

FOOD AND DRUG LAW JOURNAL

*Analyzing the Laws, Regulations, and Policies
Affecting FDA-Regulated Products*

The First Amendment and the Food and Drug Administration's Regulation of Labeling and Advertising: Three Proposed Reforms

*Jonathan S. Kahan
Jeffrey K. Shapiro*



VOLUME 58 NUMBER 3 2003

The First Amendment and the Food and Drug Administration's Regulation of Labeling and Advertising: Three Proposed Reforms

JONATHAN S. KAHAN*
JEFFREY K. SHAPIRO**

I. INTRODUCTION

The decision in *Thompson v. Western States Medical Center*¹ provided the first guidance ever from the U.S. Supreme Court on the application of the First Amendment to the Food and Drug Administration's (FDA's) regulation of labeling and advertising under the Federal Food, Drug, and Cosmetic Act (FDCA).² The Supreme Court's ruling validated an earlier trend in lower court decisions requiring FDA to evaluate its policies against a company's rights under the First Amendment to disseminate commercial speech that is neither false nor misleading.

In *Western States*, the Supreme Court struck down a statutory advertising restriction relating to pharmacy-compounded drugs. The Court's reasoning, however, appears to apply quite broadly to the full range of FDA's regulation of labeling and advertising. This is not to say that FDA's authority to comprehensively regulate core product labeling is in jeopardy. But the Court has made it clear that if Congress or FDA wishes to ban or restrict truthful commercial speech, they have a heavy burden to establish the need to do so. As the Court said, banning or restricting commercial speech "must be a last—not first—resort."³

In our view, not all of FDA's labeling and advertising requirements comport with the First Amendment as explicated in *Western States*. Pertinent aspects of the *Western States* decision are summarized briefly in the discussion below. This article focuses on the following three areas, which we believe require reform:

- FDA's restrictions on the dissemination of peer-reviewed journal articles and reference texts (collectively "enduring materials") that discuss unapproved (off-label) uses for medical products;
- FDA's restrictions on the dissemination of information about clinical experience with investigational medical devices prior to premarket clearance or approval; and
- FDA's restrictions on the dissemination of information about postapproval clinical experience with medical devices.

II. THE *WESTERN STATES* DECISION

The First Amendment provides in part that "Congress shall make no law . . . abridging the freedom of speech."⁴ In 1976, the Supreme Court held that the First Amendment

* Mr. Kahan is a Partner in the law firm of Hogan & Hartson L.L.P. in Washington, D.C. and co-director of the firm's Food, Drug, Medical Device, and Agriculture Group.

** Mr. Shapiro is a Partner in the law firm of Hogan & Hartson L.L.P. in Washington, D.C. and a member of the firm's Food, Drug, Medical Device, and Agriculture Group.

¹ 535 U.S. 357 (2002).

² Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301-397 (2000).

³ *Western States*, 535 U.S. at 373.

⁴ U.S. CONST. amend. I.

protects commercial speech.⁵ That decision struck down a law prohibiting licensed pharmacists from advertising prescription drug prices. The Court recognized that a market society requires a free flow of commercial information and also rejected paternalism as a justification for restricting information, stating that “[p]eople will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication rather than to close them.”⁶

In 1980, the Supreme Court announced a balancing test that permits the government an opportunity to justify restrictions on commercial speech. The test, set forth in *Central Hudson Gas & Electric Company v. Public Service Commission of New York*,⁷ adopts a four-part analytical framework for commercial speech protection under the First Amendment: 1) it must concern lawful activity and not be misleading; 2) the government’s interest must be substantial; 3) the regulation must directly advance the government’s interest; and 4) it must not be more extensive than necessary to serve the interest.⁸ On all of these issues, the government bears the “heavy burden” of proof of justifying its speech restriction.⁹

Until *Western States*, the Supreme Court had never considered the application of the First Amendment to the FDCA or to FDA’s regulatory requirements. The *Western States* case, however, involved a facial challenge to a provision of the FDCA added by section 503A of the Food and Drug Administration Modernization Act of 1997 (FDAMA),¹⁰ pursuant to which a compounded drug was exempted from new drug application (NDA) approval (and other requirements) if the pharmacy that compounded the drug met certain requirements, including a requirement not to advertise the specific drug.

