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**Before the  
FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**(Docket No. 02N-0209)**

Supplemental Comments of

**ABBOTT LABORATORIES**

**Responding to the Food & Drug Administration's  
Request for Comment On First Amendment Issues**

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**Respectfully Submitted**

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Abbott Laboratories (“Abbott”) respectfully submits these comments in response to the invitation in the Food and Drug Administration’s (“FDA”) *Request for Comment on First Amendment Issues*, 67 Fed. Reg. 34,942 (May 16, 2002). FDA extended the period for submitting comments on July 10, 2002. *See* 67 Fed. Reg. 45,742 (July 10, 2002).

## BACKGROUND

Abbott supports FDA’s decision to take affirmative steps to reevaluate its regulatory policies in light of governing First Amendment law. Abbott believes that FDA is wise to ask whether “there may be tensions between some aspects of FDA’s authority and judicial developments.” 67 Fed. Reg. at 34,943. Abbott also agrees with FDA that “[r]ecent years have witnessed increased attention by consumers to their own medical care.” *Id.* Now, more than ever, the public has a strong interest in the wide dissemination of useful and truthful information about drugs, medical devices, and other pharmaceutical products.

In its *Request for Comment on First Amendment Issues*, FDA set forth nine questions to facilitate discussion of issues related to its regulation of commercial speech. Abbott submitted comments, dated September 16, 2002, responding to each of those nine questions. In those comments, Abbott identified five areas in which FDA’s regulations, guidance, policies, and practices should change in order to comply with governing First Amendment law: (1) restrictions on speech relating to unapproved products (*see* 21 C.F.R. § 812.7(a)); (2) regulations prohibiting the dissemination of journal article reprints and textbooks; (3) restrictions prohibiting manufacturers from making statements regarding the analytical or clinical performance of Analyte Specific Reagents (“ASRs”) (*see* 21 C.F.R. § 809.30(d)(4)); (4) restrictions on pre-approval drug promotions (*see* FDA’s *Pre-Approval Promotion Guidance* (June 1994)); and (5) FDA’s policy of regulating financial materials under its advertisement standards. Abbott believes that FDA’s regulatory policies in each of these areas are unduly restrictive and inconsistent with governing First Amendment principles. Accordingly, they should be revisited by the agency along the lines suggested in Abbott’s September 16 comments.

These follow-on comments build on Abbott’s earlier submission with a view to helping FDA gain a better appreciation “of the evolving judicial landscape in areas that directly affect its ability to regulate words.” 67 Fed. Reg. at 34,943. Abbott believes that, by responding to recent court decisions, and adjusting its regulatory policies accordingly, FDA will be able to maintain the “overall legal credibility necessary . . . to sustain its authority to accomplish its important public health duties.” 67 Fed. Reg. at 34,943.

The comments are divided into three parts:

- Part I explains why FDA should be careful to guard against over-regulation and/or unconstitutional restrictions on speech.
- Part II discusses empirical data relevant to the question whether information recipients are capable of assessing the value of information presented to them regarding drugs and medical devices.

Part III explains why FDA should take into account the effect of its regulations on separate state requirements or prohibitions that restrict, govern, or affect speech.

## DISCUSSION

### I. FDA SHOULD BE CAREFUL TO GUARD AGAINST OVER-REGULATION AND/OR UNCONSTITUTIONAL RESTRICTIONS ON SPEECH.

The free flow of commercial information is protected under the First Amendment because “it is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed.” *Thompson v. Western States Med. Ctr.*, 122 S.Ct. 1497, 1503 (2002) (citing *Virginia State Bd. of Pharmacy v. Virginia Citizen’s Consumer Council*, 425 U.S. 748, 765 (1976)). Protecting commercial speech takes on added importance, moreover, where, as here, restrictions on speech could harm public health. As courts have recognized, when FDA imposes unduly burdensome restrictions on the speech rights of drug and device manufacturers, it not only violates the First Amendment, but it prevents consumers from obtaining beneficial, or even life-saving, information from manufacturers — the parties in the best position to have that information.

In the process of evaluating its existing regulations, guidance, policies, and practices, FDA should keep in mind its duty to construe the Food, Drug, and Cosmetic Act (“FDCA”) in a manner that avoids constitutional infirmity. *See, e.g., Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 121 S. Ct. 675, 683 (2001) (noting that “Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority”). As described below, to ensure that its regulatory policies do not run afoul of the First Amendment, FDA must have **concrete evidence** that its policies **directly** and **materially** advance a substantial governmental interest, and that they are “**no more extensive than necessary**” to achieve those interests. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980) (emphasis added).

