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Protecting Protected Speech: First Amendment Taxonomy and the Food and Drug Administration's Regulation of "Enduring Materials"

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I. *WESTERN STATES* AND *NIKE*

The U.S. Supreme Court's decision in *Nike, Inc. v. Kasky* [1] was widely anticipated, if universally disappointing. *Nike* promised, many thought, to answer one of the vexing questions of First Amendment commercial speech jurisprudence; that is, the question of its subject matter. Just which speech is commercial speech may be considerably less clear than the protections such speech is due. The answer—of no small interest to food and drug law—was not forthcoming. *Per curiam*, the Court dismissed the writ in *Nike* as improvidently granted.[2]

Nike followed in the wake of another commercial speech case of no small interest to food and drug law—*Thompson v. Western States Medical Center*.[3] There, over the Food and Drug Administration's (FDA's) objections, the Court held that certain provisions of the Food and Drug Administration Modernization Act (FDAMA)[4] restricting the advertising and promotion of compounded drugs were violative of the First Amendment, as was FDA enforcement of those provisions.[5]

In the wake of the *Western States* decision, FDA published a broadly drafted request for comments on First Amendment issues,[6] and observed succinctly that "[t]here may be tension between some aspects of FDA's authority and judicial developments."[7] Responding to that possible tension, FDA sought "public comment to ensure that its regulations, guidances, policies, and practices *continue* to comply with the governing First Amendment case law."[8] FDA provided illustrative questions—some very general and some more specific—conceived as "issues related to the FDA's regulation of commercial speech."[9] Among those questions were several regarding the agency's restrictions on speech about off-label uses (e.g., FDA's treatment of the dissemination of "enduring materials"—textbooks, journal articles, etc.—addressing off-label uses of drug or biological products).

Numerous comments have called on FDA to exercise restraint in its treatment of enduring materials. This article expands upon those comments. The question whether enduring materials ought to be judged commercial speech remains unsettled. First, this

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[1] 539 U.S. _____ (2003) (slip opinion). The dismissal of the case was accompanied by a concurring opinion and two dissents, which will be discussed *infra*.

[2] *Id.* at 1.

[3] 535 U.S. 357, 122 S. Ct. 1497 (2002). The particulars of *Western States* have been well rehearsed and will not be reproduced in this article.

[4] Pub. L. No. 105-115, 111 Stat. 2296 (1997).

[5] *See id.* at 360.

[6] *See* Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942 (May 16, 2002).

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

[8] *Id.* at 34,942 (emphasis added).

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

article will consider the Constitutional protections that apply to enduring materials if, as many suppose, such materials are examples of commercial speech. Second, the question *whether* such materials—even though distributed by, e.g., manufacturers—might more properly be seen as scientific speech will be revisited. To that end, the nondecision in *Nike* may be of some help after all.

Four conclusions will be set forth: 1) enduring materials regarding off-label uses deserve *at least* as much protection as the Constitution affords commercial speech more generally; 2) there are good reasons to think that such materials deserve a very high level of protection; 3) FDA restrictions on enduring materials are liable to be both Constitutionally suspect and futile; and 4) FDA ought, therefore, to repudiate its prior restrictions on the dissemination of enduring materials.

II. *WESTERN STATES* AND COMMERCIAL SPEECH

The breadth of FDA's query about First Amendment issues—in the wake of a case dealing with the advertising of compounding drugs—is not wholly surprising. *Western States* can be seen as the culmination of a long series of cases in which the Supreme Court and lower federal courts—increasingly— have viewed as suspect government claims that the public should be protected from (truthful) information.[10] "[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented."[11]

The *Western States* decision has been much discussed so this article will not recapitulate either the Court's decision or the secondary commentary on that discussion. Certain general points, however, are salient and important to the discussion at hand. First, and perhaps most generally, is that the First Amendment substantially protects even concededly commercial speech. At issue in *Western States* were FDAMA restrictions on the advertising of certain compounding services, as well as FDA's enforcement of those provisions. The parties agreed that the speech at issue was commercial speech and the Court's reasoning proceeded from that assumption.[12]

