American Medical Association
Physicians dedicated to the health of America

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

RE: Consumer-Directed Promotion [Docket No. 2003N-0344]

The American Medical Association (AMA) commends the Food and Drug Administration (FDA) for convening a public meeting to present the results of research on consumer-directed promotion of prescription drug products (direct-to-consumer advertising [DTCA]). The AMA has encouraged the FDA and the pharmaceutical industry to conduct or fund research on the effect of DTCA, focusing on its impact on the patient-physician relationship as well as on health care utilization and costs. The AMA is pleased that substantial research on the impact of DTCA is ongoing.

While the AMA has not conducted research on the impact of DTCA, it has been following research in this area very carefully. The purpose of this letter is to present our views on some of this ongoing research.

What is the impact of DTCA on the patient-physician relationship?

Much of the research has come from surveys of consumers and, to a lesser extent, of physicians. There appears to be consistency across surveys that DTCA may have the positive effect of increasing physician office visits, resulting in the diagnosis of previously undiagnosed conditions and in better communication between physician and patient.

On the other hand, surveys consistently show there is a subset of patients who demand specific advertised drugs from their physicians. The impact of this on the physician-patient relationship remains unclear. Many physicians continue to complain that less time is available to effectively diagnose and treat patients who have a fixation on a particular drug as the result of a commercial. Furthermore, there is the potential to create distrust in the patient-physician relationship when the physician is put in an uncomfortable and awkward position of defending why the requested advertised drug is unnecessary.

Is there fair balance in television DTC advertisements?

The AMA previously has raised concerns 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. Our concerns, however, were based solely on anecdotal evidence. At the FDA Public

meeting, 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 concerns about lack of fair balance in television DTCA are 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 encourages the FDA to give careful attention to this research data because it clearly raises concerns that there is a lack of fair balance in television DTCA. Changes in the FDA's guidance for the pharmaceutical industry on the structure of television DTC advertisements may be appropriate to ensure that these advertisements exhibit fair balance.

<u>Can consumers understand and accurately assess claims regarding the efficacy of prescription drugs in DTC advertisements?</u>

One of the AMA's main tenets for appropriate DTCA is that the advertisements should have some educational value. There is a growing body of evidence to suggest this may not be the case. Bell et al. reviewed over 300 print DTC advertisements for 101 prescription drug products in 18 popular magazines during the 1990s. They found that while the advertisements were informative, they lacked important educational information about both the condition and the treatment for which the drug was being promoted (Bell RA,

Kravitz RL, Wilkes MS. The educational value of consumer-targeted prescription drug print advertising. *J Fam Pract*. 2000;49:1092-1098).

Similarly, Woloshin et al. reviewed the contents of 67 DTC advertisements from 10 magazines published between July, 1998 and July, 1999. They found that the advertisements rarely quantified a medication's expected benefit, and instead made an emotional appeal. In contrast, over one-half of the advertisements used data to describe a drug's side effects. The authors suggested that these DTC advertisements leave readers with the perception that the drug's benefit is large and that everyone who uses the drug will enjoy the benefit (Woloshin S, Schwartz LM, Tremmel J, et al. Direct-to-consumer advertisements for prescription drugs: What are Americans being sold? *Lancet*. 2001;358:1141-1146).

At the FDA Public meeting, Dr. Woloshin and his colleague, Dr. Lisa Schwartz, from the Dartmouth Medical School, provided further evidence that print DTC advertisements present benefit information in a way that leads consumers to overestimate a drug's benefit. These researchers created a "prescription drug benefit box" for three actual print DTC advertisements in which only the names of the drugs were fictitious. The purpose of the prescription drug benefit box was to present actual data on the drug's benefit, in a concise and understandable way, that directly reflected the clinical trial data used for the drug's approval. Consumers were then asked to rate the efficacy of each of the three drugs based on print DTC advertisements that did or did not include the prescription drug benefit box. Consumers were far more likely to rate the drugs as extremely effective when the advertisement lacked the prescription drug benefit box when compared to advertisements containing the prescription drug benefit box. Thus, these researchers concluded that quantitative data about drug efficacy, as presented in the prescription drug benefit box, reduced perceived efficacy of the advertised drug and helped people more accurately gauge the benefit of the drug compared to an alternative.

The AMA encourages the FDA to give thoughtful consideration to this research because it raises the question of whether commercially driven DTCA is really as educational as its proponents would like you to believe. While the AMA recognizes the difficulties in creating "prescription drug benefit boxes" for all drugs, as was pointed out by a senior FDA official at the Public meeting, there may be ways for FDA to guide the pharmaceutical industry in designing DTC advertisements that will more objectively present benefit information.

<u>What is the impact of DTCA on health care costs and utilization?</u>

Until high-quality and unbiased research allows us to understand the impact of DTCA on health care costs and utilization, the value of DTCA will remain controversial. Although research results in this area are limited, some recent studies have concluded that DTCA does lead to increased spending on drugs. A study done by Rosenthal and colleagues at the Harvard School of Public Health, Massachusetts Institute of Technology, and Harvard Medical School for the Kaiser Family Foundation, released in June 2003, found that increases in DTCA have a significant impact on drug spending growth. The authors

estimated that in 2000, 12 percent of drug spending growth was related to increased spending on DTCA, with each additional dollar spent on DTCA yielding an additional $4.20 in drug sales in that year. Interestingly, increases in DTCA were associated with significant growth in sales for the classes of drugs studied, but not in increased market share for the individual advertised drugs (Rosenthal MB, Berndt ER, Donohue JM, et al. Demand effects of recent changes in prescription drug promotion. The Henry J. Kaiser Family Foundation, June 2003).

A report of the US General Accounting Office (GAO) also concluded that DTCA appeared to increase prescription drug spending and utilization. The GAO found that drugs promoted directly to consumers often are among the best-selling drugs, and sales for DTC-advertised drugs have increased faster than sales for drugs that are not heavily advertised to consumers. Moreover, the GAO found that most of the spending increase for heavily advertised drugs is the result of increased utilization rather than price increases (FDA oversight of direct-to-consumer advertising has limitations. US General Accounting Office. Report GAO-03-177, October 2002).

These studies may reflect an appropriate increase in spending on drug treatments that were previously underutilized. Alternatively, this could reflect wasteful spending on expensive advertised drugs for which less expensive alternatives, or no drug at all, would have worked just as well. Additional research is clearly needed to answer this important question.

Conclusion

In conclusion, the AMA is pleased to see the growth in research on the impact of DTCA, and we commend the FDA both for encouraging research on this subject and for helping to publicize the results. Based on our evaluation of the data that is available and as discussed above, the AMA believes the FDA should reassess the educational value of current DTC advertisements and whether television DTC advertisements provide fair balance in the presentation of benefit and risk information. Such a reassessment could lead to changes in FDA's guidance to the pharmaceutical industry on the structure of DTC advertisements. Further research is needed to better understand the impact of DTCA on the patient-physician relationship and on health care costs and utilization.

Sincerely,

Michael D. Maves, MD, MBA