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May 7, 2004

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

Re: Docket No. 2004D-0042  
Draft Guidances for Industry on Improving Information about Medical  
Products and Health Conditions; Withdrawal; Availability. 69 Fed.  
Reg. 6308 (February 10, 2004).

Dear Madam/Sir:

The Michigan for Affordable Pharmaceuticals Coalition (MAP) is a voluntary organization composed of employers, union groups, health care providers and health care plans that support specific reform initiatives to help contain pharmaceutical costs, while ensuring access and improved health care overall.

MAP commends the FDA for its draft guidances proposed on February 4, 2004, to improve communications to consumers and health practitioners about health conditions and medical products. The coalition has some very specific recommendations and comments on the proposed guidances. We would also like to take this opportunity to suggest the FDA reopen and review the current finalized Guidance for Consumer-Directed Broadcast Advertisements.<sup>1</sup> We view all of these guidance documents as working together to improve the value of information the public uses to make important health care decisions. And we think research supports the need to have them strengthened to address the needs of today's consumers. We also recognize that developing non-commercial sources for this information

2004D-0042

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may be in the public interest, since most DTC advertising is funded and developed by the pharmaceutical industry.

The prevailing research includes findings shared at the FDA public meeting on direct-to-consumer (DTC) advertising. The testimony shows there are benefits to advertising health information to the public. Specifically, DTC advertising can help improve the treatment rates for diseases that are under diagnosed. It can also contribute to better discussions between patients and physicians about treatments and make patients more willing to use a medication when necessary.

The benefits are well documented. However, there is also documentation for issues concerning consumer demand and use of advertised drugs (factors in pharmaceutical cost trends) and consumer safety (a factor in quality of care).

### **Consumer Demand**

There are strong indications that DTC ads affect prescribing patterns. A University of British Columbia study found 87 percent of the people who requested an advertised drug received a prescription for a new medication, compared to new prescriptions going to only 26 percent of those who did not request medicine. Interestingly, the physicians indicated that half the time when patients requested and received a DTC advertised drug, the choice of medication was only a possible, or even an unlikely choice for similar patients. This variation in choice appeared only 12 percent of the time for patients who did not ask for a drug.<sup>ii</sup>

A Mayo Clinic study revealed that 36% of physicians reported they rarely would have prescribed the drug of choice without the patient's request. The majority -- 56 percent -- reported they would only have prescribed the drug some of the time.<sup>iii</sup>

These findings correlate well with a recent study by two physicians at Brigham and Women's Hospital. Michael Fischer and Jerry Avorn looked at prescribing patterns for the treatment of high blood pressure. They found that a more appropriate choice of medicine was indicated by evidence-based guidelines in 40 percent (815,316) of the prescriptions. This stunning outcome has implicated the influence of marketing efforts as a primary explanation.<sup>iv</sup>

The influence is broad. The GAO estimates each year about 8.5 million consumers receive a prescription for a particular drug in response to a DTC ad.<sup>v</sup> Consumers are responding, but FDA consumer surveys completed in 1999 and 2002 found as much as nearly 60% of them report that ads for drugs do not provide enough information about risks and negative effects. It is especially important that manufacturers communicate risk involved with lifestyle drugs, which do not treat acute or chronic illness. Without it, consumers may be inclined to incorrectly perceive the degree of risk involved with optional treatments. After all, consumers already say that the ads portray the drugs as being better than they really are.<sup>vi</sup> Still, consumers generally believe all DTC advertising has been scrutinized by the FDA,<sup>vii</sup> lending great strength and credibility to them.

These findings, along with the other research, lead us to conclude that in addition to raising awareness, treatment and compliance, DTC advertising has a definite prescribing impact. As a result, it is imperative that consumers get balanced messaging that adequately conveys both the risks and benefits of a medication and helps them make good decisions about their health care and their safety.

### **Consumer Safety**

Testimony at the FDA hearing questioned whether that balance exists. For example, Duke University studied 29 drug broadcast advertisements and found on average, the ads devoted 30 percent of their content to benefits and only 10 percent to risks. They also found the risk content was three times more difficult to understand, based on reading grade levels, and thus, more difficult to retain. Researchers concluded that if people cannot find, understand, remember, and use the risk information, it becomes, in effect, “functionally absent” from the ads.<sup>viii</sup>

### **Comments Specific to Language in Draft Guidances**

In light of the consumer demand and safety concerns explored and justified in the FDA hearing and through other studies and statistics, MAP has developed the following specific recommendations to the draft guidances currently open for public comment.

