DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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STATEMENT OF

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BEFORE THE

SPECIAL COMMITTEE ON AGING

UNITED STATES SENATE

HEARING ON

MARKETING OR MEDICINE:

ARE DIRECT-TO-CONSUMER MEDICAL DEVICE ADS PLAYING DOCTOR?

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am Daniel Schultz, M.D., Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to discuss the Agency's role and experience in oversight of direct-to-consumer (DTC) advertising of medical devices. My testimony will review how FDA regulates the post-clearance and post-approval promotion and advertising of medical devices, including consumer-directed promotion and advertising, and clarify some important differences between the regulation of drug advertising and medical device advertising. I also will review the Agency's enforcement actions, outreach, and other compliance activities.

Part of FDA's mission to protect the public health is to help ensure that information about medical devices is not false or misleading. This is accomplished through surveillance, enforcement, and education by the Office of Compliance within CDRH in an effort to ensure proper communication of labeling and promotional information to both health care professionals and consumers.

Helping all Americans make better-informed decisions concerning their health care is a priority of the Agency. Opinion surveys conducted by FDA's Center for Drug Evaluation and Research demonstrate that DTC advertising can encourage consumers to seek information from their physician or pharmacist about an illness, condition, or medical product.

STATUTORY AND REGULATORY AUTHORITY

FDA regulates the manufacture, sale, and distribution of medical devices in the United States under authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). Medical devices are assigned to one of three regulatory classes based on the level of control necessary to provide reasonable assurance of the safety and effectiveness of the device. Devices posing the lowest risk, such as elastic bandages, are placed in Class I. Class I devices are subject to the "general controls" applicable to all devices. Class II devices, which pose incrementally greater risk and for which general controls are not sufficient to provide reasonable assurance of safety and effectiveness, are subject to "special controls" in addition to general controls. Special controls may include labeling requirements, performance standards, post-market surveillance studies, or other controls the Agency deems necessary to provide reasonable assurance of the safety and effectiveness of the device. The riskiest devices, such as some implants and life-supporting or life-sustaining devices, are placed in Class III and generally are subject to premarket approval (PMA), which means that an application must be submitted to and approved by FDA before the device may be legally marketed. PMA applications must contain information that provides a reasonable assurance of the safety and effectiveness of the device for its intended use and generally include pre-clinical testing and clinical study data.

Under the FD&C Act, FDA has regulatory authority over the labeling of all medical devices. However, FDA's regulation of medical device advertising is limited to a subset of medical devices. The Federal Trade Commission (FTC) regulates the advertising, as

opposed to the labeling, of most medical devices under sections 12-15 of the Federal Trade Commission Act, which prohibit false or misleading advertising of certain products that FDA regulates. (Title 15, United States Code [U.S.C.] section 52-55). Sections 502(q) and 502(r) of the FD&C Act authorize FDA to regulate the advertising of certain devices, which are known as restricted devices (discussed below). Section 502(r) also states that restricted devices are not subject to sections 12-15 of the Federal Trade Commission Act. Thus, FDA regulates the advertising of restricted medical devices while the FTC regulates the advertising of non-restricted devices.

Medical devices may become restricted in one of three ways. (Prescription devices may or may not be restricted devices. See sections 502(f) and 520(e) of the FD&C Act. 21 U.S.C. 352(f) and 360j(e)). Under section 520(e) of the FD&C Act, FDA may by regulation restrict a device to sale, distribution or use only upon the authorization of a practitioner licensed by law to administer or use such device, or upon other conditions that FDA prescribes in the regulation, if FDA determines that there cannot otherwise be reasonable assurance of the device's safety and effectiveness (21 U.S.C. 360j(e)). Alternatively, under section 515(d)(1)(B)(ii) of the FD&C Act, FDA may require, as a condition of approval of a Class III device, that its sale and distribution be restricted, but only to the extent that the sale and distribution of the device may be restricted by a regulation promulgated under section 520(e) of the FD&C Act (21 U.S.C. 360e(d)(1)(B)(ii)). Finally, under section 514(a)(2)(B)(v) of the FD&C Act, FDA may establish, as part of a performance standard promulgated in accordance with section 514(b) of the Act, requirements that the sale and distribution of a device be restricted, but

only to the extent that the sale and distribution of the device may be restricted by a regulation promulgated under section 520(e) of the FD&C Act (21 U.S.C. 360d(a)(2)(B)(v)). Most Class III premarket approval devices have been restricted as a condition of approval, in accordance with section 515(d)(1)(B)(ii) and a few Class I and II devices are restricted by regulation (e.g., hearing aids), in accordance with section 520(e).