The Supreme Court applied the *Central Hudson* test to this statutory advertising restriction and found it wanting. First, it was undisputed that the suppressed speech did not concern unlawful activity and was 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 skeptically, the government’s assertion that the advertising prohibition advanced this interest, based on the government’s theory that the ability to advertise is necessary to create a large-scale compounding operation. Finally, the Court held that FDAMA’s speech restriction was more extensive than necessary to serve the government’s interest because there were a number of non-speech-related alternatives that might have satisfied the government’s interest, and the government had not shown that forbidding advertising was necessary to achieve its interest, as opposed to being merely convenient. The Court stated: “If the First Amendment means anything, it means that regulating speech must be a last—not first—resort.”¹¹ Therefore, the Court invalidated the advertising ban as a violation of the First Amendment.

The Supreme Court expressly rejected any justification for the speech restriction based on paternalism. The dissent argued that suppressing the advertisements would prevent pharmacies from inducing patients to convince their doctors to prescribe unnecessary drugs. The Court responded: “We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial

⁵ *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

⁶ *Id.* at 770.

⁷ 447 U.S. 557 (1980).

⁸ *Id.* at 566.

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

¹⁰ Pub. L. No. 105-115, 111 Stat. 2296 (1997).

¹¹ *Western States*, 535 U.S. at 373.

information in order to prevent members of the public from making bad decisions with the information."¹²

The Supreme Court also indicated that a potentially (as opposed to inherently) misleading advertisement could be cured with appropriate disclosure rather than a speech ban. Thus, the dissent argued that the suppressed advertising had the potential to mislead patients about the level of risk. 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."¹³

Finally, the Supreme Court gave some examples of useful speech prohibited by the FDAMA prohibition. It stated: "If the Government's failure to justify its decision were not enough to convince us that the FDAMA's advertising provisions were unconstitutional, the amount of beneficial speech prohibited by FDAMA would be."¹⁴

This article next examines several speech restrictions that do not appear capable of surviving the type of First Amendment analysis set forth in *Western States*. Before doing so, however, it is worth noting that section 503A, which was struck down in *Western States*, was an act of Congress that prescribed detailed requirements and not merely an FDA regulation or policy. The courts do not lightly overturn acts of Congress on constitutional grounds.¹⁵ The speech restrictions discussed below were developed by FDA to implement its general statutory authority and are without a similarly detailed or specific statutory mandate. For this reason, these policies are entitled to *less* judicial deference than section 503A.

III. DISSEMINATION OF INFORMATION ABOUT UNAPPROVED NEW USES FOR MEDICAL PRODUCTS

A. FDA's Speech Restriction

Under the FDCA, a drug or medical device generally may be sold only for intended uses that FDA has approved.¹⁶ The intended uses of a drug or device may be set forth in labeling, advertising, promotional material, or oral statements by the manufacturer or its representatives.¹⁷ In practical terms, evidence of "intended use" may be found in a company's Web sites, promotional brochures, journal and radio advertising, sales talks, office visits, training materials, samples, demonstrations, and trade show displays.

A manufacturer wishing to label or advertise its already approved medical product for a new indicated use generally must submit a supplemental marketing application to FDA for approval. After FDA has approved a product for any single labeled use, a physician may use or prescribe it for other unlabeled or "off-label" uses as part of the unregulated practice of medicine. This regulatory paradox creates an incentive for the manufacturer to avoid a new marketing application by spreading the word to physicians about such off-label new uses. If physicians use or prescribe products for off-label uses, manufacturers may enjoy increased sales without the expense and uncertainty of

¹² *Id.* at 374.

¹³ *Id.* at 376.

¹⁴ *Id.*

¹⁵ *Printz v. United States*, 521 U.S. 898, 956 & n.17 (1997).

