Western States Medical Center: A Watershed Moment for FDA's Regulation of Commercial Speech

by Jeffrey N. Gibbs and Jeffrey N. Wasserstein

In April 2002, for the first time, the U.S. Supreme Court struck down a statute that restricted speech by an industry that was regulated by the Food and Drug Administration (FDA) on First Amendment grounds. On April 29, 2002, the Court issued its opinion in *Thompson v. Western States Medical Center*.[1] The Supreme Court affirmed the decision of the U.S. Court of Appeals for the Ninth Circuit,[2] striking down section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA)—a section that was added by the Food and Drug Administration Modernization Act of 1997 (FDAMA). The Court held that section 503A violated the First Amendment by prohibiting compounding pharmacies from advertising their ability to compound specific products or classes of products.

As a result of the Court's decision, section 503A is now void. Although the Court's opinion directly affects only compounding pharmacies, the implications of the decision are much greater. The *Western States* decision—coming in the wake of the *Washington Legal Foundation* (WLF) and *Pearson v. Shalala* decisions[3]—has ramifications for almost all of FDA's speech-related regulations, ranging from off-label promotion to dietary supplement claims.

Ironically, although *Western States* will have sweeping implications for FDA regulation of speech, it arises out of an area that is hardly central to the FDA regulatory scheme—compounding pharmacies. FDAMA had added section 503A to address growing concerns about FDA's regulation of compounding. Specifically, FDA—after more than 50 years of essentially ignoring most pharmacy compounding activities—in 1992 had issued a compliance policy guide (CPG) on the subject, and began actively regulating compounding.[4] Pharmacies complained to Congress about undue limitations on compounding.

Section 503A attempted to strike a balance between traditional extemporaneous compounding and large-scale compounding, which FDA believed was more akin to manufacturing. Among other restrictions, section 503A prohibited compounding pharmacies from advertising what types or classes of drugs the pharmacy could compound. The plaintiffs—several large-scale compounding pharmacies that promoted specific drugs—sued FDA to prevent the agency from enforcing the advertising restrictions.

The restrictions never took effect. The district court issued an injunction, finding that the advertising restrictions violated the First Amendment.[5] The district court held, however, that the advertising restrictions could be severed from the rest of section 503A, thus leaving section 503A in place, except for the advertising provisions.[6] FDA appealed. The Ninth Circuit agreed that the advertising restrictions were unconstitutional, but struck down all of section 503A.[7]

The Supreme Court agreed to hear the government's petition regarding the First Amendment issue.[8] The government argued before the Court that prior to FDAMA, all compounding was illegal and violated the "new drug" provisions of the FDCA. According to the government, section 503A was a valid compromise between allowing patients access to compounded drugs and protecting the integrity of the new

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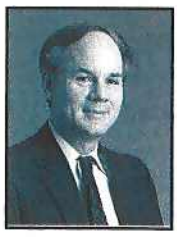

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The authors submitted an amicus *brief to the Supreme Court in* Thompson v. Western States Medical Center.

drug approval process. The government argued further that the advertising restrictions were an appropriate component of that compromise.

The Supreme Court disagreed. In an opinion written by Justice Sandra Day O'Connor for five members of the Court,[9] the Court held that "[section] 503A's provisions regarding advertisement and promotion amount to unconstitutional restrictions on commercial speech . . ."[10] Although the Court recognized that "[p]reserving the effectiveness and integrity of the FDCA's new drug approval process is clearly an important government interest,"[11] the Court held that the government failed to demonstrate that the advertising restrictions were "not more extensive than is necessary to serve" the interests asserted by the government.[12] In language that is certain to be quoted many times, the Court stated, "If the First Amendment means anything, it means that regulating speech must be a last—not first—resort."[13]

The Court also rejected the view that advertising could be banned because consumers might persuade physicians to prescribe unnecessary medications, stating, "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."[14] This language is certain to be oft cited in debates over the restriction of direct-to-consumer advertising and in other contexts.

