Docket No. FDA-2014-N-0168

COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

PROPOSED COLLECTION OF INFORMATION ON CONSUMER REACTION TO DISCLOSURES REGARDING ADDITIONAL RISKS IN DIRECT-TO-CONSUMER PRESCRIPTION DRUG TELEVISION ADVERTISEMENTS

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 79 *FED. REG.* 9217 (February 18, 2014)

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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Re: Proposed Collection of Information on Consumer Reaction to Disclosures Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements; Docket No. FDA-2014-N-0168
79 Fed. Reg. 9217 (February 18, 2014)

Dear Sir/Madam:

The Washington Legal Foundation (WLF) submits these comments in response to the Food and Drug Administration's proposed collection of certain information on consumer reaction to direct-to-consumer (DTC) television advertising for prescription drugs. The information is to be collected in connection with a research study into how well consumers understand risk information conveyed in DTC television advertising and how the content of DTC risk disclosures might be altered in order to improve consumer understanding.

WLF applauds FDA for undertaking the proposed study; it is "necessary for the proper performance of FDA's functions" because (among other reasons) the information derived from the study is likely to have considerable practical utility. In particular, the information is vital to determining the extent to which FDA may regulate the content of DTC advertising without running afoul of the First Amendment. The First Amendment permits FDA to require risk disclosures in DTC advertising only to the extent that FDA can demonstrate that such disclosures are necessary to serve the agency's interest in ensuring that consumers are not deceived by the

advertisement. Moreover, any mandated disclosures must be narrowly tailored to serve that interest. Thus, a risk disclosure requirement is not constitutionally permissible if a briefer disclosure would be better (or at least equally well) understood by an average consumer.

I. *Interests of WLF*

The Washington Legal Foundation is a public interest law firm and policy center with supporters in all 50 States. WLF regularly appears before federal and state courts and administrative agencies to promote economic liberty, free enterprise, a limited and accountable government, and the rule of law. In particular, WLF has devoted substantial resources over the years to promoting the free speech rights of the business community, appearing before numerous federal courts in cases raising First Amendment issues. *See, e.g.*, *Sorrell v. IMS Health* Inc., 131 S. Ct. 2653 (2011); *Nike v. Kasky*, 539 U.S. 654 (2003). WLF has successfully challenged the constitutionality of FDA restrictions on speech by pharmaceutical manufacturers. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). As a result of that litigation, FDA is subject to a permanent injunction limiting FDA authority to suppress manufacturer dissemination of certain journal articles/medical texts discussing off-label uses of their FDA-approved products. More recently, WLF lawyers played a key role in overturning—on First Amendment grounds—the criminal conviction of a pharmaceutical representative for conspiring to violate the FDCA; the representative's "crime" consisted of speaking truthfully about off-label uses of a drug manufactured by his company. *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).

WLF also regularly participates in FDA administrative proceedings in support of

expanded First Amendment rights. *See, e.g.*, FDA Docket No. FDA-2013-N-1430 (April 14, 2014) (response to FDA Draft Guidance on postmarket submissions to FDA of interactive promotional media); FDA Docket No. 2008-D-0053 (April 21, 2008) (response to FDA Draft Guidance for Industry on Good Reprint Practices); FDA Citizen Petition No. 2006P-0319/CPI (August 11, 2006) (documenting repeated First Amendment violations by FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) and calling on DDMAC to conform to constitutional constraints on its activities); FDA Docket No. 2011-D-0868 (March 29, 2012) (response to FDA Draft Guidance on unsolicited requests for off-label information); FDA Docket No. 02N-0209 (October 28, 2002) (response to FDA's request for public comments on First Amendment issues).

II. *First Amendment Precedent*

The federal courts have long recognized that the First Amendment, subject only to narrow and well-understood exceptions, does not countenance governmental control over the content of messages conveyed by private individuals. *See, e.g., Texas v. Johnson*, 491 U.S. 397, 414 (1989). "As a general matter, 'state action to punish the publication of truthful information seldom can satisfy constitutional standards.'" *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001) (quoting *Smith v. Daily Mail Publishing Co.*, 443 U.S. 97, 102 (1979)). While the courts have very occasionally upheld content-based speech restrictions, they have always imposed on the government a heavy burden of demonstrating the necessity of such restrictions. *See, e.g., R.A.V. v. St. Paul*, 505 U.S. 377, 382 (1992) ("Content-based regulations are presumptively invalid," and the government bears the burden to rebut that presumption.); *Burson v. Freeman*, 504 U.S.