¹⁶ For this purpose, a "drug" includes biologic products regulated under section 351(a) of the Public Health Service Act.

¹⁷ 21 U.S.C. § 321(m); 21 C.F.R. §§ 201.128, 801.4; *Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980).

conducting additional clinical studies, preparing new marketing applications, or undergoing FDA's detailed review processes.

To address this issue, FDA always has prohibited companies from producing their own marketing material discussing off-label uses or approaching physicians (or consumers) to discuss such uses. When a manufacturer violates this prohibition, FDA reserves the right to bring an "intended use" enforcement action, in which the product is deemed adulterated and/or misbranded under the FDCA, because the manufacturer's dissemination of off-label information allegedly has created an unapproved new intended use.¹⁸

In the early 1990s, FDA became concerned that some manufacturers were using indirect tactics to disseminate information about unapproved new uses. Among other things, firms were providing healthcare professionals with enduring materials mentioning such uses. These tactics did not involve company-prepared information about off-label uses, but allowed a company to simply disseminate medical and scientific information generated by third parties. In response, FDA issued a guidance document with significant restrictions on such dissemination. A district court found, however, that the guidance document facially violated the First Amendment.¹⁹

In 1997, Congress intervened by enacting section 401 of FDAMA, which amended the FDCA to permit dissemination of enduring materials discussing off-label uses, but imposed numerous requirements, including restrictions on the type of materials to be disseminated, FDA's pre-approval of the materials to be disseminated, various mandatory disclosures, the firm's agreement to seek a supplement approval covering unapproved uses discussed in the enduring materials, and various reporting and recordkeeping requirements.²⁰

The same district court then held that section 401 facially violated the First Amendment.²¹ On appeal, FDA did not challenge these findings directly. Instead, FDA argued that there was no constitutional dispute because section 401 was merely a voluntary "safe harbor" to avoid enforcement action. The appellate court accepted FDA's representation and vacated the district court's injunction as moot without reaching the merits of the district court's ruling.²²

As a result of the litigation, FDA now says it agrees that the dissemination of enduring materials discussing unapproved uses is not an "independent" violation of the FDCA. FDA reserves the right, however, to cite such dissemination as evidence that a firm has promoted its product for an unapproved new intended use illegally. In the absence of clearance or approval for the new use, the product would be rendered misbranded and/or adulterated. A firm that complies with the section 401 "safe harbor" requirements will avoid any possibility that the dissemination will be cited in an enforcement action.²³

FDA has indicated, moreover, that the typical enforcement action will be based on a combination of the dissemination of enduring materials with other violative activity. Specifically, FDA has stated:

When FDA brings an action alleging a violation . . . the trier of fact will consider whether or not the manufacturer intended that its product be used for a

¹⁸ 21 U.S.C. §§ 331(a), (d), (k); 351(f); 352(f), (o); 355(a).

¹⁹ *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998).

²⁰ *See* 21 C.F.R. pt. 99 (implementing regulations).

²¹ *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81 (D.D.C. 1999).

²² *Washington Legal Found. v. Henney*, 202 F.3d 331, 337 & n.7 (D.C. Cir. 2000).

²³ 65 Fed. Reg. 14,286 (Mar. 16, 2000).

use not approved by FDA. The manufacturer's intent will necessarily be determined on a case-by-case basis, looking at the totality of the facts and circumstances. . . . If evidence of distribution . . . forms part of the basis of FDA's claim, the trier of fact will consider the context of that activity . . . in assessing the manufacturer's objective intent.²⁴

FDA has added this limitation: "FDA is unlikely to initiate an enforcement action where the only evidence of an unapproved intended use is the distribution of enduring materials."²⁵

B. *Proposed Change in FDA Policy*

FDA should announce a revised policy in which it agrees not to cite or rely on a firm's dissemination of enduring materials to prove an unapproved new intended use in any enforcement action. If a firm truly has promoted an unapproved new intended use, FDA should bring its enforcement case based upon the violative promotional activities (e.g., advertisements, brochures, oral statements) without adding the dissemination of enduring materials to the indictment. On the other hand, if a firm has done no more than disseminate enduring materials, FDA should renounce the possibility of an enforcement action, even if the firm has not complied with the voluntary requirements in section 401.

