

BEFORE THE  
FOOD AND DRUG ADMINISTRATION  
ROCKVILLE, MD 20852

MAY 10 2004

DRAFT GUIDANCE FOR INDUSTRY AND FDA  
CONSUMER-DIRECTED BROADCAST ADVERTISING OF RESTRICTED DEVICES  
[Docket No. 2004D-0042]

COMMENTS OF THE  
NEWSPAPER ASSOCIATION OF AMERICA

May 7, 2004

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

Re: Docket No. 2004D-0042  
Draft Guidance for Industry and FDA  
Consumer-Directed Broadcast  
Advertising of Restricted Devices

These comments are submitted on behalf of the members of the Newspaper Association of America (NAA), the principal trade association representing daily newspapers. NAA represents more than 2,000 newspapers in the United States and Canada and its membership accounts for nearly 90 percent of U. S. daily newspaper circulation. Newspapers carry considerable advertising for restricted medical devices, for products as diverse as contact lenses, hearing aids, hip replacement products and Synvisc (hylan) for osteoarthritis, to name just a few. Advertisers rely on newspapers for good reason. First, newspapers are widely circulated. On an average weekday, more than 99 million American adults read a newspaper; about 116 million American adults read a newspaper on Sunday. Newspapers therefore provide the "reach" and the "frequency" to convey advertising to a broad and diverse audience on a regular basis. Second, newspapers allow advertisers to direct their ads to particular audiences, whether local, regional, or national, and also to the specific demographics of the readership of particular newspapers. Third, newspapers have the space to communicate fully

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the detailed information necessary for consumers to learn the advantages and disadvantages of medical devices so that they can participate with their physicians and other healthcare providers in the decision-making process. Fourth, newspapers can be saved and consulted repeatedly, both by the consumer who is considering the medical device and by his or her family, friends and advisers; this enduring quality is one of the print medium's great advantages. As a result, newspapers can be expected to play a significant role in providing adequate provision of the detailed information that broadcast advertisements for medical devices cannot provide.

The draft guidance recognizes the limitations inherent in a broadcast advertisement due to time constraints and allows an advertiser to make available the additional information consumers need by augmenting broadcast advertisements with print advertisements. Specifically, the draft guidance provides that a sponsor can fulfill the brief statement requirement by an approach that discloses the most serious and most common risks in the broadcast presentation and then makes "adequate provision" for dissemination of the package labeling in connection with the broadcast presentation. FDA has noted that an abbreviated, consumer-friendly version of the package labeling containing information on indications, contraindications, warnings, precautions, and adverse effects, and patient instructions for use may be utilized instead of the full package labeling, provided the consumer is told that the abbreviated labeling is not the complete labeling.<sup>1</sup> Such a consumer-friendly version of the package labeling can fit comfortably in a newspaper advertisement together with a display advertisement for the product, thus making adequate provision by means of newspapers an effective one-step process.

The key to making this approach work, as the draft guidance itself recognizes, is to make sure that the newspaper or other print advertising is disseminated effectively to the same audiences as are targeted by the broadcast advertisement, in the same timeframe as the

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1. Draft Guidance, footnote 3, page 3.

broadcast advertisement. Only if the sponsor's provision is truly adequate will a consumer whose interest in the medical device is piqued by a broadcast ad have a real opportunity to notice the complementary newspaper ad and recognize it as the place where more information is available.

To make sure that sponsors do make truly adequate provision, NAA recommends that the final guidance emphasize the need for sponsors to take care to utilize newspaper advertising that appears during the entire time the broadcast ad is running, so that consumers who see or hear the broadcast ad at the beginning, the middle, or the end of its run all have an equal opportunity to see a newspaper ad around the same time they see or hear the broadcast ad. The final guidance should also emphasize the need for sponsors to make sure that the print advertising is as wide-ranging geographically as the broadcast ad, and as targeted. If, for example, an ad is broadcast on national network or cable television, the print ad should also appear either in a newspaper ad with national circulation or in regional and local newspapers with circulations sufficient to cover the whole country. But if the broadcast ad is a regional or local spot, then the sponsor should take care to have the complementary print ad appear in newspapers with circulation in those regions or localities. Executing an advertising schedule for local or regional audiences can be easily accomplished through one-order, one-bill advertising placement firms.

In addition, FDA should monitor on a regular basis whether provision is adequate, so that consumers are assured of having the information they need about these important products. Sponsors who take advantage of FDA's enforcement discretion to use broadcast advertising with only limited information about the medical devices advertised should be willing to provide, upon request, information to satisfy FDA that their broadcast and print schedules fit together in ways that give consumers easy and effective access to detailed information about restricted medical devices.

NAA appreciates the opportunity to comment on this draft guidance and looks forward to working with advertisers and FDA to fulfill the promise of more and better information about restricted devices in broadcast and newspaper advertising.

Respectfully submitted,

A handwritten signature in black ink that reads "Paul J. Boyle". The signature is written in a cursive style with a large, stylized initial "P".

Paul J. Boyle  
Senior Vice President/Public Policy