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FDA LIMITS ON PRINT DRUG ADS VIOLATE THE FIRST AMENDMENT

by

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On April 29, 2002, the United States Supreme Court invoked the First Amendment to the U.S. Constitution and struck down legislation authorizing the Food and Drug Administration (FDA) to restrict the advertising by pharmacists of the drugs they compound. *See Thompson v. Western States Medical Center*, 122 S. Ct. 1497 (2002). Less than thirty days later, FDA took the extraordinarily proactive step of seeking comment on whether its regulations, policies and practices might violate First Amendment rights. Request for Comment on First Amendment Issues. 67 Fed. Reg. 34,942 (May 16, 2002). Comments were due to the agency by September 13, 2002, and responsive comments are due by October 28, 2002. 67 Fed. Reg. 45742 (July 10, 2002).

Many FDA regulations, guidances and practices may impinge the First Amendment rights of entities to disseminate information and the rights of the public to receive that information. One set of agency requirements is especially vulnerable — FDA's requirements that direct-to-consumer (DTC) print promotions of prescription drugs be accompanied by onerous disclosures of the drug's side effects, contraindications, and effectiveness.

Under the Federal Food, Drug and Cosmetic Act (FDC Act) and the FDA's implementing regulations, promotion of prescription drugs is divided into two categories — "labeling" and "advertising." A prescription drug's full product labeling contains the essential information necessary for a health care professional to prescribe, administer, and dispense the drug safely and effectively. This full product labeling is created during a drug's lengthy FDA review and approval process. It is a long, detailed, highly technical document that includes, among other things, information about the drug's clinical pharmacology, a summary of clinical data supporting the drug's indications and usage, contraindications, warnings, precautions, and adverse reactions, including virtually every adverse event recorded during clinical testing. *See* 21 C.F.R. § 201.57.

Apart from the full, FDA-approved product labeling, "labeling" also encompasses written, printed or graphic material that accompanies the drug. 21 U.S.C. § 321(m); *Kordel v. U.S.*, 335 U.S. 345 (1948). Labeling includes promotional material such as brochures, booklets, mailers, detailing materials, letters, and any other similar pieces of printed, audio, or visual matter descriptive of the drug. 21 C.F.R. § 202.1(l)(2). In contrast, advertising is defined much more narrowly and encompasses material published in journals, magazines, other periodicals, and newspapers, and material broadcast through media such as radio, television, and telephone communication systems. 21 C.F.R. § 202.1(l)(1). This distinction is important for a prescription drug promotion must comply with different legal requirements depending upon whether it is "advertising" or "labeling."

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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). FDA's implementing regulations specify that the information about risks in the brief summary should include "*each specific side effect and contraindication (which include side effects, warnings, precautions, and contraindications…)*" contained in the advertised drug's full, FDA-approved labeling. 21 C.F.R. § 202.1(e)(3)(iii) (emphasis supplied). These extensive disclosure requirements mean that the "brief summary" that accompanies a print advertisement must repeat all the detailed warning information from the drug's full, FDA-approved labeling. The brief summary, contrary to its name, is neither "brief," nor a "summary." Typically, the brief summary is long, highly technical and very difficult to read.

For promotional labeling directed to consumers, the disclosure requirement is even more onerous. Full drug labeling is intended for *health care professionals*. Yet, to comply with the requirements of 21 U.S.C. § 352(f), all drug labeling must bear "adequate directions for use." This means that even for booklets, brochures, mailers, letters, and other promotional labeling directed to consumers, promoters must reprint the dense medical jargon of the drug's full, FDA-approved labeling.

When held to the standards of *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980), as elucidated in *Western States Medical Center*, 122 S. Ct. at 1500, it is clear that FDA's accompanying information requirements are constitutionally infirm. The promotion of prescription drugs is certainly "commercial speech" that is entitled to protection under the First Amendment to the U.S. Constitution. *See Western States*, 122 S. Ct. at 1503; *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748 (1976). "[E]ven a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment." *Western States*, 122 S. Ct. at 1503, quoting, *Edenfield v. Fane*, 507 U.S. 761, 767 (1993).

Under the test first enunciated in *Central Hudson* and applied in *Western States*, a government restriction upon commercial speech is constitutional if, as a threshold matter, the commercial speech does not concern unlawful activity and is not misleading. *Western States*, 122 S. Ct. at 1504; *Central Hudson*, 447 U.S. at 566. If so, then the speech is protected by the First Amendment and a court must then evaluate whether the asserted governmental interest in the restriction upon speech is substantial. *Western States*, 122 S. Ct. at 1504; *Central Hudson*, 447 U.S. at 566. If the government's interest is substantial, a court next determines "whether the regulation directly advances the governmental interest asserted." *Western States*, 122 S. Ct. at 1504; *Central Hudson*, 447 U.S. at 566. Finally, the court determines whether the government restriction is "more extensive than is necessary to serve that interest." *Western States*, 122 S. Ct. at 1504; *Central Hudson*, 447 U.S. at 566. Each of these latter three inquiries must be answered in the affirmative for the restriction to be constitutional.

Certainly, prescription drug print promotion meets the first prong of the *Central Hudson* test. It is not inherently misleading and does not concern an unlawful activity. With regard to the second prong, it may also be assumed that assuring consumers receive accurate information about the prescription drug promoted is a legitimate and substantial government interest. Where FDA's accompanying information requirements plainly stumble is in the third and fourth prongs of the *Central Hudson* test.

