
**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.¹

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

¹ 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.

showing that disclosure would not suffice to cure misleadingness — government disregards a far less restrictive means.” *Pearson*, 164 F.3d at 658 (internal quotations omitted).

This judicial insistence that agencies, like FDA, show that disclaimers are ineffective before resorting to outright speech bans is thus of central importance. Most fundamentally, it ensures that FDA carefully considers ways to achieve its objectives before infringing upon free speech. It also places the burden squarely on FDA to justify its regulations. As the Supreme Court has stated, “[t]he free flow of information is valuable enough to justify imposing on would-be regulators the costs of distinguishing truthful from the false, the helpful from the misleading, and the harmless from the harmful.” *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985).

II. FDA SHOULD CAREFULLY EVALUATE EMPIRICAL DATA BOTH TO AVOID OVERREGULATION AND PROTECT PUBLIC HEALTH.

As FDA addresses the legal doctrines recounted above — and in particular the constitutional preference for speech over censorship — it necessarily must weigh and balance the benefits of increased flows of truthful consumer information with any constitutionally cognizable harms. Empirical data from case-specific contexts is therefore critical to FDA’s efforts to fashion sound regulatory policy that appropriately balances “the need and right of Americans to speak and hear information vital to their every day lives against the need to ensure that people are not misled.” 67 Fed. Reg. at 34943.

At this point, the empirical debate is being framed by different points of view from both inside and outside the government. For instance, the Federal Trade Commission’s comments, like those made jointly by various members of Congress, emphasize the practical and empirical effects of making more or less speech available to consumers in the pharmaceutical marketplace. *See* FTC Comments (Sept. 13, 2002); Comments of E. Kennedy, H. Waxman, *et al.* (Sept. 13, 2002). Similarly, John E. Calfee of the American Enterprise Institute, while focusing on very different issues, shares the Center for Science in the Public Interest’s concerns for the practical and empirical effects of different policy choices on consumer welfare. *See* Comments of J. Calfee (Sept. 13, 2002); Comments of Center for Constitutional Rights (Sept. 13, 2002); *see also* Comments of Healthcare Communication (Sept. 18, 2002).

In Abbott’s view, these commenters, although attacking the problem from differing directions, are asking the proper questions. Most importantly, all sides recognize that, in the commercial speech context, the government may regulate *only* after assembling and analyzing an administrative record sufficient to carry its context-specific, empirical burden of proving that restrictions on speech are justified.

It should therefore be common ground that FDA should take an empirical approach to evaluating any regulation of speech. The critical question before the agency is how to establish adequate market and legal mechanisms to deter manufacturers from making false claims about their health products, while still giving appropriate deference to the First Amendment. *See* Richard A. Posner, *Regulation of Advertising By The FTC* (Am. Enter. Inst. for Pub. Policy Research, 1973) (discussing mechanisms to deter misleading promotional claims by sellers). With that question in mind, FDA regulations that restrict commercial speech should be examined

and, if necessary, reformed in order to create proper incentives for manufacturers to disseminate the types of non-misleading information most helpful to consumers.

Arguments have been made on both sides of the empirical debate over how FDA should as a general matter satisfy its various (and sometimes conflicting) obligations. Those in favor of reforming FDA's current regulatory regime have marshaled particularly impressive arguments in support of their position. Numerous commenters have noted, for example, that a vast array of research and economic analysis strongly suggests that commercial speech has significant value to consumers. See FTC Comments, at 6 n.10 (Sept. 13, 2002); Comments of Pfizer Inc., at 4 (Sept. 13, 2002). These commenters emphasize that advertising is "an immensely powerful instrument for the elimination of ignorance," and argue that without the free flow of information "the incentive to compete on price and quality" is weakened and consumers are harmed. FTC Comments, at 6 n. 10, n.11 (Sept. 13, 2002) (citing G. Stigler, *The Economics of Information*, 64 J. Pol. Econ. 213, 220 (1961); H. Beales, *et al.*, *The Efficient Regulation of Consumer Information*, 24 J. L. & Econ. 491, 492 (1981)). They also place heavy emphasis on studies and data showing that direct-to-consumer advertising has positive health and economic effects. See Comments of J. Calfee (Sept. 13, 2002); Comments of Healthcare Communication (Sept. 13, 2002). And they cite to studies showing that consumers make informed decisions, and are capable of evaluating the information that is presented to them. See *id.* In their view, restricting speech harms consumers by preventing them from obtaining beneficial, or even life-saving, information. See Comments of the Freedom to Advertise Coalition, at 27-35 (Sept. 13, 2002) (stating that empirical evidence shows that direct-to-consumer advertising improves public health, enhances patient/physician relationships, does not lead to misprescribing or over-prescribing, and adequately communicates risks).