191, 198 (1992).

FDA seeks to compel drug manufacturers to disclose risk information in connection with any DTC advertising on television or radio. *See* 21 C.F.R. § 202.1 (requiring that broadcast DTC advertisements include a "major statement" that sets forth a prescription drug's major risks). Under the First Amendment, the burden rests on FDA at all times to demonstrate an interest sufficient to justify such regulation of speech.

The Supreme Court has lessened somewhat the burden of proof imposed on government speech regulators when the speech in question is deemed "commercial speech," albeit such speech is still entitled to a substantial degree of constitutional protection. *See, e.g., Central Hudson Gas & Electric Corp. v. Public Service Comm'n*, 447 U.S. 557, 562-63 (1980). In general, "commercial speech" is defined as "speech which does no more than propose a commercial transaction," a definition that likely encompasses virtually all DTC advertising for prescription drugs. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976).

Although the government has greater leeway to regulate commercial speech, putative regulators of such speech still face a significant burden. At a minimum, the Supreme Court requires that the government prove that the restriction "directly advances" a "substantial government interest" and is "narrowly tailored" to achieve a reasonable "fit" between FDA's stated goals and the agency's means of achieving them. *Central Hudson Gas & Electric Corp. v.*

Public Serv. Comm'n, 447 U.S. 557 (1980).[1] For the *Central Hudson* test to be satisfied, the Court must be persuaded that the cost of the regulation has been "carefully calculated." *City of Cincinnati v. Discovery Network, Inc.,* 507 U.S. 410, 416 n.12 (1993). As with fully protected speech, the burden of justifying its restrictions rests squarely with the government. *Bolger v. Young Drug Prods. Corp.,* 463 U.S. 60, 71 n.20 (1985) ("party seeking to uphold a restriction on commercial speech carries the burden of justifying it"); *Thompson v. Western States Medical Center*, 535 U.S. 357, 373 (2002).[2]

The government undoubtedly has an interest in regulating commercial speech to reduce the possibility that consumers might be misled by the speech. In such circumstances, the "narrowly tailored" government response is to direct the speaker to include disclaimers designed to minimize the possibility that consumers will be misled, rather than banning the speech altogether. *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985). The government's

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[1] Under the four-part *Central Hudson* test, courts consider as a threshold matter whether the commercial speech concerns unlawful activity or is inherently misleading. If so, then the speech is not protected by the First Amendment. If the speech concerns lawful activity and is not misleading, then the challenged speech regulation violates the First Amendment unless government regulators can establish that: (1) they have identified a substantial government interest; (2) the regulation "directly advances" the asserted interest; and (3) the regulation "is no more extensive than is necessary to serve that interest." *Central Hudson*, 447 U.S. at 566.

[2] The evidentiary burden is not light; for example, the government's burden of showing that a commercial speech regulation advances a substantial government interest "in a direct and material way . . . 'is not satisfied by mere speculation or conjecture; rather, a government body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree.'" *Rubin v. Coors Brewing Co.,* 514 U.S. 476, 487 (1995) (quoting *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993)).

authority to impose disclaimer requirements is subject to strict limitations, however; disclaimer requirements are constitutionally impermissible if the are "unduly burdensome" and thereby "chill protected commercial speech." *Id*. at 651.