Although section 503A is now gone, the regulatory void was quickly filled. In May 2002, FDA issued a new pharmacy CPG.[15] Not surprisingly, unlike the predecessor CPG, this one says nothing about advertisements. While this is probably the first FDA policy to be affected by *Western States*, it will not be the last.

The impact of the *Western States* decision is far-reaching. The decision calls into question every FDA regulation or policy in which the agency purports to regulate or proscribe speech by regulated industry. Indeed, the *Western States* decision speaks clearly about FDA's ability to ban any type of truthful and not misleading speech, because not even the justification of protecting the drug approval process—the lodestar of FDA's mission—was sufficient to overcome the prohibition on speech by compounding pharmacies. Section 503A's status as part of a statute was not enough to save it either, even though courts tend to be more deferential to a law passed by Congress than a regulation adopted by an agency.

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The *Western States* Court said that the agency needed to ensure that the restriction was "not more extensive than is necessary to serve" the governmental interest.[16] Under this analysis, the prohibition of promotional claims will be difficult to defend. FDA's task will be made even more challenging because many regulations and policies lack any contemporaneous findings that explain the basis for a ban. Rather, the agency generally has imposed restraints on speech without explaining why some less restrictive alternative would be inappropriate.

FDA itself recognized the significance of its loss, when it issued a notice and request for comments less than a month after the *Western States* decision "to ensure that its regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law. Recent case law has emphasized the need for not imposing unnecessary restrictions on speech."[17] At the same time, FDA stated, "FDA will continue to regulate commercial speech as part of its mandate. In particular, FDA intends to defend the [FDCA] against any constitutional challenges, as it did in the *Western States* case."[18]

In the notice, FDA raised several questions that provide some signposts as to areas that are of concern for the agency. For example, FDA sought comments on whether speech relating to drugs could be regulated more comprehensively than speech relating to dietary supplements, and whether its approach to direct-to-consumer advertisements was appropriate. Additional questions involved distinguishing conventional food claims from dietary supplement claims, and the prominence of disclaimers necessary to render such claims truthful and not misleading.[19]

It is difficult to discern what changes FDA may make based on the *Federal Register* notice itself. FDA's *Federal Register* notice has attracted plenty of attention;[20] hundreds of comments were submitted. Nine Democrats, including Sen. Ted Kennedy (D-MA) and Rep. Henry Waxman (D-CA), wrote to FDA requesting that FDA *not* revisit its First Amendment policies.[21] The *Wall Street Journal* editorialized in support of this unusual request for comments.[22] In turn, the *New York Times* urged caution in making changes.[23]

Clearly, it will take a long time for the agency to reevaluate its many

regulations and policies that curb companies' communications in light of the new case law. FDA seems to be making some distinctions based on safety and lower-risk products. For example, FDA seems to recognize a distinction between drugs and lower-risk foods and dietary supplements. The former can present safety issues that might justify more speech restrictions than claims for foods and dietary supplements, which usually present few safety issues. Similarly, FDA's questions may indicate the view that off-label uses for approved drugs are in a different category than promotion of unapproved drugs, because the safety of approved drugs already has been demonstrated, at least with regard to the approved indication.

There are numerous candidate policies and regulations for review. With regard to prescription drugs and medical devices, one obvious question is why drug and device companies should be limited to distributing only published journal reprints from peer-reviewed journals on off-label topics; why not truthful and nonmisleading abstracts or non-peer-reviewed articles? The court in *WLF* enjoined FDA's policies regarding reprints. After *Western States*, the Court's analysis may be extended to other scientific materials, such as abstracts. FDA's requirements for prior submission of certain drug promotional materials, and at least some constraints on direct-to-consumer advertising, are also now questionable.