#### **1) *Brief summary: Disclosing Risk Information in Consumer-Directed Print Advertisements***

The MAP Coalition supports the intent of this draft guidance to streamline the presentation of risk information in DTC print ads in order to more effectively communicate to consumers. Additionally, we support the recommendation that risk information be presented in language that is easy to understand for the lay reader. And we fully agree that the promotion of prescription drugs is different from the promotion for other types of products. It, therefore, needs to be: truthful, not misleading, scientifically substantiated and adequate regarding explanation of risks.

**The coalition would, however, like to recommend the following change:** In the guidance, adverse reactions are limited to 3 to 5 of the most common “non-serious” ones, most likely to affect the patient’s quality of life or compliance with drug therapy. Since the number of non-serious adverse reactions can vary from product to product, limiting the range could result in manufacturers excluding valuable information in some promotions. ***The coalition recommends removing the range and requiring manufacturers to disclose the “most important and most common adverse reactions.”***

#### **2) *Help Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms***

The MAP Coalition supports the FDA’s intention to clarify placement of “disease awareness” and “reminder” ads. As discussed in the draft guidance,

there have been instances where manufacturers have used these as “bookend” advertisements (print or broadcast) to promote their product, while avoiding disclosure of safety or effectiveness claims that are required with full “product claim” ads. Placement of awareness and reminder ads in this manner can have the same affect on consumers as stand-alone product ads, without adequate risk information. In the draft guidance, the agency recommends that awareness, reminder and product claim ads be sufficiently distinctive in terms of their thematic, graphic, visual and other presentation elements so that they will not be perceived as a single promotional piece. The Map Coalition agrees.

**The coalition would, however, like to recommend the following change:** The draft guidance discusses the need for manufacturers to avoid “close physical or temporal proximity” of awareness and reminder ads. The agency says it could consider two such communications to be in “close temporal proximity” in a broadcast advertisement if they were presented within the same 15 minutes of a half-hour program or within the same 30 minutes of an hour-long program. This could be too limited, since advertisers often sponsor longer programs or special events. ***Instead of specific timeframes only, the coalition recommends the agency consider defining “close physical or temporal proximity” as any instance where “disease awareness” and “reminder” ads run within a single program or within a span of time, which the agency believes might cause consumer audiences to perceive the two ads as one. In either case the more stringent rule should apply to accommodate the various broadcast formats.***

In closing, the MAP Coalition once again commends the FDA for working to improve communications to consumers and health care practitioners about health conditions and medical products. We urge the agency to consider our comments as it works toward finalizing the draft guidances. We also believe the current Guidance for Consumer-Directed Broadcast Advertisements needs review and updating to further ensure that prescription drug advertising clearly communicates both benefits and risks, as originally intended by the FDA. We hope the agency will consider this as a next step.

Questions concerning these comments may be directed to Timothy Antonelli at (248) 448-7372 or [tantonelli@bcbsm.com](mailto:tantonelli@bcbsm.com).

Sincerely,

Michigan for Affordable Pharmaceuticals Coalition

cc: Michigan Congressional Delegation

## References

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- <sup>ii</sup> B.Mintzes, University of British Columbia, *How Does Direct to Consumer Advertising (DTCA) Affect Prescribing: A Survey in Primary Care Environments with and without Legal DTCA*, FDA Direct-To-Consumer Promotion Public Meeting, September 22, 2003, [cited April 23, 2004] Transcript and presentation slides available online @ [www.fda.gov/cder/ddmac/DTCmeeting2003.html](http://www.fda.gov/cder/ddmac/DTCmeeting2003.html).
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- <sup>iv</sup> Fischer M, Avorn J, *Economic Implications of Evidence Based Prescribing for Hypertension: Can Better Care Cost Less?*, JAMA, 2004;291:1850-1856.
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- <sup>viii</sup> R.Day, Duke University, *Cognitive Accessibility of Prescription Drug Information*, FDA Direct-To-Consumer Promotion Public Meeting, September 22, 2003, [cited April 23, 2004] Transcript available online @ [www.fda.gov/cder/ddmac/DTCmeeting2003.html](http://www.fda.gov/cder/ddmac/DTCmeeting2003.html).