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October 28, 2002

BY HAND DELIVERY

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

Re: Docket No. 02N-0209; Response to Comments on First Amendment Issues

Dear Sir or Madam:

Health Resource® Publishing Co. (HRPC) is pleased to submit responsive comments to the Food and Drug Administration (FDA) concerning the agency's Request for Comment on First Amendment Issues (hereinafter "Comment Request"), 67 Fed. Reg. 34,942 (May 16, 2002). HRPC submitted its comments to the agency on September 13, 2002, and now responds to some of the other comments submitted to the agency.

HRPC emphasized in its comment that FDA's accompanying information requirements for direct-to-consumer (DTC) print promotion of prescription drugs are constitutionally infirm. Under FDA's current regulations and interpretation of the Federal Food, Drug, and Cosmetic (FDC) Act, all print advertising for prescription drugs must be accompanied by a "brief summary" of the drug's side effects, warnings, and contraindications. 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e). All promotional labeling for a prescription drug must be accompanied by "adequate directions for use," that is, the drug's full professional labeling, even when the promotional labeling is directed to consumers, rather than health care professionals. See, e.g., 21 U.S.C. § 352(f)(1).

As HRPC recounted, FDA and other commentators have long recognized that these accompanying information requirements for DTC print promotion must be reformed. A drug's full product labeling and the typical brief summary for a prescription drug are technical, written for a medical professional, lengthy, and of no use to the consumer. FDA's own data, and that of others, underscore that consumers do not read the dense information that accompanies prescription drug promotion, and likely cannot understand it if they do. Calls for FDA to change these regulations and interpretations date back to at least 1995.

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HRPC argued in its September 13, 2002 comment that the accompanying information requirements for print media are contrary to the First Amendment to the U.S. Constitution. FDA has publicly and repeatedly conceded, and FDA's own data show, that the onerous disclosure requirements do not directly advance any government interest. Moreover, the accompanying information requirements are more extensive than are necessary to protect consumer health in that there are less onerous alternatives for communicating useful, valuable information about prescription drugs in easy to understand formats. Thus, the requirements fail the standards the Supreme Court elucidated in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980), and Thompson v. Western States Med. Ctr., 122 S. Ct. 1497, 1504 (2002).

Consumer advocates share HRPC's concern that FDA's onerous print media disclosure requirements are not serving the public they are supposed to inform. In its comment, the National Consumers League explains that in 1996 and 1998 it convened two Roundtables of interested stakeholders who criticized the "inadequacy" of the brief summary. The National Consumers League repeats its call, again, for changing the brief summary so that it is consistent, balanced, and written in plain language a lay consumer can understand. National Consumers League Comment at 13. Similarly, AARP, Health Law Advocates, Inc., and the American Medical Association all emphasize that important risk information must be understandable, legible, and written in plain language consumers can understand. AARP Comment at 1; Health Law Advocates, Inc. Comment at 8; American Medical Association Comment at 5. The current accompanying information requirements for DTC print promotions plainly do not meet these criteria.

Commentators with diverse points of view also agree with HRPC that FDA's accompanying information requirements for DTC print promotion are unconstitutional. The American Civil Liberties Union (ACLU), in its July 26, 2002 comment, states: "The agency's position regarding direct-to-consumer print advertisement . . . is not consistent with relevant legal authority because it excessively restricts commercial speech." ACLU Comment at 3. The ACLU argues, as HRPC does, that the accompanying information requirements for DTC print prescription drug promotion would fail the Central Hudson test as applied in Western States.

John Calfee of the American Enterprise Institute, likewise, urges FDA to change its approach to mandated disclosures such as the brief summary. FDA would, Mr. Calfee posits, have considerable difficulty in defending the constitutionality of its requirement that prescription drug advertisements always include something close to the drug's complete prescribing information. Calfee, American Enterprise Institute Comment at 13.

Those calling for reform include even entities who might stand to gain financially from perpetuating the requirements that result in advertisers paying for additional pages of lengthy, detailed product information in print media. The Association of National Advertisers, the Newspaper Association of America, and the Magazine Publishers of America all urge reform of the brief summary requirements. "The first candidate for action . . . should be the brief summary

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requirements for direct to consumer prescription drug advertising.” Magazine Publishers of America Comment at 4. These commentators all express the same concerns, echoed by HRPC and others. The vast information that FDA requires accompany print promotion is not advancing any government interest in the protection of public health and is not beneficial to consumers. See, e.g., Association of National Advertisers Comment at 2; Newspaper Association of America Comment at 3.

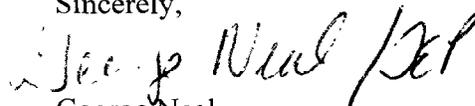
There is also broad consensus on the shape this urgently needed reform should take. Several commentators, including HRPC, National Consumers League, and the Newspaper Association of America, all suggest that FDA look to the “major statement” and “adequate provision” principles from FDA’s 1999 Broadcast Guidance.

FDA has proposed that for drugs that have an FDA-approved “patient information leaflet” or “PIL,” the PIL may replace the brief summary in print promotions. See 66 Fed. Reg. 20468 (April 23, 2001), Draft Guidance, “Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements” (<http://www.fda.gov/cder/guidance/4114dft.pdf>). However, as discussed in HRPC’s Comment at 7, the PIL is nearly as long, detailed, and technical as the brief summary. The PIL offers little improvement over the typical brief summary.

In examining the many comments submitted to FDA, on so many issues, it is plain that the accompanying information requirements for DTC print promotion are particularly egregious and highly vulnerable to First Amendment challenge. The overhaul of these requirements is long overdue. FDA and others have repeatedly admitted that the onerous and costly disclosures are not aiding consumer understanding of the prescription drugs promoted. FDA is also unfairly singling out print promotions to bear greater disclosure burdens than broadcast promotions must bear. Equally clear, while many of the commentators might and do disagree on other aspects of DTC promotion, on the issue of risk disclosures that accompany print promotions, there is uniform agreement and broad consensus – the current requirements do a disservice to consumers and must change. In this First Amendment comment process, no one has come forward to defend the truly indefensible.

HRPC urges FDA to heed the call expressed by so many, for so long. No legitimate interest is served by the current wasteful, archaic, accompanying information rules for DTC print promotions.

Sincerely,

A handwritten signature in black ink that reads "George Neal" with a stylized flourish at the end.

George Neal

President and Chief Operating Officer