III. *The Proposed Study Will Have Significant Practical Utility: It Will Determine Whether Current Risk Disclosures Are Sufficiently Narrowly Tailored to Pass Muster Under the First Amendment*

FDA's February 18, 2014 Federal Register notice expresses concern that many consumers inadequately understand a DTC advertisement's "major statement" because it is too lengthy for easy comprehension. FDA stated, "There is concern that as currently implemented in DTC ads, the major statement is often too long, which may result in reduced consumer comprehension, minimization of important risk information and, potentially, therapeutic noncompliance due to fear of side effects." 79 Fed. Reg. at 9218. FDA thus proposes to undertake a study of consumers who may benefit from being prescribed specific drugs, for the purpose of determining the sort of risk disclosures that are most likely to be understood by an average consumer. The study is designed to study FDA's hypothesis that "relative to inclusion of the full major statement, providing limited risk information along with [a disclosure that there are other product risks not mentioned in the advertisement] will promote improved consumer perception and understanding of serious and actionable drug risks." *Id.*

WLF lacks expertise in study design and thus will not comment on the adequacy of the methods FDA plans to use in collecting information regarding consumer perception. Suffice it to say that WLF strongly applauds FDA for seeking information of this sort; all can agree that the public is well served by research designed to determine the optimal means of conveying

information about prescription drugs to individuals.

WLF adds that without such information, FDA speech regulation of this sort is constitutionally suspect. FDA bears the burden of demonstrating that its risk-disclosure requirements are a narrowly tailored means of advancing FDA's substantial interest in preventing consumers from being misled by DTC prescription drug advertising. Unless FDA finds that its current, burdensome "major statement" requirement is a narrowly tailored means of advancing that interest, that requirement cannot withstand First Amendment scrutiny. Obviously, the requirement cannot qualify as "narrowly tailored" if (as FDA hypothesizes) a requirement that "limit[s] the risks in the major statement to those that are serious and actionable, and include[s] a disclosure to alert consumers that there are other product risks not included in the ad," *id.*, would provide the average consumer with a better understanding of product risks.

IV. *The Proposed Study Will Also Help to Determine Whether Any Mandatory Disclosure of Specific Product Risks Is Constitutionally Permissible*

In order to meet the *Central Hudson* test, FDA needs to do more than simply show that its risk disclosure requirements are "narrowly tailored." It must also show that the requirements "directly advance" a "substantial" agency interest. FDA undoubtedly has an interest in preventing consumers from being misled by a broadcast DTC advertisement for a prescription drug. But it is not self-evident that the average consumer would be misled by an advertisement that failed to mention any specific risks associated with the drug. The proposed study provides FDA with an excellent opportunity to determine empirically whether there is any serious danger

that the failure to include specific risk information would mislead consumers.

WLF has an alternative hypothesis. Virtually all consumers are well aware that *every* prescription drug poses significant health risks for at least *some* patients, particularly if the drug is taken for contra-indicated uses, in excessive doses, or in combination with certain other drugs. Indeed, consumers recognize that it is the existence of such risks that causes the drug to be available on a prescription-only basis; unless the risks were substantial, the drug would likely be approved for over-the-counter sales. The average consumer further recognizes that his physician is highly likely to be aware of potential risks and almost surely will not prescribe the drug unless (s)he concludes that the benefits of the drug outweigh its risks. Under those circumstances, the average consumer is very unlikely to be misled regarding a drug's risks if a broadcast DTC advertisement for the drug alerts consumers to its potential benefits, states generally that taking the drug poses significant potential health risks, lists any types of individuals who are categorically contra-indicated for the drug, and then asks the consumer to consult with his doctor for a more detailed explanation of risks. WLF urges FDA to include an examination of WLF's hypothesis within its study. Unless FDA undertakes such an examination and determines (contrary to WLF's hypothesis) that the average consumer who is not informed about specific, significant health risks will be misled into believing that the drug poses no significant health risks for him, FDA cannot meet its First Amendment burden of demonstrating that the specific risk warnings mandated under current (or proposed) "major statement" requirements directly advance FDA's interests in preventing consumer deception.

V. *Conclusion*

WLF supports FDA's proposal to undertake a study of how well consumers understand risk information disclosed in broadcast DTC prescription drug advertising. WLF urges FDA to incorporate a First Amendment analysis into its study. Its First Amendment analysis should explicitly examine: (1) the extent to which risk disclosure directly advances FDA's interest in preventing consumers from being misled by DTC advertising; and (2) how extensive a disclosure requirement can be while still qualifying as a "narrowly tailored" speech restriction within the meaning of *Central Hudson*.

Sincerely,

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