Sections 502(q) and 502(r) of the FD&C Act provide the Agency with authority to regulate restricted device advertisements. These sections of the FD&C Act impose specific requirements on the advertising of restricted devices. Section 502(q) of the FD&C Act provides that a restricted device is misbranded if its advertising is false or misleading in any particular. Section 201(n) of the Act provides that, in determining whether advertising is misleading, there shall be taken into account not only representations made or suggested in the advertising, but also the extent to which the advertising fails to reveal material facts regarding the representations made or the consequences that may result from use of the device under its labeled, advertised, or usual conditions of use.

Section 502(r) of the FD&C Act provides that a restricted device is misbranded if any of the advertising pertaining to the device does not contain a brief statement of the device's intended use and relevant warnings, precautions, side effects and contraindications. However, the 502(r) advertising requirements do not apply to any printed matter that FDA determines to be labeling under section 201(m) of the FD&C Act. That section defines

labeling as all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers or accompanying such article. Neither the restricted device advertising provisions nor any other provision of the FD&C Act addresses issues of product price or medical device coverage by insurance companies.

GUIDANCES FOR INDUSTRY

In 2004, FDA issued two draft guidances pertaining to advertising of restricted devices. One, issued in February 2004, was entitled, "Draft Guidance for Industry and FDA: Consumer-Directed Broadcast Advertising of Restricted Devices." This draft guidance is intended to assist manufacturers, packers, and distributors of medical devices who are interested in advertising their restricted devices directly to consumers through broadcast media, such as television, radio, or telephone communication systems. The draft guidance describes an approach for companies to meet the statutory requirement in section 502(r) that these advertisements contain a brief statement of the intended uses of the device and the relevant warnings, precautions, side effects, and contraindications (21 U.S.C. 352(r)(2)). In the draft guidance, FDA recommends ensuring that audiences exposed to restricted device advertisements on television and radio have convenient access to the labeling of the advertised restricted device. The proposed approach recommends reference in the broadcast ad to different sources consumers could use to obtain more detailed labeling information: a toll-free telephone number, a Web site address, a concurrently running print advertisement, and their health care professional.

The draft guidance can be found on the FDA Web site at: *http://www.fda.gov/cdrh/comp/guidance/1513.htm*l.

Also in 2004, FDA issued a draft guidance entitled, "Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms" (January 2004), which covers both drugs and medical devices. This draft guidance is intended to assist industry regarding "help-seeking" and other disease awareness communications, including a description of the specific characteristics of communications that fall into this category. Disease awareness communications are communications disseminated to health care practitioners that discuss a particular disease or health condition, but do not mention any specific drug or medical device or make any representation or suggestion concerning a particular drug or medical device. Help-seeking communications are disease awareness communications directed at consumers. Generally, help-seeking and other disease awareness communications do not constitute labeling or advertising, and therefore are not subject to regulation by FDA. The Agency believes that such communications can provide important health information to consumers and health care practitioners, and can encourage consumers to seek, and health care practitioners to provide, appropriate treatment. The draft guidance can be found on the FDA Web site at: *http://www.fda.gov/cder/guidance/6019dft.htm*.

DISTINCTIONS FROM REGULATION OF DTC DRUG ADVERTISING

There is no statutory requirement that restricted device advertisements be submitted to FDA for review prior to dissemination or broadcast. Similarly, with only rare exceptions (primarily for drug products receiving accelerated approval), there is no statutory requirement that prescription drug advertisements be submitted to FDA for review prior to dissemination or broadcast.

The main difference occurs at the time of dissemination or broadcast. Medical device companies are not required to submit to FDA copies of promotional materials for medical devices, including broadcast advertisements, at the time of dissemination. By contrast, pharmaceutical companies are required to submit to FDA copies of promotional materials for prescription drug products at the time of initial dissemination, by submission of a Form 2253.

FDA's drug advertising regulations provide that prescription drug advertisements cannot be false or misleading or omit material facts, and must present a fair balance between benefit and risk information. Further, for print advertisements, the regulations specify that a brief summary of all the risks addressed in the product's approved labeling also must be disclosed. For broadcast advertisements, the drug regulations require ads to disclose the most significant risks – the most serious and most common – that appear in the labeling. The regulations further require that broadcast advertisements either contain a brief summary of all necessary information related to risk from the labeling or make adequate provision for dissemination of the product's FDA-approved labeling in connection with the ad.