Of course, FDA may continue to require that enduring materials carry appropriate disclosures to render them truthful and nonmisleading. The agency should provide public guidance to industry indicating that no enforcement action will be brought if the dissemination is accompanied by disclosure that an off-label use has not been approved by FDA and the disseminating firm's financial interest, if any.

C. *Supporting Analysis*

The purported distinction between an "independent" violation versus "evidence" of a violation is the crux of FDA's current approach to the dissemination of enduring materials. This distinction is merely semantic. As a practical matter, every time a firm disseminates enduring materials, FDA reserves the right to bring an enforcement action alleging that the firm has created an unapproved new intended use. This legal theory always has been the basis for FDA's attempts to restrict the dissemination of enduring materials. FDA's only concession in the *Washington Legal Foundation (WLF)* litigation was to agree that it could not establish a violation merely by proving that a firm has not complied with the requirements of section 401 of FDAMA.

As a practical matter, law-abiding firms risk enforcement action unless they abandon their right to disseminate truthful, nonmisleading enduring materials. Even FDA's statement that it is "unlikely" to bring an action based solely on such dissemination offers less than meets the eye. The "unlikely" qualifier is not the same thing as saying FDA will never bring such an action. The inherent subjectivity in judging the intent of a firm's other promotional activity (or how FDA may find it combines with the distribution of enduring materials to create an allegedly illegal intent) likely will lead law-abiding firms to avoid any dissemination of enduring materials. This ambiguous enforcement policy seems crafted to allow FDA to deter protected speech without conceding that it is doing so.

²⁴ Letter from Margaret M. Dotzel, Associate Commissioner for Policy, FDA, to Daniel J. Popeo & Richard A. Samp, *Washington Legal Foundation* 6 (Jan. 28, 2002) (FDA Docket No. 01P-0250).

²⁵ *Id.*

The district court in *WLF* already has applied the *Central Hudson* test and found that FDA's restrictions on the dissemination of *bona fide* peer-reviewed enduring materials with off-label information facially violate the First Amendment. The court found that such speech was not misleading when accompanied by a disclosure noting that the off-label uses were not approved by FDA and describing the company's financial interest in the product.²⁶ It found also that requiring such disclosures was appropriate and that further restrictions violate the First Amendment because they are more extensive than necessary to prevent any misleading implication or to achieve FDA's legitimate interest in preserving an incentive for manufacturers to bring new product uses on label.²⁷ The district court also found that section 401 of the FDAMA facially violates the First Amendment for similar reasons.

FDA did not challenge the district court's *Central Hudson* holdings on appeal. While the government technically may not be subject to formal collateral estoppel on this issue in a future enforcement action, another district court surely would give great weight to the unchallenged judicial findings from six years of exhaustive litigation in the *WLF* case. Indeed, the district court's holdings were in the context of a *facial* challenge to FDA's guidance and FDAMA section 401, which is the most difficult type of First Amendment challenge to sustain.²⁸

The Supreme Court's *Western States* decision provides even more support for the district court's decision. For example, the Supreme Court has affirmed that FDA may not justify speech restrictions on the basis of a paternalistic concern that the audience will misuse the speech. The Court also indicated a strong preference for the use of disclosure (i.e., more speech) as a less restrictive alternative to resolve concerns that speech may be misleading or inimical to the integrity of the approval process. This approach is exactly the one followed by the district court in the *WLF* litigation. It is likely, then, that another district court hearing an enforcement action would conclude that exposing dissemination of enduring materials to adulteration/misbranding liability impermissibly burdens such speech.

