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AdvaMed
Advanced Medical Technology Association

February 28, 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 Medicinal Products

Dear Sir or Madam:

These comments are submitted on behalf of the Advanced Medical Technology Association (AdvaMed). AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. More than 70 percent of our members have less than $30 million in domestic sales annually.

AdvaMed appreciates the opportunity to present the device industry perspective on consumer-directed promotion of regulated medicinal products, specifically restricted medical devices. Although relative newcomers to direct-to-consumer (DTC) advertising, our members recognize the benefits of DTC promotion and fully support DTC advertising of restricted devices in broadcast and print as a way of increasing consumer awareness and understanding of devices and getting them more involved and informed in their own treatment options.

GENERAL COMMENTS ON DIRECT-TO-CONSUMER ADVERTISING

In considering DTC promotion, it is important to distinguish between materials provided to healthcare professionals and materials provided to consumers. Based on the information provided in the September 13, 2005 *Federal Register Notice*, we believe FDA's focus on DTC promotional materials provided to non-healthcare consumers is

appropriate. Unlike the pharmaceutical industry, DTC advertising of restricted devices to non-healthcare consumers in broadcast and print is a relatively new phenomenon. The majority of the device industry does not market products directly to the general public.

The medical device industry's experience with DTC advertising has been influenced by the pharmaceutical industry's experience and regulations. The device industry has taken note of the benefits to the public of DTC promotion. They include: (1) better quality dialogue between the patient and health care provider as the patient is more informed about disease states and potential medical options; (2) the ability to inform consumers of potential new medical options in a timely manner allowing them to become their own advocates; and (3) providing patient advocacy/support groups with information that may be used to communicate with members and increase awareness. Recognizing these benefits, in the future, use of DTC promotions will likely become an important component of the educational and marketing apparatus of many medical device companies. However, it is unlikely that it will reach the level of the pharmaceutical industry.

As FDA stated in the Notice of the Hearing, there are no device-specific regulations establishing requirements for the content or format of DTC advertisement for restricted devices. However, several provisions of the Federal Food, Drug and Cosmetic Act (the "Act") govern restricted device DTC advertising. Section 502(r) of the Act requires manufacturers to include "in all advertisements and other descriptive printed matter . . . a true statement . . . and a brief statement of the intended uses of the device and relevant warnings, precautions, side-effects, and contraindications . . . ." Device manufacturers vigorously adhere to the requirement to communicate to consumers relevant risk information related to the indication(s) being advertised. We believe that complying with this requirement ensures that consumers receive accurate and non-misleading risk information. We also believe that any additional regulation is unnecessary.

Because there are differences in the regulatory (or statutory) requirements governing pharmaceuticals and restricted medical devices, there are also differences in the way devices and drugs are advertised. For example, a device manufacturer is not obligated to, but may choose to, disseminate a device's labeling in connection with a DTC advertising campaign. The product labeling is generally written to educate the healthcare professional on how to safely perform a procedure with the device.[1] In these instances, providing product labeling to the consumer would be of little benefit to the consumer and it would be up to the healthcare professional to decide what information is appropriate to provide to the patient.

The way patients gain access to certain medical devices also plays a role in the way they are advertised. While consumers may easily fill a prescription for a drug, they cannot pick up most restricted devices at their local pharmacy. Selection and use of a medical

[1] We note that there are restricted devices that are used by patients (e.g., hearing aids). Such devices have labeling tailored to the patient population. In addition, in some PMA approval letters, FDA has required patient labeling for a restricted device.

device generally requires intervention by a highly trained healthcare professional providing an opportunity for a learned intermediary to influence or even dictate product selection.

RESPONSES TO THE SPECIFIC QUESTIONS POSED BY FDA

Does current DTC promotion present the benefits and risks of using medical products in an accurate, non-misleading, balanced, and understandable way?

Device manufacturers comply with the existing statutory requirement to provide "a true statement" and "a brief statement of the intended uses of the device and relevant warnings, precautions, side-effects, and contraindications. . . ." There is great effort on the part of manufacturers to present the benefits and risks of using their device in an accurate, non-misleading, and balanced way. For some devices, FDA specifies the language deemed acceptable to communicate the risks and benefits of the device. However, because most of device risk information communication is generally directed at healthcare providers, AdvaMed believes it would be useful to have guidance on how best to present risk information in the brief statement information to consumers.

Use of certain standard advertising strategies

FDA has questioned whether the use of actors or celebrity endorsers mislead consumers about the risk-benefit tradeoffs of restricted medical products. AdvaMed supports disclosure of the use of non-patients (e.g., actors) in the promotional activities and that certain parts of the information be supplied by the manufacturer.

With respect to celebrity endorsers, we believe they serve the important purpose of garnering attention for device therapies, particularly relatively unknown device therapies or device therapies where there are no realistic alternatives to treatment. AdvaMed believes that some of the Federal Trade Commission's well established principles regarding endorsements and testimonials can serve as sound guidelines for truthful and non-misleading advertising in the endorsement context. These basic principles should include: (1) The endorsement must reflect the honest opinion, findings or experiences of the endorser; (2) Endorsers represented directly or indirectly as actual users of the product should be actual users of the product or their relationship to the product should be disclosed; (3) The statements by the endorser must be as supportable as if the representations were made by the advertiser; advertisers will be held responsible for the truth of the endorser's statements, and a statement by an endorser which cannot be substantiated by the advertiser cannot be used, even if the endorser sincerely believes it to be true, particularly in the area of health and safety claims; and (4) A celebrity endorser should be contacted at reasonable intervals, especially when there have been material changes to the advertiser's product or when new information regarding the product has

been learned.[2] We strongly believe that application of these four basic guidelines help ensure the truthfulness of the endorsements and help prevent a company from using a celebrity endorser to make representations that the company otherwise lawfully would not be able to make. AdvaMed encourages the agency to use these basic principles to support the use of celebrity endorsers for medical device advertising.