Second, the Court re-affirmed the *Central Hudson* test as a framework for evaluating government restrictions on commercial speech.[13] Under that test, once commercial speech passes a threshold filter for misleading speech or speech concerning unlawful activities, restrictions on that speech must satisfy two conditions: restrictions must serve a *substantial* government interest; and restrictions may not be more extensive than necessary to serve that substantial interest.[14]

Third, the Court voiced special concern about the amount of beneficial speech a government restriction would prohibit. Indeed, the Court suggested that this concern would have been dispositive in *Western States*, even if the government's failure under *Central Hudson* had not been.[15] In particular, the Court was concerned with FDA's

[10] *See* Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976) (recognizing consumer "interest in free flow of commercial information"); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996) (characterizing the assumption that the public will respond irrationally to truthful commercial speech as "offensive"); Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998) (describing FDA's argument about the need to restrict dissemination of scientific research to the public "even more unsupportable than usual").

[11] *Western States*, 535 U.S. at 367, 122 S. Ct. at 1503 (quoting Edenfield v. Fane, 507 U.S. 761, 113 S. Ct. 1792 (1993)).

[12] *Id*. at 366, 122 S. Ct. at 1503.

[13] *See id.* at 367-68, 122 S. Ct. 1504 (citing Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557, 100 S. Ct. 2343 (1980).

[14] *See id.*

[15] *Id.* at 376-77, 122 S. Ct. at 1508-09.

attempt to limit the flow of potentially useful information to physicians. At issue in *Western States* was truthful speech about compounding services from legitimate (nonmanufacturing) pharmacies to physicians serving patients with special needs.[16] At issue for this discussion is one form of physician access to a substantially larger body of beneficial scientific speech.

Fourth, the Court was not persuaded by FDA's "fair proxy" argument (i.e., that at issue was not so much a restriction on speech *per se* as it was a restriction on nonspeech practices prohibited by the FDCA that were strongly correlated with certain speech acts).[17] The advertising at issue was, according to the government, both a marker and a commercial prerequisite for prohibited manufacturing practices; those manufacturing practices were to be limited by restricting advertising seen critical to their profitability.[18]

Here the concern is with the notion that scientific speech is a proxy for off-label promotion. FDA allows a manufacturer to *distribute* its products to physicians for unapproved uses, as long as the manufacturer does not actively *promote* its products for those uses. In FDA's view—at least to first approximation—*any* discussion may be taken to be promotion. Once a manufacturer participates in any discussion of its products for off-label use (e.g., distribution of peer-reviewed journal articles, continuing medical education (CME) sessions) the manufacturer has undertaken a prohibited form of promotion.[19] If *Western States* is an indicator, the use of speech in this manner—to ensure compliance with a different regulatory standard—is unlikely to pass constitutional muster. To that end, it should be noted both that this is yet another regulatory proxy argument and that the proxy in this case is purported to stand for yet another form of speech in any case, albeit a more conspicuously commercial one—that is, speech that promotes the off-label use of prescription drug products.

Finally, *Western States* honors the physician's expertise and authority as 1) interpreter, for patients, of information regarding prescription drugs and 2) gatekeeper between patients and potentially harmful (or helpful) prescription drugs.[20]

Western States thus does several things that do not bode well for restrictions on the dissemination of enduring materials. The case reinforces the general notion of commercial speech as protected speech; it rejects the notion that FDA speech restrictions are straightforwardly acceptable regulatory means to achieving nonspeech-related government objectives; and it recognizes, in particular, the importance of informing physicians and patients of diverse treatment options. *Western States* does not bode well for restrictions on the dissemination of enduring materials *even if* those materials are examples of commercial speech, subject to the lesser protections afforded commercial—as opposed to scientific—speech. At least one federal court has agreed, striking down statutory and regulatory constraints on enduring materials as violative of the First Amendment.[21]

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[16] *See id.*

[17] *Id.* at 371-72, 122 S. Ct. at 1506.

[18] *See id.* at 370-71, 122 S. Ct. at 1505-06.

[19] *See generally* Guidance to Industry on Dissemination of Reprints of Certain Published Original Data and Guidance for Industry, Funded Dissemination of Reference Texts, 61 Fed. Reg. 52,800 (1996); Guidance for Industry: Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,093 (1997). These guidances were, according to FDA, superseded by FDAMA's restrictions on the distribution of enduring materials. *See* Washington Legal Found. v. Henney, 202 F.3d 331, 334 n.4 (2000).

[20] *Id.* at 376, 122 S. Ct. at 1507, 1508.

[21] Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1999) *vacated as moot,* 202 F.3d 331 (2000).

III. HOW COMMERCIAL IS IT?

Western States sheds little light on the question *when* speech is commercial speech, as it observed that "[t]he parties agree that the advertising and soliciting prohibited by the FDAMA constitute commercial speech."[22] What, then, of less obviously commercial materials? How should the First Amendment view enduring materials that are not conceived—at least at the time of drafting—as advertising or other commercial materials and that may not be conceded as such in court?

The notion embedded in FDA's request for comment—that its First Amendment questions were merely questions about commercial speech—is not simply agency assumption. In particular, the notion that enduring materials—e.g., reprints of peer-reviewed scientific articles—*become* commercial speech when circulated by manufacturers was articulated in another of the agency's First Amendment defeats: *Washington Legal Foundation v. Friedman* (*WLF*).[23] That notion, I argue, rests on a mistake.[24]

In *WLF*, plaintiffs challenged restrictions imposed on enduring materials that addressed off-label uses and sought to enjoin FDA and the Department of Health and Human Services from enforcing such restrictions. The court granted plaintiffs summary judgment, finding that

> [T]he rules and regulations of the United States Food and Drug Administration ('FDA') set forth in the Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, . . . Guidance for Industry Funded Dissemination of Reference Texts, . . . and Final Guidance on Industry Supported Scientific and Educational Activities . . . are contrary to rights secured by the United States Constitution and therefore must be set aside pursuant to 5 U.S.C. § 706(2)(B) except insofar as they are consistent with the injunctive provisions below.[25]

Unlike other commercial speech cases, *WLF* faced the status of enduring materials squarely. In *dicta*, Judge Lamberth recognized the fact that such materials are not "[t]ypical 'commercial speech'" and that, consequently, resolving the status of such speech was not easy.[26]

> So, a compelling question is raised: does speech that would be fully protected as scientific and/or educational speech become transformed into commercial speech, with its reduced level of protection, by the mere fact that a commercial entity seeks to distribute it in order to increase its sales of the product addressed in the speech.[27]

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[22] *Western States*, 535 U.S. at 366, 122 S. Ct. at 1503.

[23] 13 F. Supp. 2d 51 (D.D.C. 1999) *vacated as moot,* 202 F.3d 331 (2000).

[24] What follows criticizes a specific aspect of *WLF*; its discussion of the scope of the Constitution's contemplation of commercial speech. I do not mean to be more generally critical of the opinion, which, by-and-large, is in keeping with the Supreme Court's view that the First Amendment significantly protects commercial speech.

[25] 13 F. Supp. 2d. at 74. Subsequently, the decision was extended to FDAMA's restrictions on enduring materials in 36 F. Supp. 2d 16 (D.D.C. 1999). The decision ultimately was vacated as moot. Between the initial trial and the appeal were the enactment of FDAMA and FDA's rebriefing of its position to claim: 1) that FDAMA superseded the agency's enduring materials guidances, 2) that FDAMA itself did not constrain speech, but merely provided a safe harbor for certain promotional activities, and 3) that FDAMA did not provide FDA with independent authority to constrain speech. *See WLF. v. Henney*, 202 F.3d at 335-36. Plaintiff responded that in light of the government's revised position, plaintiff had no further constitutional objection to FDAMA or the FDA enduring materials guidances. Hence, the court of appeals found no constitutional controversy remaining between the parties, and dismissed accordingly. *See id.* at 336.

[26] *WLF v. Friedman*, 13 F. Supp. 2d at 62.

[27] *Id.* at 64.

