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Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Request for Comment on  
First Amendment Issues  
Docket No. 02N-0209

The Magazine Publishers of America appreciates this opportunity to provide its views on how the Food and Drug Administration can readily incorporate both the letter and the spirit of the First Amendment into its implementation of the Food, Drug, and Cosmetic Act and other statutes.

The Magazine Publishers of America ("MPA") is the principal trade association representing the consumer magazine industry. MPA's more than 240 U.S. members publish approximately 1200 magazines, including some of the most widely distributed consumer publications in America as well as local and specialized magazines.

The magazines published by MPA's members regularly include advertisements for the products FDA regulates, including prescription and over-the-counter drugs (including biologics), foods (including dietary supplements), cosmetics, medical devices, and animal drugs. Readers of magazines have a keen interest in these advertisements, finding them a useful source of information about products they buy or are considering purchasing.

Advertising prescription drugs in magazines is not new—magazines have been providing important information to potential patients about disease symptoms and drug therapies for years. Patients have been known to tear out magazine ads to bring with them to their doctor to facilitate a well-informed discussion of their medical condition. A

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2001 study by Advanced Analytics, Inc. found that 55% of physicians rated overall DTC advertising as beneficial to patients.

Americans need to know about treatment options available to them as they assume greater control of their own health care. DTC advertisements provide important information about disease symptoms and treatments to patients who otherwise would not be aware that treatments are available.

Print advertising has some important advantages over other kinds of advertising. It can provide much more detailed information. Also, unlike much other advertising, it is permanent, and can be retained; it can therefore be read, re-read, discussed with physicians and other health care professionals, care givers, family members, and friends, and used repeatedly as an information resource during the decision-making process.

FDA Should Recognize that the First Amendment and the Purposes  
of the Food, Drug, and Cosmetic Act Are Not In Conflict

The Federal Register Notice (“the Notice”) expresses a number of concerns about a supposed tension or dichotomy between the First Amendment and enforcement of the Food, Drug, and Cosmetic Act (“the Act” or “FDCA”). 67 Fed. Reg. 34942, 34943 (May 16, 2002). MPA believes such concerns are misplaced, and asks that FDA recognize and acknowledge that the protection afforded commercial speech by the First Amendment does not detract from, but rather enhances, FDA’s ability to achieve the purposes of the Act.

In particular, FDA should reject the Notice’s false dichotomy between “the need and right of Americans to speak and hear information vital to their every day lives” (i.e., information about FDA-regulated products) and “the need to ensure that people are not misled.” *Id.* at 34943. The Act proscribes, and FDA (and other agencies such as the Federal Trade Commission) can and should regulate, commercial speech that is misleading or not truthful. Thus, the only information, whether advertising or labeling,

that is permissible under the FDCA is that which is truthful and not misleading.

Moreover, the First Amendment provides no shelter for false or misleading commercial speech. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557, 563 (1980). For these reasons, there is no tension between consumers' need for information and their need not to be misled.

FDA should also recognize that the Supreme Court, in its First Amendment jurisprudence, has already provided answers to the kinds of questions FDA has asked about direct-to-consumer advertising of FDA-regulated products. Many of FDA's questions address the potential misuse of truthful and non-misleading advertising, for example, by encouraging "over-prescribing." The Court has long since decided that speech prohibitions based on such concerns cannot survive First Amendment scrutiny. In Virginia State Bd. of Pharmacy v. Virginia Citizen Consumer Council, Inc., 425 U.S. 748, 770 (1976), for example, the Court held that efforts by pharmacists to control the flow of information about prescription drugs, and in effect to substitute their judgment for consumers' judgment must be struck down under the First Amendment. In a core passage, the Court explained the reasons underlying First Amendment protection for commercial speech. Advertising, it said, provides:

information as to who is producing and selling what product, for what reason, and at what price. So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

Id. at 765. The Court also emphasized that the First Amendment does not allow the government to proscribe dissemination of truthful information out of fear that the information would be misused, saying that consumers "will perceive their own best

interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.” Id. at 770.

The Court has several times reiterated Virginia Board’s premise that government ought not seek to suppress truthful and not misleading speech because it might be put to what the government considers undesirable uses. In 44 Liquormart v. Rhode Island, 517 U.S. 484, 503 (1996) for example, it held that:

[B]ans against truthful, nonmisleading commercial speech...usually rest solely on the offensive assumption that the public will respond ‘irrationally’ to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.

Similarly, in Thompson v. Western States Medical Ctr., the Court again rejected the argument that “the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.” 2002 U.S. LEXIS 3035, at \*34 (2002)(citing Virginia Board, 425 U.S. at 769, and 44 Liquormart, 517 U.S. at 503); see also Pearson v. Shalala, 164 F.3d 650, 658 (D.C. Cir. 1999)(rejecting “the government’s position that there is no general First Amendment preference for disclosure over suppression”).

#### FDA Should Improve the Brief Summary

FDA should take all necessary steps to avoid requiring more speech than is necessary to prevent advertisements from being misleading or not truthful. The first candidate for action in this respect should be the brief summary requirements for direct to consumer prescription drug advertising.

Under the Food, Drug, and Cosmetic Act, advertising for prescription drugs is required to contain a brief summary which contains a “true statement” of “information relating to side effects, contraindications, and effectiveness.” FDCA § 502(n), 21 U.S.C. § 352(n). FDA’s regulations broaden the requirement for safety information to include also warnings and precautions. 21 C.F.R. § 202.1(e)(1). To the extent that such safety

information is needed to balance the efficacy information in an advertisement and therefore make it not misleading, it renders the advertisement not misleading.

Disclosures required to make an advertisement not misleading are permissible under the First Amendment.

A review of the advertising of prescription drugs in consumer magazines, however, shows that the brief summaries contain more information than the consumer needs at this stage of the health care process. Often so much information is provided that very small type must be used if the brief summary is to fit on one page. Some information in the brief summary may be confusing to consumers, such as pharmacokinetic information, detailed drug interaction information, and carcinogenesis, mutagenesis, and impairment of fertility information based on animal studies.

Providing too much information in the brief summary can undermine the efficacy of the disclosure. When the length and complexity of a brief summary in consumer advertising obscure the key pieces of safety information, they paradoxically provide less, not more, of the information consumers need. As noted above, magazines are an especially useful source of information to consumers, because the print format allows them not only to read but also to retain information in which they are or might be interested. Consumers can study magazine advertisements at their leisure and re-read them alone or with family members, friends, or health care professionals, and therefore get maximum use of the information. But when the information is not readable and clear, it is less useful than it should be. Shortening the brief summary and sharpening its focus would help convey key information in a way that would encourage and reward reading it.

Further disclosure requirements, that appear to go beyond necessary safety information must be carefully scrutinized to assure compliance with First Amendment principles.

Conclusion

Print advertising in consumer publications is a uniquely valuable source of information about prescription drugs, benefiting both individual consumers and the health care system as a whole. FDA should recognize and acknowledge that any attempt on its part to restrict, reduce, or hamper truthful and not misleading direct-to-consumer advertising would not likely be permissible under the First Amendment. In addition, FDA should recognize and acknowledge that shortening and clarifying brief summaries in consumer advertising would be very much to the benefit of consumers, and would avoid conflict with the First Amendment.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'JRC', with a long horizontal flourish extending to the right.

James R. Cregan  
Executive Vice President