#### A. FDA Must Have Concrete Evidence That Its Regulatory Policies Directly Advance A Governmental Interest.

The Supreme Court has consistently held that commercial speech, including advertising and labeling, is entitled to protection under the First Amendment. *See, e.g., Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976); *see also Lorillard Tobacco Co. v. Reilly*, 121 S. Ct. 2404 (2001); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995); *In re R.M.J.*, 455 U.S. 191 (1982). The Supreme Court has stated that “[c]ommercial speech not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information.” *Central Hudson*, 447 U.S. at 561-62.

*Central Hudson Gas & Electric Corp. v. Public Service Commission* sets out the Supreme Court’s now-familiar four-prong test for determining whether government regulations impermissibly restrict commercial speech. *First*, does the expression fall within the protective scope of the First Amendment (in other words, is the expression truthful, or is it false and/or

unlawful)? *Second*, is the asserted governmental interest in regulating the speech substantial? *Third*, does the government's regulation directly advance the asserted governmental interest? *Fourth*, is the restriction on speech more extensive than necessary to serve that interest? See *Central Hudson*, 447 U.S. at 564.

The government has the burden of proving that any restriction it places on commercial speech satisfies all four prongs of the *Central Hudson* test. See *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) (citing cases); see also *Bolger v. Youngs Drug Product Corp.*, 463 U.S. 60, 71 n.20 (1983) (A "party seeking to uphold a restriction on commercial speech carries the burden of justifying it"). This burden is not satisfied by "mere speculation or conjecture," *Edenfield*, 507 U.S. at 771, or "anecdotal evidence and educated guesses," *Coors*, 514 U.S. at 490. Nor can the government satisfy its burden if the restriction "provides only ineffective or remote support for the government's purpose." *Edenfield*, 507 U.S. at 777. Rather, "a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Id.* at 770-71. Indeed, the Supreme Court has cautioned that the requirement that the government come forward with concrete evidence to support restrictions on speech is critical. Otherwise, the government "could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Coors*, 514 U.S. at 487 (citing *Edenfield*, 507 U.S. at 771).

The Supreme Court has also repeatedly held that outright paternalism cannot justify restrictions on commercial speech. It has rejected the view that "the public is not sophisticated enough to realize the limitations of advertising" or that the public is somehow "better kept in ignorance than trusted with correct but incomplete information." *Bates v. State Bar of Arizona*, 433 U.S. 350, 374-75 (1977). Such arguments, which "underestimat[e] . . . the public," rest on "dubious" grounds at best. *Id.*; see also *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) (rejecting as "almost frivolous" FDA's position that dietary supplemental claims were "inherently misleading," rendering it "virtually impossible" for consumers to exercise independent judgment). As the Court recently emphasized, the "First Amendment directs [courts] to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *Western States*, 122 S. Ct. at 1508 (citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 584, 503 (1996)).

The Supreme Court has thus been emphatic that the "general rule is that the speaker and the audience, **not the government**, assess the value of the information presented." *Edenfield*, 507 U.S. at 767 (emphasis added); see also *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 191 (1999) (noting that there is a "presumption that the speaker and the audience, not the [g]overnment, should be left to assess the value of accurate and nonmisleading information about lawful conduct"); *Riley v. Nat'l Fed'n of the Blind of N.C.*, 487 U.S. 781, 790-91 (1988) (noting that the "First Amendment mandates that we presume that speakers, not the government, know best both what they want to say and how to say it"). "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all." *Central Hudson*, 447 U.S. at 562. The Supreme Court has therefore taken the position that "people will perceive their own best interests if only they are well enough informed." *Virginia Bd. of Pharmacy*, 425 U.S. at 770. "[T]he best means" to achieving this end "is to open the channels of communication rather than

to close them.” *Id.* As the Court has observed, society as a whole has a strong interest in the “free flow of commercial information.” *Id.* at 764. Indeed, a “particular consumer’s interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day’s most urgent political debate.” *Id.* at 763. In sum, the free flow of commercial information is indispensable both to “the proper allocation of resources,” and the “formation of intelligent opinions as to how the [free enterprise] system ought to be regulated or altered.” *Id.* at 765.

**B. FDA Regulations Have Been Struck Down In the Past For Not Being Sufficiently Sensitive To First Amendment Concerns.**

A number of FDA regulatory policies have recently been struck down for not being sufficiently sensitive to First Amendment concerns. In *Thomson v. Western States Medical Center*, 122 S. Ct. 1497 (2002), for example, the Supreme Court held that FDA’s restrictions on pharmacists advertising their practice of compounding drugs violated the First Amendment. Applying the *Central Hudson* test, the Court determined that FDA had overstepped its authority by imposing speech restrictions to achieve ends that could have been achieved through less burdensome regulation. The Court explained that, even assuming FDA had a substantial interest in regulating compound drugs, the agency failed to explain why it could not “have achieved its interests in a manner” that was less burdensome on speech.