On the other hand, those opposed to relaxing existing restrictions on speech contend that regulating with a firm hand is needed to avoid harming consumers. They suggest that, in past eras with less regulation, Americans have been subjected to the promotion of ineffective and unsafe health-related products. See Comments of E. Kennedy, H. Waxman, *et al.*, at 4 (Sept. 13, 2002). These commenters assert that the "[t]he history of the FDCA is unfortunately replete with evidence that" without premarket screening of health claims, "deceptive and unsubstantiated claims about medical products proliferate, at tremendous cost to the public health." *Id.* at 5-6. They cite examples of harm to consumers, allegedly caused by promotional claims about off-label uses. See *id.* at 13-16; see also Comments of Center for Science in the Public Interest (Sept. 13, 2002) (discussing dietary supplements). And they refer to studies and evidence that they believe indicates that disclaimers are not effective, and that "information provided to doctors by pharmaceutical companies continues to lack objectivity." Comments of E. Kennedy, H. Waxman, *et al.*, at 21 (Sept. 13, 2002). Finally, they contend that history shows that permitting manufacturers to promote uses of products that have not been approved by FDA eliminates the incentive for manufacturers to prove that their products are effective. See *id.* at 22.

In evaluating such conflicting perspectives, the FDA should keep in mind that context matters. Precisely because the First Amendment is implicated, FDA has a legal obligation to avoid wholesale, indiscriminate restrictions on speech based only on generalized health and safety concerns. See *Ibanez v. Florida Dep't of Business & Professional Regulation*, 512 U.S. 136, 146 (1994) ("rote invocation of the words 'potentially misleading'" cannot "supplant the

[government's] burden" to justify restrictions on speech). Instead, it must hone its regulations to make them finely-tuned, narrowly focused, and context-specific. When less restrictive measures serve the government's interests, the Constitution mandates that they be adopted — even if the FDA might otherwise prefer to ban certain types of speech.

Among the most important contextual facts pertaining to drugs and medical devices is that, because FDA lacks authority to regulate the practice of medicine, physicians promote off-label uses of pharmaceutical products to their patients all the time. FDA's restrictions on speech, therefore, do not directly prevent the harms that some commenters fear by protecting consumers from using medical products for uses that have not been pre-approved by the agency. FDA's speech restrictions instead often have the perverse result of preventing manufacturers — the parties with the most information about their products — from educating physicians about how and when those products should and should not be used.

In sum, FDA must critically examine empirical evidence and devise practical, case-by-case solutions that account for the true informational dynamics of the dissemination of facts about medical care. Only by examining case-specific facts will FDA be able to provide optimal protection of public health, taking into account the free speech values that have been so eloquently, frequently and recently articulated by the Supreme Court. To this end, Abbott recommends that FDA work closely with leaders from Congress and other agencies, like the Federal Trade Commission, who have extensive respect for and experience with the dissemination and regulation of speech directed to consumers. Working in such a collaborative fashion, should pave the way for empirically sound, case-specific resolutions to broader policy issues framed by FDA's *Request for Comment on First Amendment Issues*.

III. FDA SHOULD TAKE INTO ACCOUNT THE EFFECT OF ITS REGULATIONS ON SEPARATE STATE REQUIREMENTS AND PROHIBITIONS THAT RESTRICT SPEECH.

In evaluating the empirical effects of restrictions on speech, FDA should be aware of the interaction of the federal and state systems. In particular, FDA should understand that both the doctrine of implied preemption and the dormant Commerce Clause broadly preclude state law from imposing greater restrictions on speech than those adopted by FDA.

A. The Supremacy Clause Precludes States From Supplementing FDA Regulations That Restrict Speech.

As a premise of sound regulatory policy, FDA should understand that its regulations pertaining to speech are exclusive and as a general matter may not be supplemented by the states, absent an express and carefully delimited FDA recognition of state authority. *See generally Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (holding that a federal statute governing cigarette advertising prevents states and localities from imposing special requirements or prohibitions on cigarette advertising). This especially holds true for restrictions on speech that FDA places on pharmaceutical manufacturers that sell their products in interstate commerce.