Could changes in the requirements for disclosure of certain information in broadcast advertising improve the usefulness of this information for consumers?

FDA has expressed concern regarding the consumer's ability to comprehend and process information contained in the major statement and has questioned whether there is a need to make changes to the requirements. Analogous to the drug requirement for a major statement is the device requirement for brief statement. The legal requirement is that the statement contains the relevant warnings, precautions, side-effects and contraindications. AdvaMed does not believe that changes to the device requirements are needed. Specifically, we believe that the basic requirement that a device manufacturer must disclose relevant information related to the indication(s) being advertised must be maintained. Recognizing that this information should be specifically tailored to non-healthcare consumers, the attention should be focused on how this information is disclosed to consumers. As stated previously, we believe that medical device specific guidance providing direction on how to tailor technical language to non-healthcare consumers would be beneficial in improving the usefulness of this information for consumers.

FDA made reference to dissemination of package labeling. While there is currently no requirement in the Act or the regulations to disseminate device package inserts to consumers, we reiterate that device package inserts are written primarily for the learned intermediary and as such would be of little benefit to consumers.

Is there a way to make information in DTC promotion of medical devices more useful to consumers?

FDA has indicated that part of the reason for holding the hearing was to determine whether regulations governing restricted device advertising are necessary. As stated previously, Section 502(r) of the Act adequately lays out the necessity for communication of relevant risk information. While additional regulation is not needed, device specific guidance is needed. See AdvaMed comments of August 10, 2004 on FDA Draft Guidances for Industry on Improving Information about Medical Products and Health Conditions (Docket Number 2004-0042).

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[2] 16 C.F.R. Sec. 255 Guidelines Concerning the use of Endorsements and Testimonials in Advertising

Guidance allows for continued innovations and refinements over time and is a more appropriate mechanism to address the diversity of medical devices and the differences in types and significance of risks. To date, guidance development in this area has addressed the issues from a decidedly drug perspective and failed to consider that devices may require a different approach.

Although there are several areas where device-specific guidance would be beneficial, we believe that the medical device industry and non-health consumers would benefit the most from the development of a guidance document addressing how to present the information contained in the "brief statement" to consumers. Device manufacturers have a great deal of expertise relaying technical information to healthcare professionals, but struggle with how to present the technical language to consumers.

The effort to address similar concerns in over-the-counter medical product labeling provides an example of what can be done. FDA has used guidance documents, such as "Write It Right" (August 1993), to address the presentation of technical information in lay language. A similar approach to the brief statement is appropriate. The length of the guidance document "Write It Right," which is 76 pages, illustrates how difficult it would be to address this topic via regulation.

In addition, the Center for Devices and Radiological Health (CDRH) has issued guidance on patient labeling for Postmarket Approval (PMA) devices. Device manufacturers and CDRH can refer to the patient labeling guidance for consumer-friendly language of the required "brief summary" information.

Further, how best to present such risk information to consumers most likely will vary depending on the medical device type. Distinguishing these factors should play a central role in the development of guidance in this area.

As FDA considers DTC guidance documents for medical devices, it is important to consider the differences between drugs and medical devices. Guidance for medical devices must take into account the distinct statutory provision governing restricted medical device advertising, as well as the unique properties of medical devices and their role in health care, and not simply mirror guidance developed for prescription drugs.

As new communication technologies emerge, they create opportunities for novel approaches to DTC promotion. What issues should the agency consider with regard to the effect of these technologies on DTC promotion?

There will always be new communication technologies. With respect to devices, if we adhere to the basics of Section 502(r) of the Act, communication of relevant risk information, the media used to disseminate the information should not matter. FDA should continue efforts to ensure that the information provided via broadcast media is written in language that will be understandable to the consumer.

What action should FDA take when companies disseminate violative promotional material to consumers?

FDA's action in response to DTC promotional material that is found violative is dependent on the circumstances. First, FDA should assess (1) the risk to public health based on the total impression of the advertisement, (2) the messages that the consumer will take away, and (3) the public health risk associated with those messages. Second, FDA should consider whether or not the product is available directly to the consumer for use or whether there is intervention by a medical professional before the consumer can obtain the product. The agency's response needs to depend on a serious consideration of these two factors.

If there is a public health risk and/or the consumer has direct access to the product, and the DTC promotional material is found violative, AdvaMed supports the actions outlined by FDA in the Federal Register Notice. However, we do believe that there would also be benefit from a guidance document that outlines FDA procedures and provides examples of what FDA would consider violative promotional material.

With regard to pre-review of promotional materials, while there is no requirement that drug or device companies submit promotional materials to FDA for review, many companies choose to do so. A company may choose to use pre-review of promotional materials as a tool; submitting promotional materials when they believe that it is useful to receive FDA's input and/or imprimatur prior. AdvaMed supports this voluntary use by companies and suggests that more resources are needed within CDRH to provide timely and meaningful review and feedback on these voluntary submissions.

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AdvaMed appreciates the opportunity to provide these comments. To provide FDA with a complete picture of our view of the differences between device and drug regulation in this area, I have attached our August 2004 comments on DTC advertising. If you have any questions regarding our comments, please feel free to contact me directly.

Respectfully submitted,

Carolyn D. Jones

Carolyn D. Jones
Associate Vice President
Technology and Regulatory Affairs

Attachment