



June 2, 2000

Dockets Management Branch
Food and Drug Administration
HFA 305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 00D-0785: "Guidance on Medical Device Patient Labeling."

Dear Madam or Sir:

The Health Industry Manufacturers Association (HIMA) is pleased to submit these comments on the Food and Drug Administration's (FDA's) draft document titled "Guidance on Medical Device Patient Labeling." HIMA is a Washington D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture more than 90 percent of the \$68 billion of health care technology products purchased annually in the United States, and more than 50 percent of the 159 billion purchased annually in the world.

HIMA appreciates the opportunity to provide the following comments on the draft guidance.

General Comments

We commend FDA's motives in developing a guidance document that describes how to make medical device patient labeling understandable to and usable by patients. We agree that labeling intended for patients should be clear, well written, and provide all of the information that a patient will require to operate the device.

The ultimate challenge is to provide needed information without overwhelming the user with unnecessary information. We believe that some of the information FDA has recommended be included in patient labeling will not improve user understanding of how to use these devices and may dilute the impact of more important user information. It is difficult to get users, whether they are physicians, patients or lay caregivers to read the instructions for use. If we cloud patient labeling with additional information of questionable value to the user, we may lose the benefits already gained in this area.

FDA's recommendations are to be applied to a wide span of medical devices. Some of the recommendations may not be applicable across devices. Reviewers must understand that manufacturers are not accountable for the entire content of the guidance document. It must be clear that labeling for a patient-operated device (e.g., a glucose

World Leaders in Health Care Innovation

1200 G STREET, N.W., SUITE 400
WASHINGTON, D.C. 20005-3814
(202) 783-8700 FAX (202) 783-8750

www.himanet.com

5655 .00 JUN -2 P4:07

00D-0785

OC2

monitor) may require a different structure and approach than labeling for a device where the patient's role is passive (e.g., an implantable cardio defibrillator). To force labeling for both types of devices into the same mold would be counterproductive, resulting in patient labeling with less rather than more utility.

It is unclear where this guidance document fits in regards to over-the-counter (OTC) devices, which have a long established history of consumer-friendly, informative labeling that has been painstakingly developed by industry with input from consumers and FDA. FDA's use of the term "patient" implies that a physician or other learned intermediary is involved with prescribing or recommending use of the device. In which case, the term "patient" would appear to refer to "prescription" devices. FDA should clarify whether this guidance is intended to apply to labeling for OTC devices or whether it is strictly intended for prescription medical devices.

Specific Comments

- When should you use medical device patient labeling

The guidance document recommends that patient labeling be used when patients or lay caregivers provide health information to aid their health care practitioner in deciding to use or not use devices in prevention, treatment or diagnosis. Although we do not believe that it is FDA's intent, we believe that FDA's recommendation would require patient labeling for all devices. Patients provide physicians with health information that aid them in determining what drugs, diagnostic tests, monitoring devices, etc. will be recommended. The guidance would require patient labeling for all such patient-physician interactions. Patient labeling is most important for devices operated or monitored by lay users. Patient labeling is also important to convey information to the lay persons regarding the risks and benefits associated with the use of a device or device procedure recommended by their physician. We recommend FDA limit the examples to these types of situations.

- Content and Organization

FDA suggests the subject and sequence for patient labeling. While we agree that the medical device patient labeling should flow logically and FDA's guidance is one way of organizing the information, it may not be the best way for every type of device. The suggestions focus heavily on the device, which may be appropriate for products that are operated by patients where the focus is on the device and what to do with it, i.e., operating instructions, maintenance, and troubleshooting. If the patient's role vis-à-vis the device is essentially passive, the labeling will convey less specific, less technical information. In which case, FDA's suggested content and organization might not be the best way of presenting such information.

We would not object to a list of topics or information that might be included in patient labeling, but the organization and wording should be at the discretion of the manufacturer. There is simply no compelling reason for all of the companies to conform to a single template.

- Purpose of the Device (Indications for Use)

The guidance document recommends that manufacturers briefly describe the FDA-cleared or approved indications for use. While the purpose of the device would provide important information to the user, for many devices the nuances of the indications for use would be either confusing or meaningless to patients. In addition, for a large number of devices, the patient's physician has already made the decision that the device would be appropriate, even if not strictly indicated. HIMA recommends that adding information regarding the cleared or approved indications for use be at the discretion of the manufacturer.

- Alternatives to the Device and Treatment

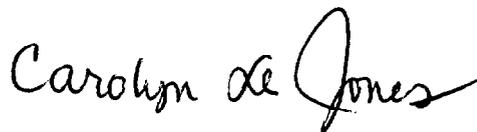
FDA recommends that the manufacturer inform the patient of other viable appropriate alternatives to the device and treatment. FDA is suggesting that manufacturers assume the role of the patient's physician. In some cases providing such alternatives would constitute interference in the patient-physician relationship. Also, if a manufacturer fails to inform a patient of one of a number of viable alternatives, it is unclear what legal liability this may impose on manufacturers. Therefore, HIMA requests that this information not be included in patient labeling.

- Clinical Studies

The guidance document recommends that manufacturers provide the patient clinical study information in simple, plain language. It is unclear how such information will assure the safe and effective use of devices. If meaningful clinical study information could be presented in simple, plain language, such information would be of no use to most patients. If FDA's ultimate goal is to assure that patients use devices properly and know and understand the risks and benefit of the device, such extraneous information may dilute the effect of more important information contained in the patient labeling. We suggest that FDA allow such information to be made available to patients upon request.

HIMA appreciates the opportunity to comment on FDA's draft guidance document.

