

First Amendment Protection of Commercial Speech

New Opportunities to Educate Healthcare Providers

by Anne Marie Murphy

The US Food and Drug Administration (FDA) not only regulates healthcare products such as drugs, biologics, and medical devices, it also attempts to regulate the words that manufacturers use to describe them (1). The FDA is charged with ensuring the safety and effectiveness of drugs and other products that fall under its jurisdiction (2). The safety and effectiveness of such products often depend not only on their chemical composition, but also on the dissemination of appropriate information, such as instructions for use.

This dual task of regulating products and product information can put the FDA in a precarious position. Despite good intentions, the agency's attempts to regulate the words that manufacturers use to label and promote their products can sometimes end up ripe for constitutional challenge under the First Amendment. This article focuses primarily on one such challenge and its ramifications: the Washington Legal Foundation's (WLF's) battle with the FDA over a manufacturer's First Amendment right to disseminate truthful, nonmisleading scientific information about off-label uses of approved products.



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FIRST AMENDMENT PROTECTION OF COMMERCIAL SPEECH

The First Amendment prohibits certain government restrictions on "freedom of speech." A special category, *commercial speech*, is protected to a somewhat lesser degree than other speech, such as political speech. Political speech is largely exempt from government regulation; commercial speech is not. A drug manufacturer's product labeling, advertising, and promotional materials are considered commercial speech.

Under the Constitution, provided that commercial speech does not concern an illegal activity,

courts will strike down laws and other government restrictions on the dissemination of truthful, nonmisleading information *unless* the government can pass the three-part *Central Hudson* test (named after the US Supreme Court case in which it was first enunciated). To survive a constitutional challenge, the burden is on the government to show

- a substantial interest in restricting the speech
- that the restriction directly advances that interest
- that the restriction is "[no] more extensive than is necessary to serve that interest" (3).

The burden is on the government to prevail on all elements of the *Central Hudson* test. Like other government practices that restrict commercial speech, FDA regulations and policies that limit drug manufacturers' labeling, advertising, and promotional materials must pass the *Central Hudson* test to survive a First Amendment challenge.

Off-Label Communications:

Manufacturers communicate with prescribers in many ways, including product labeling and promotional materials. Manufacturers also commonly educate healthcare providers by disseminating scientific literature, such as reprints of scientific journal articles that describe clinical studies of, or experience with, their products. Those articles often discuss product uses that are not included in the FDA-approved product labeling or package insert. Historically, the FDA has objected when manufacturers disseminate off-label reprints, reprints of scientific journal articles that discuss off-label uses. The FDA's prohibition of the dissemination of off-label reprints prompted a lawsuit on constitutional grounds.

WLF LITIGATION AND OFF-LABEL REPRINTS

Once a product is approved, physicians are free to prescribe it as they see fit. The FDA does not interfere, for example, with a physician who chooses to prescribe a drug for an off-label use. The FDA has no jurisdiction over the practice of medicine (4). Indeed, in many

contexts, such as oncology or pediatric medicine, off-label use of approved products is essential. In the FDA's view, however, promoting a product for an off-label use changes its intended use. Furthermore, the FDA has argued — and the courts have agreed — that changing the intended use without changing the FDA-approved labeling renders the product "misbranded" and therefore illegal (5). Thus, although it does not try to regulate the off-label use of approved products, the FDA prohibits manufacturers from promoting a product for such uses. In the past, that prohibition went so far as to include a policy that essentially barred a manufacturer from distributing off-label reprints, unless the distribution was in response to an unsolicited request for information. The WLF sued the FDA arguing that the policy was an unconstitutional restriction on speech.

WLF was initially successful. The trial court deemed off-label reprints to be commercial speech and thus applied the *Central Hudson* test to assess the constitutionality of the FDA's prohibition against dissemination. The FDA was able to show a substantial interest (protecting public health), but the agency failed to meet the *Central Hudson* test because the restriction burdened more speech than necessary. The court issued an injunction that barred the FDA from prohibiting manufacturers from distributing peer-reviewed, published, off-label reprints to medical professionals, provided the

information was not false or misleading. Favoring disclosure over suppression — a common theme in First Amendment jurisprudence — the court specified that the FDA had the authority to require that the manufacturer distributing the reprint disclose its financial interest in the product and that the use discussed in the article had not been approved by the FDA (6).

