



Bristol-Myers Squibb Company

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February 23, 2006

**Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852**

Re: Docket No. 2005N-0354, Consumer-Directed Promotion of Regulated Medical Products; Federal Register: September 13, 2005 (Volume 70, Number 176)

Dear Sir or Madam:

Bristol-Myers Squibb (BMS) is a global pharmaceutical and related health care products company with principal businesses in pharmaceuticals, infant formulas, and nutritional products. BMS has provided comments on direct-to-consumer (DTC) related guidance documents in the past and we welcome the opportunity to respond to the Docket No. 2005N-0354, Consumer-Directed Promotion of Regulated Medical Products.

Our company's mission is to extend and enhance human life by providing the highest quality pharmaceutical and related health care products. Consistent with our mission, we are committed to accurate, understandable and educational direct-to-consumer (DTC) communication. We firmly believe that DTC advertising of prescription medicines and medical devices can benefit public health by increasing awareness about diseases, educating patients about drug products and motivating them to contact their physicians and to engage in discussions about treatment options. Further, appropriate DTC communications supports the likelihood that patients will receive appropriate care for conditions, particularly those that are under-diagnosed or under-treated, and encourage compliance with prescription drug treatment regimens.

To support its commitment to provide accurate, understandable and educational DTC communication, BMS implemented a DTC Communications Code, which was posted on the company website on June 13, 2005. In addition, BMS voluntarily complies with the Pharmaceutical Research and Manufacturers of America (PhRMA) Guiding Principles on DTC

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Advertisements about Prescription Medicines (“PhRMA Guiding Principles”) which went into effect on January 1, 2006.

These initiatives are consistent with and support FDA’s interest in ensuring appropriate DTC communications about prescription medicines. The BMS Code and PhRMA Guiding Principles also reflect our commitment to effective self regulation. To help ensure that we deliver on our DTC communication goals, BMS maintains formal internal review and approval processes for proposed DTC advertisements and seeks external guidance from health care professionals and consumers. Further, PhRMA has established an Office of Accountability that will triage to its members complaints and concerns about DTC advertising practices that appear to be inconsistent with the PhRMA Guiding Principles.

DTC advertising should respect the role of the health care professional

At its core, the BMS Code recognizes and respects the fundamental role of the health care professional in determining whether a particular prescription medicine is appropriate for a particular patient. Even the most accurate DTC advertising that effectively communicates product risks and benefits cannot place the consumer in a position to make treatment decisions with prescription drugs. We agree that consumers simply do not have the training or expertise to make such decisions and DTC advertising should not suggest otherwise. Rather, DTC advertising for prescription medicines must emphasize and support the role of the health care professional. This is best accomplished when the DTC advertisement encourages consumers to discuss the risks and benefits of treatment options with their physicians who are in the best position to diagnose and recommend any appropriate course of treatment.

We also believe that DTC advertising of new products, products with which health care professionals would have little or no experience, should be delayed for an appropriate period of time. Under the BMS Code, we have pledged to focus our initial promotional and educational efforts for new drugs on health care professionals. During the twelve month period following the launch of a new medicine, BMS will not engage in mass media advertising (television, radio and print) to consumers. We believe this policy will help support the ability of health care professionals to make appropriate treatment decisions with new medicines and to respond to questions from patients about available therapies.

DTC advertising should provide disease state information

BMS is committed to providing disease awareness information as part of our outreach to consumers. DTC advertising of prescription drugs has been very effective in educating millions of consumers about conditions, such as high cholesterol, that are often under diagnosed and under- treated. Although we recognize the importance of providing disease state information to consumers, it is important to note that in branded product advertising we must ensure that

disease information does not imply uses for products beyond their approved labeling. This requirement necessarily places some constraints on our ability to provide comprehensive information about diseases and their consequences. For example, if a product is only indicated for the chronic phase of a disease, providing information about the disease from its inception to the development of secondary outcomes may not be possible as part of product advertisements.

On the other hand, non product-related disease awareness and prevention communications are important for the medical community, patients and caregivers. The BMS DTC Code and the PhRMA Guiding Principles reinforce industry's commitment to disease state awareness communications. Nevertheless, pharmaceutical companies are not, and should not be, the only or primary source of disease state education or awareness information.