Respectfully submitted,



Carolyn D. Jones
Associate Vice President
Technology and Regulatory Affairs



June 2, 2000

Dockets Management Branch
Food and Drug Administration
HFA 305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 00D-0785: "Guidance on Medical Device Patient Labeling."

Dear Madam or Sir:

The Health Industry Manufacturers Association (HIMA) is pleased to submit these comments on the Food and Drug Administration's (FDA's) draft document titled "Guidance on Medical Device Patient Labeling." HIMA is a Washington D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members manufacture more than 90 percent of the \$68 billion of health care technology products purchased annually in the United States, and more than 50 percent of the 159 billion purchased annually in the world.

HIMA appreciates the opportunity to provide the following comments on the draft guidance.

General Comments

We commend FDA's motives in developing a guidance document that describes how to make medical device patient labeling understandable to and usable by patients. We agree that labeling intended for patients should be clear, well written, and provide all of the information that a patient will require to operate the device.

The ultimate challenge is to provide needed information without overwhelming the user with unnecessary information. We believe that some of the information FDA has recommended be included in patient labeling will not improve user understanding of how to use these devices and may dilute the impact of more important user information. It is difficult to get users, whether they are physicians, patients or lay caregivers to read the instructions for use. If we cloud patient labeling with additional information of questionable value to the user, we may lose the benefits already gained in this area.

FDA's recommendations are to be applied to a wide span of medical devices. Some of the recommendations may not be applicable across devices. Reviewers must understand that manufacturers are not accountable for the entire content of the guidance document. It must be clear that labeling for a patient-operated device (e.g., a glucose

World Leaders in Health Care Innovation

1000 G STREET, N.W. SUITE 400
WASHINGTON, D.C. 20005-3811
(202) 783-6700 FAX (202) 783-5750

www.hima.org

5654 '00 JUN -2 P4:07

monitor) may require a different structure and approach than labeling for a device where the patient's role is passive (e.g., an implantable cardio defibrillator). To force labeling for both types of devices into the same mold would be counterproductive, resulting in patient labeling with less rather than more utility.

It is unclear where this guidance document fits in regards to over-the-counter (OTC) devices, which have a long established history of consumer-friendly, informative labeling that has been painstakingly developed by industry with input from consumers and FDA. FDA's use of the term "patient" implies that a physician or other learned intermediary is involved with prescribing or recommending use of the device. In which case, the term "patient" would appear to refer to "prescription" devices. FDA should clarify whether this guidance is intended to apply to labeling for OTC devices or whether it is strictly intended for prescription medical devices.

Specific Comments

- When should you use medical device patient labeling

The guidance document recommends that patient labeling be used when patients or lay caregivers provide health information to aid their health care practitioner in deciding to use or not use devices in prevention, treatment or diagnosis. Although we do not believe that it is FDA's intent, we believe that FDA's recommendation would require patient labeling for all devices. Patients provide physicians with health information that aid them in determining what drugs, diagnostic tests, monitoring devices, etc. will be recommended. The guidance would require patient labeling for all such patient-physician interactions. Patient labeling is most important for devices operated or monitored by lay users. Patient labeling is also important to convey information to the lay persons regarding the risks and benefits associated with the use of a device or device procedure recommended by their physician. We recommend FDA limit the examples to these types of situations.

- Content and Organization

FDA suggests the subject and sequence for patient labeling. While we agree that the medical device patient labeling should flow logically and FDA's guidance is one way of organizing the information, it may not be the best way for every type of device. The suggestions focus heavily on the device, which may be appropriate for products that are operated by patients where the focus is on the device and what to do with it, i.e., operating instructions, maintenance, and troubleshooting. If the patient's role vis-à-vis the device is essentially passive, the labeling will convey less specific, less technical information. In which case, FDA's suggested content and organization might not be the best way of presenting such information.

We would not object to a list of topics or information that might be included in patient labeling, but the organization and wording should be at the discretion of the manufacturer. There is simply no compelling reason for all of the companies to conform to a single template.

- Purpose of the Device (Indications for Use)

The guidance document recommends that manufacturers briefly describe the FDA-cleared or approved indications for use. While the purpose of the device would provide important information to the user, for many devices the nuances of the indications for use would be either confusing or meaningless to patients. In addition, for a large number of devices, the patient's physician has already made the decision that the device would be appropriate, even if not strictly indicated. HIMA recommends that adding information regarding the cleared or approved indications for use be at the discretion of the manufacturer.

- Alternatives to the Device and Treatment

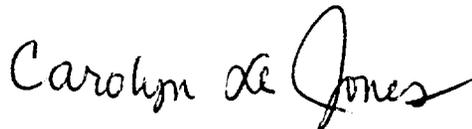
FDA recommends that the manufacturer inform the patient of other viable appropriate alternatives to the device and treatment. FDA is suggesting that manufacturers assume the role of the patient's physician. In some cases providing such alternatives would constitute interference in the patient-physician relationship. Also, if a manufacturer fails to inform a patient of one of a number of viable alternatives, it is unclear what legal liability this may impose on manufacturers. Therefore, HIMA requests that this information not be included in patient labeling.

- Clinical Studies

The guidance document recommends that manufacturers provide the patient clinical study information in simple, plain language. It is unclear how such information will assure the safe and effective use of devices. If meaningful clinical study information could be presented in simple, plain language, such information would be of no use to most patients. If FDA's ultimate goal is to assure that patients use devices properly and know and understand the risks and benefit of the device, such extraneous information may dilute the effect of more important information contained in the patient labeling. We suggest that FDA allow such information to be made available to patients upon request.

HIMA appreciates the opportunity to comment on FDA's draft guidance document.

Respectfully submitted,



Carolyn D. Jones
Associate Vice President
Technology and Regulatory Affairs