



**Medtronic**

*When Life Depends on Medical Technology*

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**DOCKET NO. 2005N-0354**

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
<http://www.fda.gov/dockets/ecomments>

**Re: Docket No. 2005N-0354 Public Hearing on Consumer-Directed Promotion  
of Regulated Medical Products**

Dear Sir or Madam:

Medtronic is the world leader in medical technology, providing lifelong solutions for people with chronic disease. We offer products, therapies and services that enhance or extend the lives of millions of people. Each year, 5 million patients benefit from Medtronic's technology, used to treat conditions such as diabetes, heart disease, neurological disorders, and vascular illnesses.

Medtronic supports the comments submitted by the Advanced Medical Technology Association (AdvaMed) in response to FDA's September 13, 2005 Federal Register Notice relating to consumer-directed promotion of medical products (the "Federal Register Notice").

We applaud FDA for seeking public input on the issues related to direct-to-consumer (DTC) promotion of medical devices. Medtronic agrees that the regulatory framework for the labeling and advertisement of medical devices differs from that of prescription drugs. We support the comments submitted by AdvaMed to Docket Number 2004D-0042 on August 10, 2004, relating to two Draft Guidances for Industry on Improving

Information about Medical Products and Health Conditions, and incorporate those comments by reference herein (“2004 AdvaMed Draft Guidance Comments”).

Medtronic also incorporates herein by reference its comments submitted to Docket 2004D-0042 on August 10, 2004. We continue to believe that it is imperative that differences in the way devices and drugs are advertised is recognized in the regulatory scheme, and we welcome FDA guidance that takes this into account.

In particular, we note the potential public health benefit of DTC communications to raise awareness of innovative therapies for serious, intractable diseases. For refractory or rare conditions, even healthcare providers may be unaware of new therapies. Patients or their families may need to identify healthcare providers with specialized training and knowledge to access these therapies, and the first step is to know that such therapies exist. Communications to raise awareness of such therapies and to encourage patients to seek them out serve a public health interest. Subjecting such communications to the same regulatory requirements as prescription drug advertising would discourage these important health messages.

The complexity of the therapy and how the patient gains access to the therapy should also be taken into account. Evaluating whether a device therapy is appropriate for a patient can be a multi-step process involving health care professionals of different specialties. Payers often require pre-authorization of device therapy based on demonstrated medical necessity. Complex device therapies often require considerable commitment on the part of the patient, family and health care team, typically including substantial patient/family education, and evaluation of complex risk/benefit information. It is very different from filling a prescription at the local pharmacy. DTC communications about such therapies should be truthful, balanced, and not misleading, but should not be expected to provide comprehensive risk/benefit information that may be more appropriately provided by the health care team. Unlike pharmaceutical adverse events profiles, risks from most medical devices are local and most frequently determined by the specific situation of the patient. We request that the Agency consider the diversity of medical products, how patients gain

access to them, and the way in which risks are determined and understood when issuing any guidance on DTC communications.

Medtronic's comments on the specific questions in the Federal Register Notice are below:

1. Does current DTC promotion present the benefits and risk of using medical products in an accurate, nonmisleading, balanced and understandable way?

Medtronic supports consumer-friendly presentation of relevant information in DTC communication. Not all the information in the brief statement<sup>1</sup> will be relevant to a consumer audience, particularly where the device user is a health care professional rather than the patient. Medtronic requests that FDA recognize that the information considered relevant and necessary can vary depending on the circumstances, including the intended audience (e.g., health care professional vs. patient), the intended message (e.g., raising awareness of therapy options vs. promoting a particular product), and on the particular therapy (e.g., a prescription product available at the local pharmacy vs. an implantable device that requires extensive pre-implant screening) in any regulatory guidance issued by FDA.

