional in tone or character. To ensure that IME programs and publications are objective and unbiased, the third-party institution or organization sponsoring the IME program or publication must be responsible for and retain complete control over the structure, content, and faculty.

BMS takes steps to ensure the independence of a BMS grant-funded IME program. Allocation of support for IME programs is determined solely by the grants function in USP Medical Affairs. The review of IME requests for funding is based on the Company's medical strategy and analysis of unmet medical need, combined with an assessment of the quality of the proposed program. Although USP Medical Affairs reviews and evaluates an IME proposal, BMS has no involvement with the development of the content, the organization and/or operations of the supported IME program. Marketing and Sales have no role or involvement in the process that determines what IME will be supported by the Company.

All requests for funding are reviewed for compliance with relevant legal and industry requirements. BMS policies and procedures for the support of IME are informed by FDA's Guidance for Industry Supported Scientific and Educational Activities, the Standards for Commercial Support of the Accreditation Council for Continuing Medical Education ("ACCME") and the P/RMA Code. Any BMS assistance with, or presence at, an IME program must be consistent with BMS policies and procedures on Independent Medical Education. BMS funds must never be used to induce or reward the use, prescription, or recommendation of BMS products. Return on investment analyses and other tracking for business generation may not be conducted in connection with charitable contributions, other corporate giving or grant support.

Related Policy:
USP-POL-0003, Independent Medical Education

D. GOVERNMENT PRICING AND CONTRACTING

State and federal governments are major purchasers and payers of BMS products. The federal government contracts with healthcare plans to provide drug benefits under Medicare Part D, reimburses for products under Medicare Part B, and participates in reimbursement to pharmacy providers under Medicaid and other programs. The government (such as the Veterans Administration or Department of Defense) may also be a direct purchaser of BMS products. Since the government relies on BMS pricing data to determine purchase prices, reimbursement rates, and rebates for BMS products, the Company has an obligation to accurately report BMS pricing information so that taxpayer money will be appropriately used to support these programs.

BMS is committed to ensuring that all pricing information reported to the government for BMS products is complete and accurate. BMS employees and Third Parties working in the areas of government pricing, contracting, and related regulatory functions must follow all BMS policies and procedures governing collection, calculation, verification, or reporting of BMS price information. All other BMS employees and applicable Third Parties are responsible for safeguarding against actual or potential violations of the government pricing and reporting rules by only offering discounts, incentives and payments for services approved by the Company, and by keeping accurate records. Only appropriate documentation of financial arrangements with customers will ensure that price reporting to the government is accurate; there can be no secret or "off-invoice" discounts, and no offers of goods or services in lieu of properly documented and disclosed discounts.

An impermissible practice is the promotion of products based on the actual amount paid by the purchaser and the amount reimbursed according to government reimbursement formulas. This

practice is known as “marketing the spread” and means that sales are being promoted on the basis of profit to be made from taxpayer funded programs. BMS does not market the spread.

Related Policy:

US-POL-0013, Government Price Reporting

E. OTHER STANDARDS

1. Privacy

The protection of patients’ and others’ privacy is an important goal of the Company. Individual patients’ health information is very sensitive, and BMS’s customers have obligations under federal and state law to protect the privacy of such information.

The Company has a Corporate Privacy Policy in which BMS pledges to protect and respect the personal information on employees, customers, patients, consumers, research subjects, shareholders, vendors, consultants and competitors to which BMS has access. The Privacy Policy provides that BMS must process personal data fairly and lawfully; the Company must inform and obtain consent, where required by law; protect personal information with adequate security measures; and must file with local public authorities, where required by law.

During the course of doing business, the Home Office may purchase and use physician prescription information from Health Information Organizations. BMS utilizes this information in accordance with all applicable state laws and the American Medical Association-Prescribing Data Restriction Program (“PDRP”). By enrolling in PDRP, physicians can prevent field personnel from accessing information about their prescribing practices. It is inappropriate to use prescriber-level prescription data to coerce, badger or otherwise pressure a physician to prescribe a particular product.

Marketing personnel must be familiar with procedural documents that define the corporate standards for data collection and protection of customer-facing websites, as well as email campaigns for customers, and the requirements for collecting and protecting personal information on BMS internet sites. In the event personal information is breached, Employees and Third Parties must follow the specific requirements for notification.