Shortly after the injunction was issued, new federal legislation — the FDA Modernization Act (FDAMA) — went into effect. Among many other changes, FDAMA allowed manufacturers to distribute off-label reprints, but subject to many conditions. The FDA went back to the court that issued the injunction and asked for clarification on how the injunction applied to the new law. The court held that the new FDAMA provisions pertaining to the conditions under which off-label information could be distributed were likewise unconstitutional (7).

The FDA then appealed the injunction. During oral argument before the court, however, the FDA announced that it would not take enforcement action against a manufacturer based solely on the distribution of off-label reprints. The FDA said that if a manufacturer violated the Federal Food, Drug, and Cosmetic Act (FD&C Act) by illegally promoting a product, it could use distribution of off-label reprints as evidence of the violation, but that the distribution of off-label reprints could not be the sole basis for the violation (8). In response to what appeared to be a shift in agency policy, WLF's attorney said he would no longer object on constitutional grounds. This apparent agreement between the parties led the court to vacate the injunction to the extent it was based on constitutional law. However, although the injunction has been vacated by the court, the logic underlying the district court's decision fully survives.

After the injunction was vacated, the FDA published a notice in the *Federal Register* stating its policy on



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the distribution of off-label information. The FDA said it may proceed with enforcement, on a case-by-case basis, of off-label promotion based at least in part on the written materials, such as off-label reprints, disseminated by manufacturers. The FDA stated that in any such enforcement action, a manufacturer could raise a First Amendment defense (9). With publication of this *Federal Register* notice, more than eight years of litigation produced an FDA policy pronouncement so unsound that, on its face, it invited a constitutional challenge upon the agency's first attempt to enforce it. Indeed, as Judge Lamberth noted in his WLF opinion:

After six years' worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved, and the country's drug manufacturers are still without clear guidance as to their permissible conduct. To say that FDA's March 16, 2000 Notice finally clarifies the situation is a farce; the Notice specifically invites a constitutional challenge to each and every one of its enforcement actions. (10)

THE US SUPREME COURT WEIGHS IN

Although legally inconclusive, the WLF matter is not the only commercial speech litigation directly targeting the FDA's policies. In a recent challenge to an FDA prohibition against advertising the availability of compounded drugs, the US Supreme Court applied the *Central Hudson* test. In reaffirming *Central Hudson* as the appropriate test, the Court struck down another FDA restriction on commercial speech in 2002.

Pharmaceutical compounding is

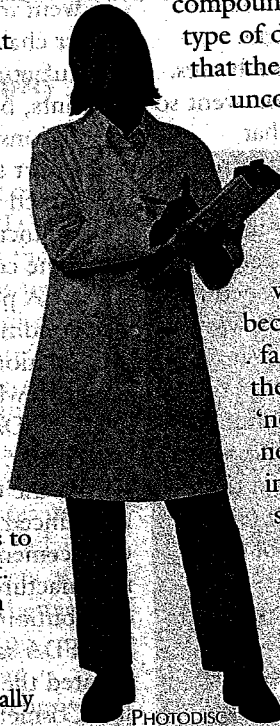
the combining or mixing of ingredients by a pharmacist to make a customized drug that would otherwise be unavailable for a particular patient. Pharmacists may dispense compounded drugs only to fill a licensed practitioner's prescription (11). In *Thompson v. Western States Medical Center*, the Supreme Court struck down Section 503A of the FDCA. That provision prohibited a compounding pharmacist or physician from advertising that he or she could compound a particular drug or type of drug. The Court found that the prohibition was an unconstitutional restriction on protected commercial speech (12). The Court concluded that the government's restriction was unconstitutional because the "Government failed to demonstrate that the speech restrictions were 'not more extensive than is necessary to serve [its] interests'" in regulating the speech (13). Indeed, the Court noted that the FDA had at its disposal multiple "non-speech-related means" to achieve its goal (13).

