

American Medical Association

Physicians dedicated to the health of America



Michael D. Maves, MD, MBA
Executive Vice President, CEO

515 North State Street
Chicago, Illinois 60610

312 464-5000
312 464-4184 Fax

2321 70 MAY -6 9221

May 3, 2004

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

RE: Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions [Docket No. 2004D-0042]

The American Medical Association (AMA) commends the Food and Drug Administration (FDA) for issuing three draft guidances for industry to improve information provided to consumers and health care practitioners by medical product firms about medical products and health conditions (Federal Register. 2004;69(27):6308-6309). The AMA is pleased to offer the following comments.

The AMA strongly supports the draft guidance entitled, "Help Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms" (Disease Awareness Guidance). The AMA agrees with the FDA that these "help-seeking" communications can be effective tools to disseminate information to consumers and health care practitioners about untreated and inadequately treated health conditions. The AMA concurs with the FDA's recommendations on the content of disease awareness communications. Furthermore, the AMA believes that the FDA has taken a reasonable approach to ensure that disease awareness communications are not inappropriately linked to reminder promotions or product claim promotions in ways that would lead consumers to perceive the two pieces as one advertisement or one promotional labeling piece.

Regarding the draft guidance entitled, "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" (Brief Summary Guidance), the AMA agrees with the FDA that pharmaceutical companies need to present risk information in direct-to-consumer (DTC) print advertisements in a way that is more consumer-friendly, so that key risks about prescription drug products will be better understood. The current practice of simply including the complete risk-related sections of the FDA-approved professional labeling (package insert) verbatim, in small type in DTC print ads is not useful.

The AMA supports the FDA's recommendation for pharmaceutical companies to use the "Highlights" section of FDA-approved professional labeling as the basis for conveying risk information, using consumer-friendly language, in DTC print ads. However, as is pointed out in the draft guidance, the final rule on professional labeling that would require a "Highlights" section still remains unpublished. As we have done many times previously,

the AMA urges the FDA to issue its final rule on professional labeling, that would include this new “Highlights” section, as soon as possible.

The AMA is disappointed that none of the draft guidances focus on the issue of fair balance in DTC broadcast (i.e., television) advertisements. The AMA previously has raised concern about fair balance in DTC advertisements shown on television. For example, some of the ads are very effective at using pleasing, not to mention distracting, visuals as the major risk information is being discussed in audio only.

At the September, 2003 FDA public meeting on DTC advertising, research was presented by Dr. Ruth Day of Duke University on the cognitive accessibility of prescription drug information. Her research provides evidence that the AMA’s concern about lack of fair balance in television DTC advertisements is justified.

Dr. Day described cognitive accessibility as the ease with which people can find, understand, remember, and use drug information. When she looked at television DTC advertisements for 29 drugs, she found the following:

- Serial position effect – Risk information in television DTC advertisements consistently was found in the middle or just past the middle of the ads, a location that makes it very difficult for a person to process and retain the information.
- Linguistic analysis – On average, the ratio of total sentences devoted to benefit versus risk information in television DTC advertisements was approximately three to one. Furthermore, the readability level for benefit information was, on average, three or more grade levels lower than the readability level for risk information. Thus, it would be much more difficult for a person to process risk information.
- Semantic analysis – The word “you” was commonly used in presenting benefit information in television DTC advertisements, but was rarely used in presenting risk information. The effect of this is that persons will perceive the benefits as things that will happen to “them,” but will perceive the risks as things that will happen to “somebody.”

When Dr. Day actually performed experiments looking at these effects in people, she found that people remembered indications of advertised drugs about 70% to 90% of the time. In contrast, when the same people were asked about side effects, their ability to remember went down significantly. Thus, the conclusion is that because of the way television DTC advertisements are constructed, people are much better able to understand and retain information about indications and benefits than about side effects and risks of the advertised drugs.

The AMA believes these research data clearly raise concerns that there is a lack of fair balance in television DTC advertisements for prescription drugs. Thus, the AMA encourages the FDA to modify both its August, 1999 “Guidance for Industry: Consumer-Directed Broadcast Advertisements,” and its new draft guidance, “Consumer-Directed

Broadcast Advertising of Restricted Devices” (Device Broadcast Advertising Guidance), to ensure that television DTC advertisements are structured in a way that fairly balances the benefits and risks for both prescription drugs and restricted devices.

In conclusion, we encourage the FDA to consider the AMA’s views and recommendations to improve information provided to consumers and health care practitioners by medical product firms about medical products and health conditions. In particular, issuance of a final rule on the format and content of professional labeling for prescription drugs, including a “Highlights” section, and modification of FDA guidances on DTC broadcast (i.e., television) advertisements to improve fair balance in these DTC ads should go a long way to achieve this goal. The AMA would be pleased to further discuss these issues with the FDA.

Sincerely,

A handwritten signature in black ink, appearing to read "M D Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA