FDA in the Dock: The Supreme Court's Western States Decision

by Jonathan S. Kahan and Jeffrey K. Shapiro

The U.S. Supreme Court recently struck down a restriction on drug advertising under the Federal Food, Drug, and Cosmetic Act (FDCA) as a violation of the First Amendment. This decision, *Thompson v. Western States Medical Center*,[1] is likely to have a major impact on the way the Food and Drug Administration (FDA) regulates labeling, advertising, and promotion in the future.

The immediate issue in *Western States* was a challenge to 21 U.S.C. section 353a, added to the FDCA by the Food and Drug Administration Modernization Act of 1997 (FDAMA). Under section 353a, a compounded drug was exempted from new drug application (NDA) approval requirements if the pharmacy that compounded the drug fulfilled certain requirements, which included refraining from advertising the specific drug. The Supreme Court held (by a 5-4 vote) that this advertising restriction violated the First Amendment.

The *Western States* ruling was the first time the Court has reviewed FDA's regulation of speech under a First Amendment analysis. For the past 25 years, however, the Supreme Court has ruled repeatedly that the First Amendment protects commercial speech. A little more than 20 years ago, the Court developed a balancing test specifically intended to determine whether government regulation has impermissibly infringed on commercial speech, in *Central Hudson Gas & Elec. Co. v. Public Serv. Comm'n of New York*.[2]

Under the *Central Hudson* test, commercial speech is eligible for First Amendment protection if it concerns lawful activity and is not misleading. If this threshold is satisfied, then the speech may be regulated, but only if: 1) the government's interest is substantial; 2) the regulation directly advances the government's interest; and 3) the regulation is not more extensive than necessary to serve the interest. On all these issues, the government bears the "heavy burden" of justifying the speech restriction.[3]

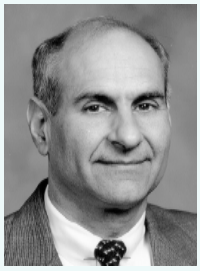
The Supreme Court applied the *Central Hudson* test to section 353a, and found the provision wanting. First, all parties agreed that the suppressed advertisements for compounded drugs did not concern unlawful activity and were not misleading. Second, the Court agreed that the government had a substantial interest in permitting small-scale compounding without NDA approval while subjecting large-scale drug manufacturing to NDA approval. Third, the Court accepted—although somewhat skeptically—the government's assertion that the advertising restriction advanced this interest, based on the government's theory that the ability to advertise is necessary to grow and maintain a large-scale compounding operation. Finally, and most importantly, the Court held that FDAMA's speech restriction was more extensive than necessary to serve the government's interest.

The Court specifically found that there were a number of nonspeech related alternatives that might have satisfied the government's interest, and that the government had not shown that forbidding advertising was necessary to achieve its interest, as opposed to being merely convenient. Notably, the Court admonished: "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort."[4]

The dissenters argued that suppressing the advertisements would work a benefit by helping to prevent pharmacies from inducing patients to convince their doctors to prescribe unnecessary drugs. The Court expressly rejected this paternalistic justification: "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."[5]

The dissenters also argued that the suppressed advertisements could mislead patients about the risks of compounded drugs. The Court responded by observing that this concern could be "satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown."[6]

The Supreme Court's ruling validates a trend evident in the lower courts to require FDA to justify its regulations against a company's right under the First Amendment to disseminate



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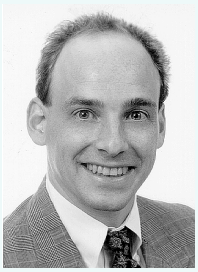

commercial speech that is neither false nor misleading.[7] FDA generally has attempted to compartmentalize or minimize these decisions. It will no longer be able to do so.

All of FDA's speech restrictions are now subject to evaluation under the *Central Hudson* test. FDA's new policy that warning letters and untitled letters must be reviewed by the Office of the Chief Counsel will help ensure that enforcement actions also pass muster under the *Central Hudson* test. FDA will have the burden of justifying its speech restriction in detail without merely invoking the public health rationale of the FDCA as the basis for restricting or banning truthful, nonmisleading speech. For example, the *Western States* decision may require FDA to rethink its controversial policy restricting the dissemination of peer-reviewed journal articles that discuss off-label uses for approved products. Another example of an area ripe for review is FDA's long-standing restrictions on the dissemination of scientific information about investigational products (e.g., 21 C.F.R. § 812.7).

A few of the less-noticed features of the *Western States* decision are worth emphasizing. First, section 353a was an act of Congress and not merely an agency regulation or policy. The courts do not lightly overturn acts of Congress on constitutional grounds; however, the courts are somewhat less deferential to agency regulations and policies. Therefore, speech restrictions developed by FDA without an explicit statutory mandate likely will receive *less* judicial deference than section 353a. For example, FDA's restrictions on dissemination of peer-reviewed journal articles and industry sponsorship of continuing medical education (CME) seminars discussing off-label uses are based upon the agency's interpretation of its general statutory mandate. These policies are likely to receive less judicial deference than did section 353a.[8]

Second, the Supreme Court rejected any justification for section 353a resting upon possible misuse of information by *patients*. This rejection of paternalism could be a factor in evaluating FDA's policies aimed at restricting information that reaches *physicians*. If the courts will not allow FDA to paternalistically restrict the flow of medical information to patients, they are even more likely to reject this justification with regard to physicians, whom they rightly regard as a more sophisticated audience.

Third, section 353a's advertising "restriction" was really a *quid pro quo* and not an outright speech ban. The section dangled before pharmacies the benefit of avoiding NDA requirements for compounded drugs in exchange for their agreement not to advertise the drugs. The Court's invalidation of section 353a suggests that FDA may no longer be able to bargain away its pre-approval authority in this fashion. As evidenced by Congress's enactment of section 353a itself, this bargain had represented an attractive compromise (or, in some cases, an offer that industry could not refuse) to resolve disputes over the extent of FDA's pre-approval authority. FDA's weakened ability after *Western States* to enter into this type of compromise likely will alter the dynamics of these disputes.

Finally, the Court strongly indicated that when speech is potentially misleading, the First Amendment favors a disclaimer to render the speech nonmisleading over a restriction or outright ban. In other words, FDA will be forced to look at the possibility that *more* rather than *less* speech may resolve its public health concerns. This approach will require an entirely new orientation by FDA and legal practitioners alike.

It appears that FDA already has started looking at how best to comply with *Western States*. Within weeks of the decision, the agency requested public comments "to ensure that its regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law."[9] In the request, FDA set forth nine questions to help focus the comments. Many of these questions asked for evidence rather than simply legal analysis, suggesting that FDA is attempting to develop a supportive administrative record for its existing policies and/or proposed changes. The ninth question was a catch-all, asking: "Are there any regulations, guidances, policies, or practices that FDA should change in light of governing First Amendment authority?"[10]

FDA's prompt initiative is a hopeful sign that the agency intends to take a serious look at the impact of *Western States*. Although some FDA officials view their public health mandate as paramount over the First Amendment (and will never be convinced otherwise), it appears possible that FDA's management will seize this opportunity for fresh thinking. The *Central Hudson* test, after all, is a balancing test that gives considerable scope and weight to government's interests. There is not necessarily a conflict between giving the First Amendment its due and protecting the public health. Rather, as the Supreme Court itself emphasized in *Western States*, the free flow of truthful and nonmisleading information about medical products is more likely to contribute to the public health than detract from it.

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1 No. 01-344 (Apr. 29, 2002).

2 447 U.S. 557, 566 (1980).

3 44 Liquormart v. State of Rhode Island, 517 U.S. 484, 516 (1996); *see* Board of Trustees v. Fox, 492 U.S. 469, 480 (1989).

4 *Western States*, slip op. at 15.

5 *Id.* at 16.

6 *Id.* at 18.

7 *E.g.*, Pearson v. Shalala, 164 F.3d 650 (1999) (holding that FDA is required under First Amendment commercial speech doctrine to consider whether appropriate disclaimers would negate the potentially misleading nature of health claims); Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81 (1999) (holding that provisions in FDAMA and implementing regulations restricting dissemination of peer-reviewed journal articles were unconstitutional under *Central Hudson* test), *appeal dismissed as moot, judgment vacated in part*, 202 F.3d 331 (D.C. Cir. 2000).

8 *See, e.g.*, Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998) (FDA's guidances on permissible CME sponsorship and dissemination of peer-reviewed journal articles were unconstitutional under the *Central Hudson* test), *appeal dismissed as moot, judgment vacated in part*, 202 F.3d 331 (D.C. Cir. 2000).

9 Notice; request for comments, 67 Fed. Reg. 34,942 (May 16, 2002).

10 *Id.* at 39,944.