The FDA clearly recognizes the importance of these and other commercial speech decisions. In fact, shortly after the Supreme Court's decision in *Western States*, the agency published in the *Federal Register* a request for public comment on a comprehensive list of issues related to the agency's regulation of commercial speech. According to the agency, it sought public comment to "ensure that its regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law" (14). The breadth of the agency's request and the volume of the public's response have been remarkable and highlight the importance of the issues. The FDA has received more than 700 public

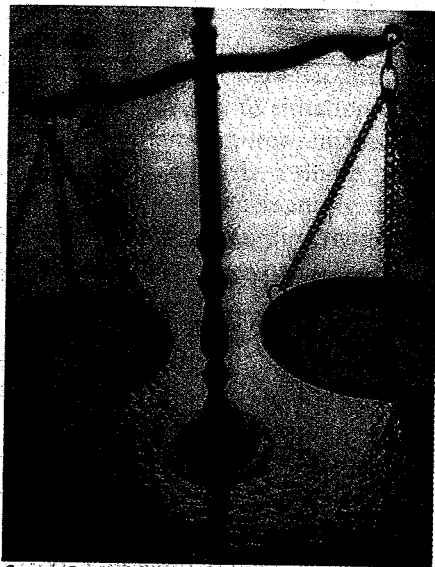
comments on First Amendment issues. The agency has not yet responded to those comments.

The agency's solicitation of comments on how to comply with new commercial speech case law is commendable. To achieve its stated goal, however, real changes in policy will be required. Specifically, the FDA's policy on the dissemination of off-label information about approved products must be clarified and revised. Under the Constitution, the FDA may not attempt to restrict the dissemination of truthful, non-misleading scientific information, including materials that discuss off-label uses of regulated products. In certain medical specialties, such as oncology, off-label use of drug products can be the standard of care. Thus, FDA restrictions on the flow of valid scientific information on off-label use from the manufacturer to the healthcare provider may have a negative effect on public health. In revising its policy, the FDA should recognize the importance of the free flow of scientifically valid information. Indeed, a manufacturer's First Amendment right to disseminate scientifically valid, truthful, nonmisleading information is broad and should not be limited to peer-reviewed, published articles. Dissemination of abstracts or posters that summarize scientifically sound studies, for example, is also protected under the First Amendment.

As a result of the WLF litigation, many drug companies are now proactively distributing off-label reprints of valid articles. But uncertainty about the FDA's policies remain. The agency's failure to clarify and reform the policy, as Judge Lamberth noted, continues to invite constitutional challenges, as well it should. Indeed, as the leading experts on their own products, manufacturers may be in the best position to ensure wide dissemination of important scientific information. It is wholly consistent with the FDA's mission to promote and protect the public health for the agency to facilitate, not hinder, the



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flow of this important scientific information on regulated products.

REFERENCES

1 *Fed. Regist.* 2002, 67, 34,942-34,943; 16 May 2002.

2 Federal Food, Drug, and Cosmetic

Act (FDCA) Section 903(b), 21 USC; Section 393(b). Describing the FDA's mission to promote and protect the public health.

3 *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 566 (1980).

4 *Fed. Regist.* 1972, 37 16,503; 15 August 1972. ("Once the new drug is in a local pharmacy . . . the physician may, as part of the practice of medicine, lawfully . . . vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.")

5 FDCA Section 301, 21 USC Section 331.

6 *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 69 (DDC 1998).

7 *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81 (DDC 1999).

8 *Washington Legal Found. v. Henney*, 202 F.3d 331, 335-336 (DC Cir. 2000).


9 *Fed. Regist.* 2000, 65 14,286; 16 March 2000. Subsequently, the WLF filed a motion to confirm and enforce the earlier injunction. The court denied that motion, noting that the injunction had been wholly vacated. See *Washington Legal Found. v. Henney*, 128 F. Supp. 2d 11 (DDC 2000).

10 *Washington Legal Found. v. Henney*, 128 F. Supp. 2d 11, 15 (DDC 2000).

11 *Limited FDA Survey of Compounded Drug Products*, www.fda.gov/cder/pharmcomp/survey.htm.

12 *Thompson v. Western States Medical Center*, 535 U.S. 357, 122 S. Ct. 1497, 1509 (2002).

13 *Thompson v. Western States Medical Center*, 535 U.S. 357, 122 S. Ct. 1497, 1506 (quoting *Central Hudson*, 447 US at 566).

14 *Fed. Regist.* 2002, 67 34942. 

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