It is a familiar and well-established principle that the Supremacy Clause of the United States Constitution invalidates states laws that "interfere with, or are contrary to," federal law.

Gibbons v. Ogdén, 9 Wheat 1, 211 (1824). State law is impliedly preempted if federal regulation is sufficiently comprehensive that no room is left for state regulation. See *Hillsborough County v. Automated Medical Labs., Inc.*, 471 U.S. 707, 713-14 (1985) (discussing the different ways that federal law may supersede state law). Moreover, state laws can be preempted by federal regulations as well as by federal statutes. See *id.*

There can be no doubt that regulating speech describing medical drugs and devices sold nationwide is a “peculiarly federal concern.” *Boyle v. United Technologies Corp.*, 487 U.S. 500, 505 (1988); see also 21 U.S.C. §§ 331-335 (giving FDA authority to impose penalties for the adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce). As FDA correctly recognizes, FDA is charged with carefully balancing “the need and right of Americans to speak and hear information vital to their every day lives against the need to ensure that people are not misled.” 67 Fed. Reg. at 34943. State regulations, however well intended, inevitably, or almost inevitably, conflict with FDA’s own responsibility to strike this delicate empirical balance between freedom of speech and whatever limitations on speech are absolutely and unavoidably needed.

Buckman. As FDA revisits its speech-restrictive regulations, the Supreme Court’s recent decision in *Buckman Company v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2000), should be especially closely examined. In *Buckman*, the Supreme Court addressed the question whether federal law impliedly preempts state-law tort claims alleging fraud on FDA during the regulatory process for obtaining FDA clearance prior to the marketing of certain medical devices. The Court answered that question in the affirmative, determining that “plaintiffs’ state law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law.” *Id.* at 348. The Court explained that “[t]he conflict stems from the fact that the federal regulatory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives.” *Id.* The Court then noted that the balance sought by FDA could “be skewed by allowing fraud-on-the-FDA claims under state tort law.” *Id.*; see also *Rodriguez v. United States*, 480 U.S. 522, 528 (1987) (“[d]eciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice — and it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute’s primary objective must be the law”); *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000).

It was significant, the Court explained, that the FDCA “set[s] forth a comprehensive scheme” of regulation, *id.*, and that FDA “has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud.” *Id.* at 349. In the Court’s view, “[t]his flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives.” *Id.* at 349. Accordingly, the Court determined that “[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Administration’s judgment and objectives.” *Id.* “As a practical matter, complying with the FDA’s detailed regulatory scheme in the shadow of 50 [s]tates’ tort regimes will dramatically increase the burdens facing potential applicants — burdens not contemplated by Congress in enacting the FDCA and the [Medical Devices Act].” *Id.*

Nor can *Buckman's* rationale be viewed as in any way limited or confined to its facts. *Buckman* itself was unanimously decided, with seven justices joining the principal opinion. Moreover, *Buckman's* rationale employs the same essential reasoning previously laid out in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). In *Geier*, the Court held that Department of Transportation airbag regulations preempted a state-law tort suit accusing American Honda of negligently failing to design an airbag into a 1987 Honda Accord. The Court noted that there are sound reasons why a federal agency responsible for public health and safety might want to regulate only so far and no further. It then concluded that state tort law claims were preempted because they would otherwise serve as an obstacle to the achievement of federal regulatory goals. *See id.* at 883. As it did later in *Buckman*, the *Geier* Court refused to assume that more regulation is always better, specifically rejecting petitioners' argument that federal regulations should be interpreted to impose only a minimum standard. *See id.* at 874. Rather, the *Geier* Court emphasized, as *Buckman* later did, that because the federal regulatory scheme was detailed and finely-tuned, state tort laws would necessarily interfere with the tradeoffs that federal regulators had carefully made among alternative goals and objectives. *See id.* at 874-81.

The Request for Comment. FDA's *Request for Comment* presents the question of state authority to supplement FDA regulations in a context only slightly different than that of *Buckman*. Whereas *Buckman* involved attempted state law supplementation of FDA-regulated technical speech directed to FDA, the *Request for Comment* directly implicates the permissibility of state law supplementation of FDA-regulated technical speech to consumers of FDA-regulated products.

