



TAKING AIM AT DRUG PROMOTION AND STILL MISSING THE TARGET

by

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May 2008 will be a period of intense, uncomfortable scrutiny for those who market prescription drugs direct-to-consumers (DTC). Among other things, a subcommittee of the U.S. House of Representatives' Energy and Commerce Committee examines the loaded question, "Direct-to-Consumer Advertising: Marketing, Education, or Deception?" Amid these concerns, it is virtually certain that some existing Food and Drug Administration (FDA) requirements applicable to DTC print promotions will (once again) garner no attention even though they confuse consumers and burden and chill effective communications in violation of the constitutional commercial speech rights of drug marketers.

FDA regulates the "labeling" and "advertising" of prescription drugs. FDA deems written material that "accompanies" the drug, such as brochures about a prescribed therapy and "refill reminder" letters, to be promotional "labeling" that must include the drug's "adequate directions for use."¹ This requirement "is generally fulfilled by including the full approved labeling for the product (the 'package insert' [PI])." 70 Fed. Reg. 54,054, 54,055 (Sept. 13, 2005). The PI is an FDA-approved scientific and medical document "written for the healthcare practitioner" that contains the clinical information necessary for the medical professional to safely and effectively *prescribe* the drug to the patient. 71 Fed. Reg. 3921, 3922 (Jan. 24, 2006). It was never intended for the patient.

Print advertisements for prescription drugs must include a "brief summary" of the advertised drug's side effects, contraindications, and effectiveness. 21 U.S.C. § 352(n)(3); 21 C.F.R. § 202.1(e). "To meet the 'brief summary' requirement, sponsors typically reprint, in small type, whole sections of the [PI], which is generally written in terms that are not easily understood by the average consumer." 61 Fed. Reg. 24,314, 24,315 (May 14, 1996).

These extensive disclosure requirements mean that the accompanying information materials are very difficult or even impossible for a patient to comprehend. The PI is, after all, intended for *health care professionals*. Over ten years ago, FDA acknowledged that the PI and brief summary are "relatively inaccessible to consumers," are of "questionable" value, and may not be effective or informative for patients. 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995). As Dr. Robert Temple, now FDA Director for Medical Policy, bluntly acknowledged, the current brief summary is "neither brief nor a summary," and "I think you won't find a great deal of disagreement about that among FDA staff either."² "[M]any consumers do not have the technical background to understand fully the information typically included in prescription drug and biological advertisements to fulfill the 'brief summary' requirement." 61 Fed. Reg. at 24,315.

Not surprisingly, research has consistently documented that the traditional brief summary (and

¹21 U.S.C. §§ 352(f)(1) ("adequate directions for use") and 321(m); 21 C.F.R. § 202.1(l)(2) (definition of labeling).

²FDA Public Hearing: *Direct-to-Consumer Promotion*, Oct. 18, 1995) (statement of Robert Temple, M.D.) (available at: <http://www.fda.gov/cder/ddmac/DTCPANEL5.HTM>).

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certainly the far more complex and technical PI from which the brief summary is derived) is not consumer-friendly in content or format. According to FDA's own research, 41% of consumers reported not reading print advertisements' brief summaries at all, and 55% of those who did read brief summaries reported finding them hard to understand.³

The societal costs of FDA's accompanying information requirements extend beyond merely befuddling the audience they are intended to inform. Including a "brief summary" in a print advertisement requires the sponsor to pay for an additional page in a newspaper or magazine. Including the drug's PI in patient labeling such as refill reminders or in-pharmacy brochures requires that the manufacturer pay for several additional pages. These requirements impose enormous costs upon drug sponsors and pharmacies, while providing no benefit to consumers.

It is likely that FDA's brief summary/PI requirements are constitutionally infirm under the standards of *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980) and *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002). These accompanying information requirements chill and deter protected commercial speech. Under established Supreme Court precedent, FDA's restrictions upon commercial speech are constitutional only if: 1) The asserted governmental interest in the restriction is substantial; 2) The regulation directly advances the governmental interest asserted; and 3) The restriction is no more extensive than is necessary to serve that interest. *Western States*, 535 U.S. at 367; *Central Hudson*, 447 U.S. at 566.⁴

FDA's brief summary/PI requirements likely meet the first prong of this test. There is a substantial government interest in assuring that prescription drug promotions are truthful and do not mislead patients. Where FDA's accompanying information requirements stumble is in the last two prongs of the *Central Hudson* test.

By FDA's own repeated admissions, patients are not reading and are unlikely to understand a document that recites each side effect and contraindication from the PI. Thus, requiring the PI or the full brief summary with DTC print promotions is not directly advancing any government interest in promoting consumer health.

Additionally, the accompanying information requirements are more extensive than are necessary to protect consumer health. There are less burdensome means to communicate important information about prescription drugs to consumers. Examples include the "patient package insert" (FDA-approved patient labeling), a consumer-friendly version of the "Highlights" of the PI, or the broadcast model – fair balance and adequate provision.

In sum, FDA would be unlikely to be able to defend a serious challenge to its DTC print advertising and promotional labeling accompanying information requirements. Consumers do not understand and read the PI or typical brief summary, and there are less burdensome, more effective ways to communicate important prescription drug information to patients. Of particular concern with promotional labeling is that these are highly beneficial communications that help patients maximize therapeutic outcomes, adhere to the prescribed therapy, and learn about alternative treatment options. Burdening these useful communications with a full PI for the health care professional or the highly technical brief summary is harmful to patients and to the sponsoring manufacturers who bear the brunt of compliance with requirements FDA has conceded do not advance or protect the public health.

As the scrutiny of DTC continues, it is important to recall that in some instances, the solution does not lie in enhancing and augmenting the FDA requirements. Where those requirements are already confusing patients, the agency is obligated to find more effective and useful communication strategies.

³Kathryn J. Aikin, Ph.D., *Direct-to-Consumer Advertising of Prescription Drugs: Preliminary Patient Survey Results*, FDA (May 10, 2002) (available at: <http://www.fda.gov/cder/ddmac/DTCnational2002a/index.htm>); see also Princeton Survey Research Associates, *Consumer Reaction to DTC Advertising of Prescription Medicines; 8th Annual Survey*, *Prevention*, June 2005; Kimberly A. Kaphingst & William DeJong, *The Educational Potential Of Direct-To-Consumer Prescription Drug Advertising*, 23 HEALTH AFF. 143 (2004).

⁴DTC promotion meets the threshold requirement that it concern lawful activity and not be inherently misleading. It is well-established that the promotion of prescription drugs is protected, lawful commercial speech and is entitled to constitutional protection. See *Western States*, 535 U.S. at 368; *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).