With regard to medical devices, FDA currently prohibits manufacturers of devices that have been cleared through the premarket notification process (510(k)) from actually stating that the device has been cleared in any way that implies FDA approval.[24] This essentially has prevented companies from making the truthful, nonmisleading statement that a device is 510(k)-cleared. FDA also has an outright ban on any claims for analytical or clinical performance for analyte-specific reagents.[25] Similarly, FDA prohibits device manufacturers from making any performance claims for in vitro diagnostic devices that are labeled as "research use only."[26]

As discussed above, restrictions on health claims for dietary supplements and for conventional foods are also suspect, provided the claims are truthful and not misleading. FDA's authority to prohibit such claims is questionable in light of the *Pearson* and *Western States* decisions. The requirement for prior submission to FDA of health claims also would seem vulnerable. FDA eventually may be limited to

working out appropriate disclaimer language in lieu of its current authority to prohibit health claims until such claims have been demonstrated to meet the standards set forth in 21 C.F.R. section 101.70.

A subsequent court of appeals decision striking down a policy enforced by the Drug Enforcement Administration regarding medical communications underscores the vulnerability of some of FDA's rules and procedures. The Ninth Circuit found unconstitutional a federal policy that said a physician's registration to prescribe controlled substances could be revoked if the doctor "recommended" marijuana for medical use.[27] The court found that the policy restricting communications did not have the "narrow specificity" required under the First Amendment.

It is far from clear what changes will be made as a result of FDA's *Federal Register* notice soliciting comments. It is clear, however, that *Western States* will force FDA to reassess the way in which it regulates speech. Δ

[1] 122 S. Ct. 1497 (2002).

[2] 21 U.S.C. § 353a.

[3] Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81 (D.D.C. 1999); Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). WLF sued FDA over FDAMA provisions and FDA policies that, among other things, prohibited the dissemination of truthful off-label reprints from peer-reviewed journals, claiming that the statutory provisions and the FDA policies violated the First Amendment. *Pearson* involved dietary supplement manufacturers suing FDA over restrictions on health claims for dietary supplements. The *Pearson* plaintiffs similarly claimed that FDA's restrictions violated the First Amendment.

[4] Compliance Policy Guide § 7132.16 (1992).

[5] Western States Medical Center v. Shalala, 69 F. Supp. 2d 1288 (1999).

[6] *Id.* at 1309-10.

[7] Western States Medical Center v. Shalala, 238 F.3d 1090, 1097-98 (2001).

[8] Neither party presented the severability issue to the Court.

[9] Justice Breyer, joined by the Chief Justice, Justice Stevens, and Justice Ginsberg, dissented. The dissent focused on advertisements aimed at patients, not physicians.

[10] Thompson v. Western States, 122 S. Ct. at 1500.

[11] *Id.* at 1505.

[12] *Id.* at 1506 (quoting Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980)).

[13] *Id.* at 1507. The Ninth Circuit quoted this language in striking down a federal policy relating to medical communications in *Conant v. Walters*, discussed below.

[14] *Id.*

[15] COMPLIANCE POLICY GUIDE MANUAL § 460.200 (2002).

[16] Thompson v. Western States, 122 S. Ct. at 1506.

[17] 67 Fed. Reg. 34,942 (May 16, 2002).

[18] *Id.* at 34,943.

[19] The use of disclaimers was a prominent part of the D.C. Circuit's opinion in *Pearson*. The court in *Pearson* held that if FDA was concerned about the misleading nature of health claims for dietary supplements, the solution was more speech (i.e., using disclaimers to qualify the health claims) not less speech. *Pearson*, 164 F.3d at 657.

[20] Jonathan S. Kahan & Jeffrey K. Shapiro, *FDA in the Dock: The Supreme Court's* Western States *Decision*, FDLI UPDATE, Sept./Oct. 2002, at 29.

[21] *Free Speech and the FDA*, WALL ST. J., Sept. 20, 2002, at A10.

[22] *Id.*

[23] *Keep Drug Makers Honest*, N.Y. TIMES, Oct. 18, 2002, at A30.

[24] 21 C.F.R. § 807.97.

[25] *Id.* § 809.30(d).

[26] FDA, Draft Compliance Policy Guide (CPG), Commercialization of In Vitro Diagnostic Devices (IVD's) Labeled for Research Use Only or Investigational Use Only—Draft, at 6 (Jan. 5, 1998), *available at* www.fda.gov/cdrh/comp/ivddrfg.pdf.

[27] Conant v. Walters, No. 00-17222 (9th Cir. Oct. 29, 2002).