DTC advertising must be in language consumers can understand

Fundamental to appropriate and effective DTC advertising is that the communication must be in consumer-friendly language. In our DTC Code, we pledge to communicate risks and benefits of our products in language consumers understand. To fulfill this promise, we would welcome the opportunity to work with FDA on consumer comprehension standards, which could be used to assess the effectiveness of DTC communications. The lack of clear comprehension standards in the current environment has resulted in a great deal of variability in the quality of consumer communications.

FDA should provide guidance for the use of the Internet in DTC advertising

The most evolutionary communication technology is the Internet, which can be used for both promotional labeling and advertising activities. The Internet can be used as a valuable health care education tool with a broad reach of audience and targeting opportunities. This medium also is very flexible and dynamic, allowing for the use of various communication vehicles, such as consumer-focused product Web pages, linked documents (with the possibility of printing), pop-up banners, videos, sound recordings, etc... The regulations address some of these activities separately, but do not provide guidance on how they should interact when presented together. It is important for the agency to provide clear direction on internet communications, to ensure accurate and appropriate use of this technology in DTC communications.

FDA and industry should have more opportunities for consultation

Traditional enforcement actions such as untitled and Warning letters alone are not an efficient way to inform on FDA position on advertising practices, especially in an environment where industry has demonstrated a commitment to compliance and is eager to ensure that its advertising meets the letter and spirit of the law. Too much reliance on enforcement also is not consistent with the public interest since enforcement letters often seek to halt practices that have gone on

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for some period of time.

BMS encourages FDA to continue to seek resources for DDMAC to allow it to continue providing timely advisory comments on advertising issues. BMS has long recognized the value of submitting new DTC mass media (television, radio, print) materials to DDMAC for advisory comments prior to use. Comments provided by DDMAC through this process are very helpful in supporting compliance. We also encourage DDMAC to continue work with its therapeutic review teams in order to reduce the risk of inconsistent interpretations of the advertising regulations.

DTC advertising can benefit from more research on its impact on behavior

With the implementation of the PhRMA Guiding Principles and industry member DTC advertising codes, new market research should be conducted to gain insight on the impact of DTC advertising on consumer behavior. Most available market research provides attitudinal data (opinion surveys) rather than information on the effect of consumer advertising on health outcomes. This research should be unbiased and conducted in a collaborative way, involving FDA and key stakeholders, such as the health care professional community, sponsors, and patients groups¹. The results from such research efforts would help better understand the impact of prescription drug advertising on a lay audience that is becoming more sophisticated in its understanding of, and more demanding in its desire for, meaningful health care information.

Conclusion

There is consensus that the way DTC promotion and advertising is conducted is very important. Sponsors refer to existing advertising regulations and guidance documents to develop DTC advertising and disease awareness campaigns that are truthful, non-misleading, scientifically substantiated and in language that consumers can understand. Nevertheless, there is still room for clarification, especially on the consumer comprehension standards and the use of various communication vehicles through the Internet. In addition, we need to have a common understanding of the goals of DTC advertising. This understanding would be helpful in guiding decisions on communicating safety information. At BMS, we believe that no DTC advertisement could ever place the consumer in a position to make treatment decisions. That role must be preserved for the health care professional who has the necessary expertise and

¹ A similar collaboration, led by an American Medical Association (AMA) affiliated group, resulted in a study conducted by a team of researchers from Harvard University/Massachusetts General Hospital and Harris Interactive. This research on DTC was published as Health Affairs Web Exclusives: "Consumers' Reports On The Health Effects Of Direct-To-Consumer Drug Advertising", February 26, 2003, Joel S. Weissman, David Blumenthal, Alvin J. Silk, Kinga Zapert, Michael Newman, Robert Leitman & "Physicians Report On Patient Encounters Involving Direct-To-Consumer Advertising", April 28, 2004, Joel S. Weissman, David Blumenthal, Alvin J. Silk, Michael Newman, Kinga Zapert, Robert Leitman, Sandra Feibelmann.)

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experience to determine the appropriateness of a particular therapy for a particular patient. To support the role of the health care professional, the goal of DTC prescription medicine advertising must be to give the consumer a good understanding of the disease or condition discussed in the advertisement and an appreciation of the key risks and benefits of the advertised product sufficient to result in meaningful dialogues between patients and physicians.

BMS appreciates the opportunity to provide comments and commends FDA for this initiative.

Sincerely,



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