A particularly unwise aspect of FDA's announced policy is its apparent intent to bring enforcement action by combining enduring materials with violative conduct. By combining protected and unprotected speech in this fashion, FDA actually may jeopardize its entire enforcement case. As stated in *Street v. State of New York*:

[W]hen a single-count indictment or information charges the commission of a crime by virtue of the defendant's having done both a constitutionally protected act and one which may be unprotected, and a guilty verdict ensues without elucidation, there is an unacceptable danger that the trier of fact will have regarded the two acts as "intertwined" and have rested the conviction on both together.²⁹

The dissemination of enduring materials (with appropriate disclosures) already has been judicially determined to be speech enjoying significant First Amendment protection. Therefore, a general jury verdict could be fatally tainted if there is any possibility that it was even partly based on such protected speech. By renouncing any reliance on

²⁶ *WLF v. Friedman*, 13 F. Supp. 2d at 68-69.

²⁷ *Id.* at 72-73.

²⁸ *United States v. Salerno*, 481 U.S. 739, 745 (1987) ("A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid.").

²⁹ 394 U.S. 576, 588 (1969).

dissemination of enduring materials, FDA would avoid risking the ultimate success of its enforcement actions against truly violative conduct.

In sum, FDA should renounce its policy of citing dissemination of enduring materials as a basis for an alleged violation, if the proper disclosures are provided to ensure that the dissemination is truthful and not misleading. FDA also should provide public written guidance on the appropriate disclosures in accordance with those set forth by the *WLF* district court.

IV. DISSEMINATION OF INFORMATION ABOUT INVESTIGATIONAL MEDICAL DEVICES

A. *FDA's Speech Restriction*

Under 21 C.F.R. section 812.7(a), a sponsor may not “promote . . . an investigational device, until after FDA has approved the device for commercial distribution.” Under 21 C.F.R. section 812.7(d), the sponsor may not “[r]epresent that an investigational device is safe or effective for the purposes for which it is being investigated.” In an enforcement letter, FDA has stated:

Although the FDA encourages full exchange of scientific information concerning investigational devices, including dissemination of scientific findings through scientific/medical publications or conferences, safety or effectiveness conclusions and statements of a promotional nature are unacceptable. Information concerning investigational devices may be provided only for the purpose of soliciting clinical investigators and study subjects. Enclosed is a guidance document entitled, *Guidance for Industry and FDA Staff, Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects*, to assist you in this area.³⁰

The first sentence of this passage recites that FDA is open to the exchange of scientific information in specialized publications or conferences (but not in lay media). The underlined sentences, however, contradict the first sentence by limiting acceptable dissemination of truthful clinical information about an investigational device to the limited purpose of recruiting investigators and study subjects.

In fact, FDA historically has objected to the dissemination of truthful, nonmisleading information about ongoing or completed studies of investigational devices, and even to video footage of investigational procedures, unless the purpose was to recruit investigators and study subjects. When such dissemination takes place, FDA typically does not allege that the information is false or misleading. Rather, FDA takes the position that such dissemination is promotional in violation of section 812.7(a) and/or that it represents the device as safe or effective in violation of section 812.7(d).

B. *Proposed Change in FDA Policy*

FDA should amend 21 C.F.R. section 812.7(a) by adding the following:

This provision is not intended to restrict the full exchange of scientific information concerning the device, including dissemination of scientific findings in

³⁰ Warning Letter to Presby Corp. 3 (Jan. 7, 2000) (emphasis supplied), available at http://www.fda.gov/foi/warning_letters/m3329n.pdf (last visited Sept. 17, 2003).

scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the device for a use for which it is under investigation and to preclude commercialization of the device before it is approved for commercial distribution.

This amendment to section 812.7(a) would merely conform it to existing language already in the parallel drug/biologic regulation.³¹

More importantly, FDA should affirm in clear, sensible, and publicly available written guidance that it is acceptable for companies to disseminate truthful, accurate, and fairly balanced information about clinical experience with investigational devices not commercially available in the United States (or, if commercially available for other uses, requiring modification to be capable of performing the investigational use). Such information might include, for example, preliminary or final results from a U.S. or foreign study or video footage showing the device in actual clinical use. The information might be disseminated in scientific or lay media.