By contrast, FDA's device regulations do not contain specific requirements regarding the content of advertisements for restricted medical devices. Regulation of restricted device advertising thus stems directly from the statute, sections 502(q) and (r) discussed earlier, under which a restricted device is misbranded if its advertising is false or misleading in any particular or does not contain a brief statement of the device's intended use and relevant warnings, precautions, side effects and contraindications. In addition, the February 2004 draft guidance is meant to assist companies to achieve compliance with these statutory requirements.

PROMOTIONAL MATERIAL AND TYPES OF ADVERTISING

For restricted devices, CDRH regulates advertisements in addition to the promotional labeling that is disseminated by or on behalf of the medical device's manufacturer, packer or distributor. This includes materials that companies disseminate or place for publication that are directed to consumers and physicians, such as ads printed in magazines, journals and newspapers, ads broadcast over television, radio and telephone, brochures, and detailing pieces. The majority of the materials produced are intended for promotion to health care professionals, such as detail aids used by manufacturer representatives, convention displays, file cards, booklets, and videotapes, which are distinct from advertising directed toward consumers.

Of the three different types of advertising that companies use to communicate with consumer, CDRH regulates two of them, "product-claim" and "promotional reminder"

ads. The third type, "help-seeking" and other disease awareness ads, are not generally regulated by FDA, as described in the 2004 draft guidance and discussed earlier.

"Product-claim" ads are those ads which generally include both the name of a product and its indications for use, or make a claim or representation about a medical device. "Promotional reminder" ads may disclose the name of the medical device and certain specific descriptive information or price information, but they do not give the device's indications for use or make any claims or representations about the device.

OVERSIGHT

CDRH's Office of Compliance (OC) is responsible for the surveillance and enforcement of violations contained in the promotional materials of all medical device companies. OC staff review trade complaints about promotion from competitors, health care professionals, and consumers. OC also reviews promotional activities in the commercial exhibit halls of scientific meetings and promotional meetings. Trade complaints are the primary source from which CDRH receives information regarding promotional violations by medical device companies. OC, however, does not track the number of trade complaints received. In rare instances, companies send proposed new DTC broadcast concepts to OC for review and comment in advance of use, although companies are under no statutory obligation to submit their concepts or follow OC's advice. Generally, though, OC does not see final broadcast ads before airing on TV or radio. OC's involvement is mainly post hoc, once the materials have appeared in the public domain.

Educational Programs for Industry

FDA seeks to increase voluntary compliance by industry through educational programs. These programs include:

Outreach Programs: CDRH staff participate in many panel discussions and presentations for groups including industry, law firms, consultants to industry, and marketing and advertising agencies. These programs are intended to increase the understanding of these groups concerning the statutory requirements relating to promotion of medical devices so industry can better comply with these requirements.

Web site Postings: CDRH posts on its Web site all Warning Letters relating to violations involving the promotion of medical devices. These letters serve as useful examples of violations that the Agency has acted against and help industry understand what types of promotion are unacceptable.

Guidances: FDA has published guidances in areas for which industry seeks clarification. Guidances help industry understand FDA's current thinking and recommend how to comply with the FD&C Act.

Public Hearing on DTC Promotion: On November 1-2, 2005, FDA held a public hearing to provide an opportunity for broad public participation and comment on DTC promotion of regulated medical products, including prescription drugs for humans and animals, vaccines, blood products, and medical devices. FDA held this hearing because it believes the Agency, the industry, and other members of the public that have experience with DTC

promotion need to understand what regulatory issues may need to be addressed. FDA was interested particularly in hearing the views of individuals and groups most affected by DTC promotion, including consumers, patients, caretakers, health professionals (physicians, physicians' assistants, dentists, nurses, pharmacists, veterinarians, and veterinarian technicians), managed care organizations, and insurers, as well as the regulated industry. FDA obtained valuable information from its stakeholders at this public meeting and in comments submitted to the docket for the meeting. FDA is using this information to help guide its policy on the regulation of DTC promotion.