FDA has conceded, publicly and repeatedly, that its requirements that the brief summary or full package labeling accompany DTC promotions are not truly advancing any government interest in promoting consumer health and welfare. Seven years ago, in the *Federal Register* notice announcing a public hearing on DTC promotion, FDA summarized the disclosure requirements for print promotion and noted that the full package insert and the brief summary are usually written in technical language, are "relatively inaccessible to consumers," are of "questionable" value, and may not be effective or informative. 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995).

At the public hearing that followed, Dr. Robert Temple, then FDA Associate Director for Medical

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Policy, bluntly acknowledged that the "brief summary" was an oxymoron:

> Let's say we all agree for the sake of argument that the current brief summary, which is neither brief nor a summary — like the Holy Roman Empire was neither holy nor an empire — isn't very helpful. I think you won't find a great deal of disagreement about that among FDA staff either.

DTC Public Hearing, Statement of Robert Temple, Oct. 18, 1995 (Panel 5).

FDA's own data from April 2002 underscores the futility of the accompanying information requirements for print media. FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) recently disclosed the preliminary results of its survey of DTC advertising of prescription drugs. *See* Preliminary Patient Survey Results Direct-to-Consumer Advertising of Prescription Drugs (http://www.fda.gov/cder/ddmac/DTCnational2002a/index.htm) May 10, 2002. That survey reveals that over 70% of respondents read little or none of the brief summary. Fewer people are reading the brief summary now than they did three years ago.

The societal costs of FDA's accompanying information requirements extend beyond merely confusing the audience they are intended to inform. To include a "brief summary" in a print advertisement, the sponsor must pay for an additional page in a newspaper or magazine. Examples of this excessive, impossibly dense, and very costly verbiage can be found in almost any circulated publication. In July 2002, *The Washington Post* carried full page advertisements for MOBIC® — while the reverse side of advertisement carried a three column, tiny print reprint of whole sections of the drug's full prescribing information. Advertisements in weekly circulars such as *U.S. News and World Report* had similar tiny print reprints for Allegra-D®, Prevacid®, and Altace®.

For promotional labeling, such as letters, brochures, or newsletters, the sponsor must also include several additional pages to accommodate the drug's full product labeling. These requirements impose enormous costs upon drug sponsors and advertisers, while providing no benefit to consumers.

The accompanying information requirements fail the final prong of the *Central Hudson* test, for they are more extensive than is necessary to serve the interest of consumer health and welfare. *See Western States*, 122 S. Ct. at 1504; *Central Hudson*, 447 U.S. at 566. There are other less burdensome and less costly methods of communicating important information about prescriptions drugs to consumers. These vehicles include the "adequate provision" model set out in FDA's Guidance for Industry – Consumer-Directed Broadcast Advertisements (August 1999) (Broadcast Guidance) (http://www.fda.gov/cder/guidance/1804fnl.pdf) and in the requirements for the dissemination of "useful written information" with pharmacy-dispensed prescription drugs, Sec. 601(b), Public Law No. 104-180, 21 U.S.C. § 353 note.

Under the Broadcast Guidance, a consumer-directed broadcast advertisement for a prescription drug need not provide a brief summary during the broadcast if the sponsor makes "adequate provision" for a consumer to receive the drug's full product labeling.[1] The adequate provision requirement is satisfied with some or all of the following:

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[1]Under the Broadcast Guidance, an advertisement must meet the following requirements in addition to making adequate provision for dissemination of the full package labeling: (1) not be false or misleading in any respect; (2) state that the drug is available only by prescription; (3) state that only a prescribing healthcare professional can decide whether the product is appropriate; (4) present a fair balance between information about effectiveness and information about risk; (5) include a major statement conveying all of the product's most important risk information in consumer-friendly language; and (6) communicate all information relevant to the product's indication (including limitations on use) in consumer-friendly language. Broadcast Guidance at 2.

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- Disclosure in the advertisement of a toll-free telephone number for consumers to obtain the product package labeling by mail, fax, email, or by having it read to them over the phone.

- Reference in the advertisement to additional product information in concurrently running print advertisements.

- Making package labeling available in a variety of publicly accessible sites (e.g., pharmacies, doctors' offices, grocery stores, public libraries).

- Disclosing an Internet web page (URL) address in the advertisement that provides access to the full product labeling.

- Disclosing in the advertisement that pharmacists, physicians and other health care providers may provide additional product information.

Broadcast Guidance at pgs. 2-3.

A second excellent model for the communication of important information about prescription drugs to consumers is the "useful written information" that must accompany dispensed prescription drugs. The "useful written information" option stems from Public Law No. 104-180, 110 Stat. 1569. The goal of Public L. No. 104-180 was the distribution to consumers of "useful written information" about the prescription drugs they receive. Useful information must be:

> scientifically accurate, non-promotional in tone and content, sufficiently specific and comprehensive as to adequately inform consumers about the use of the product, and in an understandable, legible format that is readily comprehensible and not confusing to consumers expected to use the product.

Pub. L. No. 104-180, 110 Stat. 1594. Like the Broadcast Guidance, this "useful written information" is a superb model for reform of the brief summary and full product labeling accompanying information requirements for DTC promotion.

The heavy burdens FDA regulations and guidances impose upon print DTC promotion are unlikely to withstand constitutional challenge. FDA itself has conceded that the onerous disclosures do not further any government interest in promoting consumer health and welfare. The education and information functions of the brief summary and full package labeling requirements could easily be met by adopting an existing, less burdensome disclosure model that is less inimical to the First Amendment and more useful and usable to consumers. FDA could undertake significant reform of these unconstitutional requirements through issuance of a guidance. Hopefully, FDA will use the upcoming review of its regulations, guidances and policies that may violate the First Amendment to address these important issues.

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