

BEFORE THE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MD 20852

REQUEST FOR COMMENT ON FIRST AMENDMENT ISSUES
[Docket No. 02N-0209]

COMMENTS OF THE
NEWSPAPER ASSOCIATION OF AMERICA

September 12, 2002

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BY HAND

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 Newspaper Association of America (“NAA”) is pleased to submit these comments on how the Food and Drug Administration can ensure that its regulations, guidances, policies, and practices are in accordance with the First Amendment. In particular, NAA requests that FDA substantially reduce the required content of brief summaries in direct-to-consumer prescription drug advertising. Taking this step is necessary under the First Amendment, and also will make it much easier for consumers to focus on the most important information in brief summaries, without having to cut through lengthy presentations of information not helpful to them. It will also have the benefit of eliminating serious inequities between broadcast and print media which FDA’s current policies have created in the area of direct-to-consumer prescription drug advertising.

NAA is the principal trade association representing daily newspapers. Its members publish approximately 2000 newspapers, which account for 87% of U.S. daily newspaper circulation. More than half of adult Americans read a daily newspaper on an average weekday, and nearly two-thirds of American adults read a Sunday newspaper in an average week. Nearly half of adults rely on daily newspapers for advertising and information on prescription and over the counter medications, a percentage more than twice that of any other medium.

As FDA is now well aware, truthful and not misleading commercial speech, including advertising for prescription drugs, is entitled to First Amendment protection. Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976).

Accordingly, FDA's regulation of such speech is unlawful unless the regulatory interest the agency asserts is substantial, directly advances the asserted interest, and is not more extensive than necessary. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557, 566 (1980). FDA's current brief summary requirements do not meet these standards.

Section 502(n)(3) of the Food, Drug, and Cosmetic Act ("the Act" or "FDCA"), 21 U.S.C. § 352(n)(3), authorizes FDA to promulgate regulations requiring that prescription drug advertising include a "true statement" of "information in brief summary relating to side effects, contraindications, and effectiveness." FDA's regulations, 21 C.F.R. § 202.1(e)(1), essentially repeat the statutory language, although the term "side effects and contraindications" is broadened somewhat to include also "warnings" and "precautions" (hereinafter "safety information").

As a practical matter, however, FDA is generally understood to require much more in brief summaries in print advertising than is permissible under the First Amendment. Even a cursory look at direct-to-consumer prescription drug advertisements in the print media, including newspapers, reveals that "brief summaries" are lengthy, complicated presentations of most if not all the information found in package inserts. As such, they are far more extensive than the brief summary provisions of the statute and regulations contemplate.

FDA's requiring so much information cannot withstand review under the criteria laid down in Central Hudson because the Act already provides an effective means of providing complete information about prescription drugs to consumers and health professionals. Thus, Section 502(f) of the Act specifies that the labeling for drugs (including prescription drugs) must contain "adequate directions for use." 21 U.S.C. § 352(f). That information, generally contained

in the package insert (also called the full prescribing information), is provided with the drug itself and through a variety of other means as well, including promotional labeling such as detail pieces, the Physician's Desk Reference, and company Web sites.

Because the complete package insert for a drug is widely available, as required by statute, there is no need—much less any substantial interest—in requiring that it also be available as part of the brief summary. Nor does requiring direct-to-consumer advertisements to contain information far beyond what consumers need directly advance any governmental interest. Also, lengthy and detailed brief summaries in print advertisements are far more extensive than necessary to serve the needs of health care professionals and patients, who can readily get complete prescribing information when they need it. Under Central Hudson, therefore, a requirement of a lengthy and detailed brief summary cannot stand.¹

FDA has already recognized that the brief summary requirements of Section 502(n)(3) of the Act, 21 U.S.C. § 352(n)(3), need not be lengthy recitations of numerous details about a medication but rather a short clear statement of significant safety issues attendant in use of a drug. In particular, broadcast advertisements for prescription drugs are required to carry only “the major side effects and contraindications” so long as adequate provision is made for dissemination of the full prescribing information. 21 C.F.R. § 202.1(e)(1). Yet even while allowing broadcast advertisements to provide just the brief summary information the statute requires, and no more, FDA continues to demand much more of the brief summaries in print advertisements. The disparity between the two regimes is unfair to print media, and provides no additional benefits to consumers. FDA should therefore make it clear that print and broadcast

1. Because Section 502(n)(3) of the Act, 21 U.S.C. § 352(n)(3), does not authorize FDA to require so much information in a brief summary, FDA's current approach of demanding so much also is in excess of statutory authority and therefore impermissible under Section 706 of the Administrative Procedure Act, 5 U.S.C. § 706.

advertisements for prescription drugs will be treated the same. Utilizing the same system for direct-to-consumer print advertising as is now used in broadcast would provide print readers with what they really need—a brief summary of safety information. It would also avoid the First Amendment problems inherent in FDA's requiring print advertisements to carry much more information in the brief summary than is necessary or appropriate, and put an end to the discrimination between print and broadcast that now exists.

NAA therefore calls upon FDA to make it clear, either by interpreting its existing regulations or by revising them, that a brief summary need do no more than fulfill the purpose of Section 502(n) of the Act: provide a short, clear, accurate statement of the major benefits and risks of a prescription drug.

Respectfully submitted,

A handwritten signature in black ink that reads "David S. J. Brown". The signature is written in a cursive style with a long horizontal line extending to the right.

David S. J. Brown
Senior Vice President/
Public Policy and
General Counsel