ENFORCEMENT RELATED TO PROMOTION AND ADVERTISING OF MEDICAL DEVICES

CDRH's surveillance and enforcement activities cover promotion and advertising directed at both consumers and health care providers. For example, last year, CDRH initiated a major enforcement initiative in the area of off-label promotion of medical devices directed to health care professionals. On March 12, 2007, CDRH met with twenty different manufacturers of biliary (pertaining to bile duct or gallbladder) stents to discuss off-label promotion and use of biliary stents in vascular applications. When indicated for use in treatment of malignant biliary obstruction, biliary stents have been cleared by FDA as Class II devices, through review of premarket notification (510(k)) submissions containing in-vitro bench testing. In contrast, vascular stents have been reviewed and approved as Class III devices, following submission of PMA applications containing additional pre-clinical testing and clinical study data. At the March 12 meeting with biliary stent manufacturers, CDRH identified several instances where we believed

companies were promoting their biliary stent products for uses beyond those cleared by the Agency in the firms' 510(k) submissions.

CDRH requested that firms review their devices' labeling, including all promotional labeling contained on their Web sites, to ensure they were consistent with the indications for use that were cleared in the firms' 510(k) submissions. CDRH also requested that firms stop promoting biliary stents at vascular meetings. CDRH asked that firms inform their customers of the risk of serious adverse events when biliary stents are used off-label in the peripheral vasculature. CDRH also requested that the firms conduct appropriate clinical trials to create accurate and adequate labeling and instructions for use in the peripheral vasculature in support of a PMA application. For several months after the meeting, CDRH worked with companies to ensure that they fully implemented corrective actions in an effort to achieve compliance with the law. Ultimately, all companies involved in the meeting followed CDRH's requested actions. Since the meeting, several companies have initiated clinical trials regarding the use of biliary stents in the vasculature in an effort to obtain PMA approval and appropriate labeling for this intended use of these devices. OC confirms the continued compliance of the companies that were involved in the meeting through periodic monitoring and review of their promotional materials for their biliary stent products.

The prevalence of DTC advertising for restricted medical devices is a fraction of that for drugs, but is increasing. OC performs targeted surveillance and investigation of DTC advertisements for restricted devices and promotional labeling for all devices. Examples

include biofeedback devices, ultrasound devices used in general imaging, cardiac, and intraoperative applications and surgical instrument devices used to cut cardiac tissue. Enforcement tools that are available to address misbranded or adulterated devices include the issuance of regulatory correspondence such as untitled letters and Warning Letters, as well as enforcement actions including seizures, injunctions, civil money penalties, and referrals for criminal investigation or prosecution. Untitled letters cite violations that do not meet the threshold of regulatory significance for a Warning Letter. Warning Letters are issued for violations of regulatory significance that, if not promptly and adequately corrected, could lead to enforcement actions without further notice.

The Agency has issued untitled letters and Warning Letters to companies for broadcasting and disseminating DTC advertising and promotional labeling that violate the FD&C Act. FDA's enforcement actions request that companies stop using the violative materials. In some cases, the Agency asks companies to send corrective letters to correct product misimpressions created by false or misleading materials. FDA attempts to target its resources at the violations with the greatest public health impact.

CONCLUSION

FDA is committed to ensuring that medical device promotion and advertising, including DTC advertising, is truthful and not misleading, that it helps consumers make better informed choices about their health and health care, and that it helps prevent potential misconceptions about benefits and risks of the advertised treatment.

Proponents of DTC promotion of medical products argue that it has educational value and will improve the physician-patient relationship, increase patient compliance with therapy and recommended physician visits, and generally satisfy consumer interest in obtaining desired medical product information. Opponents contend that consumers do not have the expertise to evaluate accurately and comprehend such advertising, that physicians will feel pressure to recommend treatment that is not needed, and that DTC promotion will damage the physician-patient relationship and increase the price of medical products. FDA believes that, if done properly, medical device advertising can provide consumers with important information about medical devices and new indications for existing medical devices, as well as information about symptoms of treatable illnesses and other conditions. Done properly, medical device advertising can assist consumers in taking a proactive role in improving their health. However, to be of value, these advertisements must not be false or misleading.

As a result, FDA will continue to monitor DTC advertising to help ensure that promotional activity is truthful and not misleading. Through these efforts, the Agency will maintain vigilance in this area and continue enforcement practices necessary to address the unique issues and challenges presented by consumer-directed advertising of restricted medical devices and to target violations with the greatest public health impact.

This concludes my remarks, Mr. Chairman. I will be glad to answer any questions you may have.