Medtronic supports identifying the prescription status of restricted devices and reinforcing the importance of the patient/physician interaction in evaluating whether the therapy is right for the patient and in communicating relevant benefits and risks. For example, advertisements could include language such as, "This therapy is not for everyone. Please consult your physician. A prescription is required. For further

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<sup>1</sup> Section 502(r) of the Federal Food, Drug and Cosmetic Act (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 ...", often referred to as the "brief statement."

information, please contact (toll-free number/website).” For devices that are surgically implanted and may have surgery-specific risks, language such as “As with any surgical procedure, the (name of procedure or device) may present risks. Please consult your physician,” which respects the role of the physician as the intermediary who can best provide the patient with information on the specific surgical procedure and relevant risks.

Medtronic supports application of certain principles of the existing FTC guides concerning use of endorsements and testimonials<sup>2</sup> to medical products advertising, including restricted devices. The use of celebrities in advertisements in accordance with these principles can serve the important public health purpose of affording greater visibility of innovative device therapies, therapies where there are no alternative treatments, and therapies associated with rare or stigmatized diseases. These communications should not be discouraged.

FTC’s longstanding principles regarding endorsements and testimonials are based on sound tenets of truthful and nonmisleading advertising. These 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. These four basic principles help ensure that a company cannot use a celebrity endorser to make representations that the company otherwise would not be able to make. Medtronic encourages the agency to use these basic principles in supporting the use of celebrity endorsers for medical device advertising.

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<sup>2</sup> 16 C.F.R. 255

2. Could changes in certain required prescription drug disclosures – the package insert for print “promotional” labeling and the brief summary for print advertisements – improve the usefulness of this information for consumers?

Medtronic has no comment on this question.

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

Medtronic incorporates by reference the 2004 AdvaMed Draft Guidance Comments, which recommended specific changes to the proposed mechanisms for disclosing information to consumers in connection with broadcast advertising, including, without limitation:

- Clarifying that the brief statement need refer only to the warnings, precautions, side effects and contraindications relevant to the indication discussed in the advertisement;
- Clarifying that the brief statement may be tailored to the intended audience (for example, omitting technical warnings relevant only to the physician using a device);
- Eliminating the required dissemination of device labeling, as the device labeling is typically a user's manual that does not provide useful risk/benefit information to patients, and the manufacturer is not legally required to distribute the device labeling to meet its brief statement requirements;
- Modifying the proposed mechanisms for voluntary dissemination of product labeling in view of the differences between prescription drug and device labeling and distribution channels.

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

The Agency's guidance on patient labeling for medical devices <sup>3</sup> has been helpful to industry, and we suggest the Agency consider developing guidance on consumer-friendly brief statements for DTC advertisements for medical devices.

5. 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?

Medtronic believes that the general advertising and promotional principles can be applied to new communication technologies without additional regulation. New communication technologies, such as the internet, enable consumers to find more in-depth information on medical products, and Medtronic believes the Agency should support this valuable resource for consumers and health care professionals. Manufacturers can serve an important public health role by providing truthful, non-misleading and balanced information on diseases and therapies via the internet with far more depth than can be accomplished in a 60-second broadcast advertisement or even a print ad. The Agency's current guidance on broadcast advertisements does not apply to technologies such as the internet, which Medtronic believes is appropriate, as the technology allows the manufacturer to provide easy access to the brief statement.

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

We believe the Agency should provide guidance to the industry on acceptable practices, to the extent consistent with resources. When a company distributes material found violative, the company should respond with a corrective action plan, and, for recurring violations, a preventive action plan. The plan should be tailored to the violations, and should take into account the public health risk posed by the violation, including whether the medical product is available directly to consumers for use without intervention by a

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<sup>3</sup> Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers, dated April 19, 2001.

health care professional. Medtronic does not support mandatory pre-review of device DTC advertising, but does not object to voluntary, industry-initiated pre-review of DTC advertising that presents novel issues, to the extent that FDA has adequate staff to perform the review in a timely manner. However, in the vast majority of cases, we believe FDA's resources are more effectively allocated to developing guidance and taking action against violators.

We thank the Agency for the opportunity to comment on this important topic, and look forward to working with the Agency to develop guidances that set clear and appropriate standards that recognize the differences between prescription pharmaceuticals and restricted medical devices.

Respectfully submitted,

/s/

Susan Alpert, Ph.D., M.D.

Vice President, Chief Quality and Regulatory Officer  
Medtronic, Inc.