Related Policies:

BMS-CP-016, Privacy

USP-DIR-0017, The Utilization of Prescriber-Level Prescription Data

USP-DIR-0002-4, Tracking Prescribing Behaviors of Healthcare Professionals by Field Sales Representatives

2. State Laws

Individual states have adopted their own laws directed at the pharmaceutical industry. Some of these laws regulate prescription drug sales and marketing practices; others are focused on pricing

aspects while some are directed at clinical trials. These laws may prohibit, or require reporting, the provision of educational items, gifts or meals to healthcare professionals. State laws may also require the reporting of grants or other types of pharmaceutical company activities or support relative to healthcare professionals.

BMS provides information regarding state-specific policies, compliance with any restrictions and reporting requirements in applicable states. Employees and Third Parties must comply with state law requirements.

3. Institutional Guidelines

Public or private institutions, such as hospitals, clinics, and group practices, may implement policies and procedural requirements relating to some or many of the topics covered in this Code. Employees may be asked to sign a document, such as a vendor access agreement, confirming adherence to the institution's policies and procedures, to submit documentation, and/or to pay a fee. It is Company policy that Employees may not enter into such agreements, either orally or in writing, without obtaining prior approval from the Law Department.

4. Records Management

The Company's records are an important asset, and, accordingly, must be protected and maintained pursuant to established principles and applicable laws and regulations. The BMS Records Management Policy and Directive establish the purpose, requirements and expectations for managing records at BMS. There are three essential components to the BMS Records Management Program, as follows:

- 1) Records Retention Schedules
- 2) Records Retention Hold Notices (Legal Holds)
- 3) Disposal of Records

Related Policies:

BMS-CP-005, BMS Records Management

BMS-CD-005, BMS Records Management

IV. ADDRESSING POTENTIAL COMPLIANCE CONCERNS AND VIOLATIONS

A. REPORTING POTENTIAL COMPLIANCE CONCERNS AND VIOLATIONS

BMS is committed to compliance with local, state, and federal laws, rules and regulations, the laws of other countries where the Company does business, and its own policies regarding ethical and compliance responsibilities. BMS corporate policy requires that employees promptly report concerns about business practices or individual misconduct to the BMS Office of Compliance and Ethics (“OCE”). If an employee believes that an illegal or unethical activity, or a violation of Company policy, may have happened or might happen, the employee must report that concern. Any employee who is concerned that any other employee has violated, or may violate, any law or corporate policy may report this concern to:

- his or her supervisor
- an attorney in the BMS Law Department
- an appropriate management representative
- the Office of Compliance and Ethics (OCE)
- a Human Resources representative
- 1-800-348-5526
- helpline@bms.com

B. CONSEQUENCES FOR NON-COMPLIANCE WITH THE U.S. HEALTHCARE LAWS, BMS POLICIES, PROCEDURES AND OTHER REQUIREMENTS

Violations of the requirements of the U.S. federal healthcare programs can be prosecuted by both the Office of Inspector General and the Department of Justice. The Federal Anti-kickback Act and the False Claims Act allow for civil monetary penalties and criminal prosecution, punishable by fine or imprisonment. BMS and its employees may be liable for violations of any of these laws. Conviction of a company of a criminal offense often results in that company’s exclusion from participation in the federal healthcare programs, which means that the company’s products would not be reimbursed by Medicare, Medicaid, and other federal healthcare programs.

Violations of FDA requirements also can result in civil enforcement action or criminal prosecution, of a company or an individual. FDA may also choose one of a number of regulatory enforcement mechanisms that are intended to correct and prevent misleading communications or other violations of the FDCA including monetary penalties. Finally, the government may choose the False Claims Act, with its severe financial penalties, as an avenue to pursue a company that promotes off-label in contravention of the requirements of the FDCA.

Disciplinary Process for Compliance Violations

The Company complies with all state, federal, and local laws that govern the promotion of BMS products to prospective customers and interactions with healthcare professionals. Any Employee who fails to adhere to these laws, this Code, and other policies and procedures referenced herein, or who fails to complete all required compliance training in the required time frame, and any Employee who directs or knowingly permits an Employee under his or her supervision to do so, will be disciplined accordingly, up to and including termination of employment. The Company complies fully with all of its reporting obligations regarding violations of its compliance and other standards.

An Employee remains an at-will employee of the Company at all times, including during any progressive disciplinary process. The willful failure of an employee to substantially perform his or her duties at any time, including during the disciplinary process, may result in a termination for cause. For information about the disciplinary process, please consult the Human Resources Policy on Formal Discipline and related SOP.

Related Policies:

BMS-CP-027, Reporting Potential Compliance Incidents

HR-POL-001, Formal Discipline