This issue of supplemental state authority pertains to whether and by how much states may change an empirical balance that FDA has struck. As described above, any speech-restrictive regulations that FDA promulgates must be justified by empirical analysis addressing specific claims and products, and establishing precisely how much speech, if any, is the minimum necessary to prevent contemplated harms. But once an FDA dividing-line has been drawn, states may well try to redraw that line. For instance, states have been known to address issues closely related to FDA regulations governing the promotion of drugs and medical products through application of their law of tort under theories such as those that impose liability for alleged breaches of a supposed "duty to warn."

The vital point is that any slight differences between allegations of tortious failure to disclose information *to the FDA* (the question in *Buckman*) and allegations of tortious failure to disclose information *to consumers* (the question implicated by the *Request for Comment*) is not material for ultimate preemption conclusions. In both instances, the *Buckman* rationale for displacing state authority applies. In *Buckman* itself, the Supreme Court's preemption determination turned on the observation that federal preemption doctrines necessarily prohibit states from "skewing" the "somewhat delicate balance between statutory objectives" as struck by FDA. *Buckman*, 531 U.S. at 348. In *Buckman*, FDA's finely-tuned balance was struck between, on the one hand, the need to compel parties to make truthful disclosures in FDA filings and, on the other, the need to ensure that FDA filings that are preconditions for marketing new medical devices are not so burdensome as to choke off the flow of such devices. *See id.* at 347-50. Because FDA had struck this delicate balance, the Court concluded that states were not free to tilt it in a preferred direction. Specifically, it concluded that states may not tilt FDA's balance

through the application of tort doctrines requiring additional thoroughness in disclosures to FDA. *See id.*

Here, a similar finely-tuned balance is at issue. As FDA resolves the challenging issues described above — mindful of the constitutional preference for speech over censorship — it necessarily must reconcile the benefits of increased flows of truthful consumer information with any constitutionally cognizable harms these flows entail, such as an alleged capacity to mislead. *See* Comments of E. Kennedy, H. Waxman, *et al.* (Sept. 13, 2002). State regulation that seeks to refine such an FDA-struck balance, by compelling additional or different disclosures under theories of breach of duty to warn and the like, will unavoidably upset FDA's own reconciliation of competing federal interests. *See Buckman*, 531 U.S. at 350 (“State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives.”).

It thus bears emphasis that, in shaping and overseeing the implementation of the FDCA, FDA has interpreted the law as forcing it to regulate right up to the limits permitted by the First Amendment. Assuming that this is the case, moving the delicate balance struck by FDA in either direction would violate either the FDCA (by restricting too little speech) or the First Amendment (by restricting too much).

Accordingly, unless FDA expressly creates room for state authority imposing additional liability on manufacturers — and thus additional restrictions on speech — state law effectively restricting speech will necessarily be preempted as an obstacle to the full achievement of FDA's objective of finding the delicate First Amendment balance under the FDCA. *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (discussing standards for obstacle preemption); *see also English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990) (same); *Maryland v. Louisiana*, 451 U.S. 725, 747 (1981) (same). This is especially true in light of the elastic and case-specific nature of state law tort claims. As the Supreme Court recognized in *New York Times v. Sullivan*, state tort law can have just as much influence on behavior as statutory law. *See New York Times v. Sullivan*, 376 U.S. 254, 265 (1964) (“The test is not the form in which state power has been applied but, whatever the form, whether such power has in fact been exercised”); *see also Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); *Medtronic, Inc. v. Lohr*, 518 U.S. 479 (1996). *New York Times* and progeny establish the impossibility of relying on *ad hoc* jury verdicts in speech-sensitive areas. They accordingly demand that this balance be struck elsewhere; specifically through a reticulated scheme of federal displacement of important aspects of state common law. *See Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 349-50 (1974). In the present context, of course, this balance can only be struck by FDA.