The reasoning of *Western States* may have important ramifications for FDA. Most importantly, *Western States* reaffirms the Court’s retreat from statements in earlier cases suggesting that restrictions on speech could be upheld if the government demonstrated merely a “reasonable fit” between the ends and means of its regulatory scheme. *See, e.g., Lorillard Tobacco*, 533 U.S. at 561; *Posados de Puerto Rico Ass’n v. Tourism Co.*, 478 U.S. 328, 341 (1986). In *Western States*, the Court made clear that if the government can “achieve its interests in a manner that does not restrict speech, or restricts less speech, the [g]overnment must do so.” *Western States*, 122 S. Ct. at 1506. Put simply, “[i]f the First Amendment means anything, it means that regulating speech must be a last — not first — resort.” *Id.* at 1507.

Even before the Supreme Court’s decision in *Western States*, however, FDA regulations implicating commercial speech were already being struck down with some regularity in the lower courts. For instance, in *Pearson v. Shalala*, the D.C. Circuit addressed whether FDA could stop manufacturers from including certain “health claims” on the labels of dietary supplements. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999). FDA regulations prohibited manufacturers from making such claims unless they were supported by “significant scientific agreement.”

FDA asserted that its regulations were lawful because “health claims lacking ‘significant scientific agreement’ are *inherently* misleading and thus entirely outside the protection of the First Amendment.” *Id.* at 655 (emphasis in original). The court rejected this assertion as “almost frivolous,” and chastised the agency for being too paternalistic. The court explained that it was not as if the health claims had “such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment . . . as if the consumers were asked to buy something while hypnotized.” *Id.*; *see also Health Alliance v. Shalala*, 953 F. Supp. 526, 529 (S.D.N.Y. 1997) (rejecting the argument that health claims that have not been FDA approved are

inherently misleading). The court further reasoned that, while FDA's interests in protecting public health and preventing consumer fraud were substantial, FDA's interests were not directly advanced by its outright ban on speech. The court also suggested that "a less draconian method — the use of disclaimers" — could adequately serve the government's interests. *Id.* at 654; *see also Health Alliance*, 953 F. Supp. at 531 (noting that "[t]he First Amendment does not permit the FDA to prohibit . . . presumptively valid, non-misleading health claims that have been preliminarily determined to be supported by significant scientific agreement. . . for an indefinite period."). Accordingly, the court concluded that, as a general matter, FDA could not use outright bans, unless it could provide empirical evidence that disclaimers "would bewilder consumers and fail to correct for deceptiveness." *Id.* at 659.

Similarly, in *Washington Legal Foundation v. Friedman*, and in *Washington Legal Foundation v. Henney*, the district court for the District of Columbia held that FDA had violated the First Amendment by forbidding drug manufacturers from distributing to doctors independent journal articles describing off-label uses for drugs and medical devices. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (1998), *vacated on other grounds*, 202 F.3d 331 (D.C. Cir. 2000); *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81 (1999), *vacated on other grounds*, 202 F.3d 331 (D.C. Cir. 2000). Striking down FDA guidance documents, the court emphasized that FDA's general interest in "protecting and promoting the public health" was not sufficiently narrow to justify FDA's speech restrictions. *Henney*, 56 F. Supp. 2d at 86 n.6. In the court's view, more, not less, speech benefits public health: "Through the government's well intentioned efforts to prevent misleading information from being communicated, a great deal of truthful information will also be embargoed. In this case the truthful information may be life saving information, or information that[t] makes a life with a debilitating condition more comfortable." *Friedman*, 13 F. Supp. 2d at 73. Because information recipients are well-equipped to assess the value of information presented, the court concluded that manufacturers should be permitted by FDA to engage in full and complete disclosure and truthful dissemination of information.<sup>1</sup>

**C. Disclaimers, As Opposed To Outright Speech Bans, Are Preferred To Ensure That Regulation Is No More Intrusive Than Necessary.**

The overall lesson from these cases is that FDA should avoid restricting speech, except when necessary to achieve legitimate governmental ends. When FDA deems it necessary to restrict speech, moreover, it should seek to adopt regulatory policies other than outright speech bans. Disclaimers, for example, are "constitutionally preferable to outright suppression." *Western States*, 122 S. Ct. at 1508. As noted by the D.C. Circuit in *Pearson*, "[w]hen government chooses a policy of suppression over disclosure — at least where there is no

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<sup>1</sup> The *Washington Legal Foundation* cases were eventually vacated on other grounds. On appeal, the D.C. Circuit held that FDA lacked authority to impose the commercial speech restraints it had defended before the trial court. Finding that no constitutional controversy survived, the D.C. Circuit vacated the trial court decision and remanded the case. *See Washington Legal Foundation v. Henney*, 202 F.3d 331, 340 (D.C. Cir. 2000). The trial court's First Amendment analysis of FDA restraints on the commercial speech rights of drug and device manufacturers is nonetheless consistent with increasing judicial attention to the issue of whether FDA's regulatory policies unnecessarily restrict commercial speech.