FDA's guidance should clarify that such information is not inherently promotional or a representation that the investigational device is safe or effective. Rather, the agency should indicate that appropriate disclosure will be required. For example, FDA could require that the information be accompanied by a disclosure indicating that 1) the device is investigational in the United States and not available commercially, 2) no definitive conclusions can or should be drawn from preliminary clinical experience or individual case studies, 3) the device must complete an FDA premarket review process, 4) FDA will be the final arbiter as to whether the product enters commercial distribution in the United States, 5) FDA's ultimate clearance or approval may be for a more limited use than originally sought or depicted in the clinical information being disseminated, and 6) disclosure of the speaker's financial interest in the product or other relationship with the device sponsor when applicable.

C. Supporting Analysis

The requested amendment to 21 C.F.R. section 812.7(a) should not be objectionable to FDA. The regulations governing investigational drugs and biologics already include such language. Adding it to the device regulation would assure greater regulatory consistency. It also would clarify the intent of the regulation in a manner that is consistent even with FDA's restrictive interpretation in the Presby Corporation warning letter quoted above. The only distinction between the two is that the requested language permits dissemination of scientific findings "in lay media" while the Presby Corporation Warning Letter limits dissemination to "scientific/medical publications or conferences." FDA has never articulated, however, a basis for allowing dissemination of scientific findings about investigational drugs and biologics in the lay media, but not investigational devices. We believe that 21 C.F.R. section 812.7(a) should be amended to conform to 21 C.F.R. section 312.7(a).

As to the broader guidance suggested in this article, a *Western States* analysis supports the contention that FDA's policy in this area is too restrictive. Under *Western States*, the threshold inquiry is whether the speech is misleading or concerns unlawful activity. In this case, the speech does not concern unlawful activity because the clinical use of the product is permitted under an investigational device exemption (IDE) regulation³² in the United States or the laws of the foreign country in which the clinical study takes place.

³¹ See 21 C.F.R. § 312.7(a).

³² See 21 C.F.R. pt. 812.

As FDA has recognized, reports of the clinical experience with an investigational product represent important scientific and educational information. Such information is not inherently misleading if described in an accurate and balanced way. To the extent that FDA believes the information is potentially misleading, disclosures such as those suggested in this article can address that concern. Also, it is worth noting that in most cases the audience for information about investigational products is a sophisticated one (e.g., physicians), which should further mitigate concerns that the information is potentially misleading. Under *Western States*, it is appropriate to use disclosure to cure potentially misleading speech.

Does FDA have a substantial interest in the speech restriction? We are not aware that FDA has articulated fully the interest underlying its restrictive interpretation of 21 C.F.R. sections 312.7 and 812.7. It might be inferred that the agency's interest is in preventing sponsors from creating a misimpression among potential customers about the investigational product's capabilities prior to completion of FDA's review. Presumably, the harm would occur if FDA approves the product with more limited labeling than suggested by the preliminary results. Of course, if the agency finds that the final data do not support approval, then the dissemination of preliminary clinical information will not cause any harm because the product will never reach the market.

Does the speech restriction directly advance the interest asserted? By shutting down virtually all truthful, nonmisleading information about clinical experience with investigational devices, FDA likely will prevent sponsors from potentially creating the misimpression among prospective customers for the product.

Is the speech restriction more extensive than necessary to serve this asserted interest? Absolutely. The dissemination of truthful, nonmisleading information about clinical experience with investigational products is crucial to the progress of medicine and science. FDA acknowledges this fact in the Presby Corporation Warning Letter, which states, "FDA encourages full exchange of scientific information concerning investigational devices."³³ Yet, FDA's approach is to clamp down as tightly as possible on this information, thus burdening a significant amount of concededly useful and important speech.

The rationale for all of these restrictions on truthful speech appears to be a concern about the potentially misleading effect the information may have at some time in the future after product approval has been granted. In *Western States*, the Supreme Court made it very clear that this type of concern must be addressed with appropriate disclosure—i.e., that more speech rather than less speech is the appropriate way to cure any potential for speech with recognized value that may still have the capacity to mislead.