But the fact that FDA, not common law juries, must be responsible for striking First Amendment balances means that FDA's own administrative processes must be the ultimate source of any state authority over FDA-regulated commercial speech. FDA should accordingly be aware that framing defensible reservoirs of supplemental state authority would at least be difficult and perhaps impossible. State law governing claims of failure to warn, deception, and the like vary all the way from that of states like Michigan, which strictly limits the availability of punitive damages and recognizes compliance with FDA regulations as a defense, *see* M.C.L.A. §§ 600.2946, 600.2959; to states like Pennsylvania which permits much more liberal supplemental of FDA regulations, *see Buckman*, 531 U.S. at 343; *see also Burton v. Danek Med.*,

Inc., No. 95-5565, 1999 WL 118020 (E.D. Pa. Mar. 1, 1999). Any general FDA authorization of state supplementation through common law as such would inevitably produce impositions on speech that vary widely across states. For this reason, FDA may carve out reservoirs of state regulation, if at all, only through administrative law mechanisms that specifically and carefully pre-determine which state laws are and are not compatible with its own policy choices. In the absence of mechanisms of this unusual type, no state regulation whatever is permissible.

B. The Dormant Commerce Clause Precludes States From Supplementing FDA Regulations That Restrict Speech.

Any state regulation above and beyond what FDA might require would also raise serious constitutional concerns under the dormant Commerce Clause. The Commerce Clause of the United States Constitution provides that only Congress may regulate interstate commerce. See U.S. Const. art. I, § 8, cl. 3. Courts have inferred from this affirmative grant of authority to Congress a negative or “dormant” limitation on the authority of states to enact legislation affecting interstate commerce. See *Healy v. The Beer Inst. Inc.*, 491 U.S. 324, 326 n.1 (1989). That limitation reflects “the Constitution’s special concern both with the maintenance of a national economic union unfettered by state-imposed limitation on interstate commerce and with the autonomy of the individual States within their respective spheres.” *Id.* at 335.

The Supreme Court has adopted a two-tiered approach to analyzing state economic regulation under the dormant Commerce Clause. See *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573, 578-79 (1986). When a state statute directly discriminates against out-of-state manufacturers, the statute is invalid and further inquiry is unnecessary. See, e.g., *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982). When, however, a state statute regulates evenhandedly and has only indirect effects on interstate commerce, a balancing test is applied: the statute is valid only if the state’s interest is legitimate and the burden on interstate commerce does not clearly exceed the local benefits. See *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

Under dormant Commerce Clause analysis, as under implied preemption analysis, state regulations that go beyond FDA’s finely-tuned regulatory scheme to impose even greater restrictions on speech are unconstitutional. Specifically, such regulations fail the *Pike* balancing test. Again, the First Amendment prohibits restrictions on commercial speech unless they are both justified by empirical evidence and “no more extensive than necessary.” *Central Hudson*, 447 U.S. at 566. But state regulations that exceed federal speech-restrictive requirements will by definition violate *Central Hudson* by producing a federal-state combination of regulations that is “more extensive than necessary.” Because no state can have legitimate interests in violating the First Amendment, and states’ legitimate interests in consumer protection will already have been addressed by FDA, such regulations will burden the nationwide market for medical products and information, while producing no legitimate local benefits. Accordingly, state attempts to supplement FDA regulations will also fail a *Pike* balancing analysis.

C. FDA Should Expressly Preempt Any State Laws That Are Not Impliedly Preempted Or Precluded Under the Dormant Commerce Clause.

For the above reasons, as a jurisprudential matter, practically all speech-restrictive state laws will be superseded by implied preemption doctrines, dormant Commerce Clause doctrines, or both. If there are any gaps, however, FDA should expressly preempt those remaining areas of state law. As the Supreme Court stated in *Buckman*, “complying with the FDA’s detailed regulatory regime in the shadow of 50 [s]tates’ tort regimes will dramatically increase the burdens” faced by manufacturers. *Buckman*, 531 U.S. at 350. Nevertheless, plaintiffs might well attempt to use litigation strategies to get around implied preemption and dormant Commerce Clause doctrines that would otherwise preclude state efforts to supplement FDA regulations. If FDA ever foresees the possibility that state law, and especially state tort law, might actually and significantly restrict speech, it should respond quickly to prevent that result through use of its powers of express preemption.

CONCLUSION

Given the First Amendment’s strong preference for unrestricted speech, FDA may restrict speech only by building its regulatory edifice on a sound foundation of empirical evidence. FDA should be aware that such regulation necessarily precludes state supplementation under implied preemption and dormant Commerce Clause doctrines.