This approach is especially appropriate here because the link is attenuated between the potentially misleading speech and the audience action (purchasing the product). Ongoing clinical experience with an investigational product tends to evolve over months, and even years, before FDA's review process is complete. Even if the preliminary results are not vindicated completely by the final data, the product labeling that FDA ultimately approves is an intervening influence that will describe accurately the appropriate use of the product and the supporting data. In those rare cases when FDA believes egregious conduct has created an indelible misimpression, the agency can require counter-balancing statements in the approved labeling. All in all, FDA has restricted unnecessarily the flow of preliminary scientific information about investigational devices.

³³ Presby Corp. Warning Letter, *supra* note 30, at 3.

V. DISSEMINATION OF POSTAPPROVAL INFORMATION ABOUT MEDICAL DEVICES

A. FDA's *Speech Restriction*

When a premarket application (PMA) device receives approval, the agency approves labeling that typically summarizes the clinical data supporting approval. Under current FDA policy, a manufacturer must label and promote the device solely on the basis of this data. The agency's position is that when postapproval clinical experience differs from the data in the approved labeling, the manufacturer may not disseminate the new data without approval of a PMA supplement allowing such dissemination. Failure to obtain the required PMA supplement, according to FDA, is a violation of 21 C.F.R. section 814.39, which requires approval of changes to a device's labeling that could affect safety or effectiveness. Alternatively, in some cases, FDA has not cited section 814.39, but has alleged that dissemination of postapproval clinical data is misleading unless the agency has reviewed and approved it.

B. *Proposed Change in FDA Policy*

FDA should allow manufacturers to disseminate evolving clinical experience with the use of their device. The agency should permit two types of labeling. The first type would be the traditional FDA-approved labeling that cannot be altered without approval of a PMA supplement. Alternatively, FDA should create a second tier of "postapproval clinical experience" whereby firms would be permitted to disseminate new clinical information concerning their PMA-approved devices (whether generated by the firms or independent third parties) without an approved PMA supplement, as long as the information is truthful, accurate, and fairly balanced both as to the results and the nature and quality of the study from which the data were generated. To avoid any misleading implication, firms would be required to disclose that FDA has not reviewed or approved the new information. Firms also can be required to disclose any financial involvement with the studies that generate the information.³⁴

C. *Supporting Analysis*

A *Western States* analysis supports the requested change in FDA's policy. Under *Western States*, the threshold inquiry is whether the speech is false or misleading or concerns unlawful activity. In this case, the clinical studies clearly do not concern unlawful activity. On the contrary, they represent legitimate scientific and medical investigation and research. As such, they cannot be characterized as inherently misleading. In particular, they are not inherently misleading merely because FDA has not reviewed them. As the district court observed in *WLF v. Friedman*, "FDA is not a peer review mechanism for the scientific community."³⁵

To the extent that FDA believes the information is potentially misleading, disclosures such as those suggested in this article can address that concern. In most cases, the

³⁴ Our proposal and supporting analysis are addressed to dissemination of information to healthcare providers, rather than directly to lay patients. While the Supreme Court made it clear in *Western States* that the First Amendment applies just as much to advertising directed at a lay audience, the nature of the target audience may call for a somewhat different proposal and supporting analysis. This article's discussion is restricted to situations in which a firm wishes to disseminate information to healthcare providers.

³⁵ *WLF v. Friedman*, 13 F. Supp. 2d at 67 (quotation marks and citation omitted).

audience for information about investigational devices is a sophisticated one (e.g., physicians), which should further mitigate concerns that the information is potentially misleading. Under *Western States*, it is appropriate to use disclosure to cure potentially misleading speech.

Does FDA have a substantial interest in the speech restriction? FDA's interest in preserving the integrity of the approval process³⁶ is not implicated because the information relates to clinical experience with the product for its approved use, and not an unapproved new intended use. Most likely, FDA would argue that its interest is in preserving the integrity of the approved labeling by preventing manufacturers from disseminating unapproved additional information.

Does the speech restriction directly advance the interest asserted? By requiring manufacturers to adhere to the script set forth in the approved labeling, and proscribing dissemination of information about postapproval clinical experience (absent a PMA supplement), FDA does advance its interest in preserving the integrity of the approved labeling.

Is the speech restriction more extensive than necessary to serve the interest? Yes. FDA's approach limits the efficient dissemination of useful and valuable information to the healthcare community regarding postapproval study and experience with devices. While it is true that a manufacturer may obtain a PMA supplement approval to disseminate the information, this process is time-consuming, cumbersome, and expensive, as the Supreme Court recognized in *Western States*.³⁷ Furthermore, some of the information is likely to be helpful to the healthcare community even when it is not of the quality that would be appropriate for approved labeling.

A more flexible approach actually would do more to disseminate a more nuanced and robust understanding of device performance as it develops from postapproval use and study. Healthcare professionals frequently make patient care decisions based on data that do not rise to the level of controlled clinical trials such as typically are described in the approved labeling. They attend CME meetings, symposia, scientific meetings, and Grand Rounds. They read published journal articles, textbooks, case studies, reports of clinical studies, and scientific abstracts, and engage in discussions with their colleagues. Healthcare professionals are experienced and adept at critically evaluating the varying quality of information that may contribute to their decisionmaking.³⁸ By prohibiting manufacturer involvement in the dissemination of this information, FDA forecloses those with the greatest economic incentive to efficiently disseminate this information from doing so.

FDA's policy of prohibiting manufacturers from contributing to the dissemination of this information is not based on a statutory mandate. By hypothesis, the information relates to a use that already has received FDA approval pursuant to the statutory requirement. FDA's policy is based instead on a restrictive interpretation of its regulations requiring a PMA supplement for a significant labeling changes and/or the mistaken presumption that information is inherently misleading if FDA has not reviewed it. FDA clearly has the authority to adopt a new approach.

FDA's interest in preserving the integrity of the approved labeling can be met by recognizing two tiers of labeling. The first tier would be the traditional core labeling that FDA explicitly approves. The second tier would be postapproval information accompanied by prominent disclosure that FDA did not review the information. There also would be disclosure of the extent of the manufacturer's financial involvement in the underlying

³⁶ See *Western States*, 535 U.S. at 357.

³⁷ *Id.* at 369-70.

³⁸ *WLF v. Friedman*, 13 F. Supp. 2d at 70.

study, if any. FDA might even wish to create a required format that healthcare professionals would come to recognize as second tier postapproval information disseminated by manufacturers. Finally, FDA could require that the information be truthful, accurate, and fairly balanced in a manner that would allow the recipient to make an informed judgment about its value.

It is neither practical nor wise for manufacturers to submit a PMA supplement prior to dissemination of any new postapproval information about a medical device. Our proposal would allow manufacturers to disseminate such information without filing a new PMA supplement to amend the approved labeling. Nonetheless, if a significant body of useful data were developed, manufacturers likely would find it advantageous to obtain FDA approval of updated labeling, if only to enhance the credibility of the data for marketing purposes or to ameliorate the product liability risk. Healthcare practitioners could be expected to evaluate lesser data critically, based on truthful and accurate descriptions of the source, the nature of the study, and the results. Manufacturers also could be required to provide the full range of favorable and unfavorable information to avoid a misleading selection. Ultimately, this flexible approach would increase the supply of truthful and nonmisleading information in the market—as the Supreme Court requires—without compromising FDA's approved labeling.

VI. CONCLUSION

We believe it is appropriate for FDA to reconsider carefully its regulation of labeling and advertising in light of the *Western States* decision. Although many of FDA's policies will withstand scrutiny, it is clear that other policies will require revision. We believe it is inappropriate and unhelpful for FDA to implement regulatory policies that attempt to impede the flow of truthful and nonmisleading information to healthcare providers. On the contrary, freeing up the flow of information will result in a better healthcare environment for the public. In our view, the reforms discussed in this article would be a big step in the right direction.