To answer the question, the district court turned to the Supreme Court's decision in *Bolger v. Youngs Drug Products Corporation*.[28] According to Judge Lamberth,

> *Bolger* directs a reviewing court to look at three factors in determining whether a form of communication merits full or reduced First Amendment protection. These factors are: (1) whether the speech is concededly an advertisement; (2) whether the speech refers to a specific product; and (3) whether the speaker has an economic motivation for disseminating the speech.[29]

Supposing this to be the three-pronged test for commercial speech, *WLF* finds the first prong satisfied under the plain meaning of the terms. According to the dictionary, "[a]n advertisement 'call[s] public attention to, especially by emphasizing desirable qualities so as to arouse a desire to buy or patronize.'"[30] Even Judge Lamberth's dictionary quotation is somewhat strained, however; he does not quote the definition for the noun "advertisement" at all, but just one case of the second listed sense of the verb "advertise."[31] Fishing thus in the Lexicon, Judge Lamberth obscures the fact that CME materials and, especially, journal reprints, are not paradigm cases of advertisement at all—cases listed in various dictionaries as, e.g., "a paid notice or announcement published in some public print (as a newspaper, periodical, poster, or handbill)."[32]

The objection here is not simply that the court, in its fact-finding, fastened on one viable dictionary definition rather than another for a pivotal phrase. Rather, it is that the court, in so doing, obscured precisely that which made the question of enduring materials difficult in the first place; that is, the fact that these materials are not paradigmatically "advertisement" and are not designed or drafted with commercial ends in mind. Not incidentally, this maneuver represents—at the very least—an unheralded extension of its own authority: the Supreme Court's opinion in *Bolger*.

The speech at issue in *Bolger* did not involve refereed articles or scholarly texts. At issue, rather, were pamphlets *produced and disseminated* by a manufacturer with commercial ends in mind. Hence, there was no question of the materials being transformed from higher to lower forms of speech by the details of their distribution.

Bolger regarded the First Amendment status of advertising pamphlets to be used in "a campaign of unsolicited mass mailing."[33] Of the three types of such pamphlets, the only one taken to present a significant issue was the third: "informational pamphlets discussing the desirability and availability of prophylactics in general or Young's products in particular."[34] One of two examples of this type of pamphlet featured an extensive description of particular branded products produced by the manufacturer.[35] Economic motivation alone was deemed "clearly . . . insufficient by itself to turn the materials into commercial speech." (Prong 3).[36] Reference to a particular product, by itself, did "not by itself render the pamphlets commercial speech." (Prong 2)[37] Even the fact that the

[28] 463 U.S. 60 (1983).

[29] *Id.* That was not quite the direction in *Bolger*, but that point will not be argued here.

[30] *Id.* (quoting WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY (1990)).

[31] *See* WEBSTER'S NINTH NEW COLLEGIATE DICTIONARY (1990).

[32] WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE (unabridged 1993); *see also* THE OXFORD AMERICAN DESK DICTIONARY AND THESAURUS (2001) (offering handbill, circular, junk mail, classified advertisement).

[33] 463 U.S. at 62.

[34] *Id.*

[35] *Id.* at n.4. The other example was more general, although it mentioned the manufacturer (and his products) as sponsor of the pamphlet.

[36] *Id.* at 67.

[37] *Id.*

pamphlets were "conceded to be advertisements" was insufficient for commercial speech classification. (Prong 1)[38] Sufficient—in the case of pamphlets *designed as advertising*—were all three.

Several observations can be made about *Bolger*. First, the purported three-part test itself is not said to be definitive. Rather, the Court said that "[t]he combination of *all* these characteristics . . . provides strong support for the District Court's conclusion that the informational pamphlets are properly characterized as commercial speech."[39] Second, on Judge Lamberth's reading, there is no clear sense in which the first prong is not merely the conjunction of the second and third. That is, according to the *WLF* construct, we ask first whether something is advertising (which means 1) speech calling attention to a particular product that 2) is aimed at promoting sales or patronage); second, whether the speech concerns a particular product; and third, whether the speech is born of economic motivation. What, precisely, do prongs two and three add to prong one? The *WLF* reading of "advertisement," if unproblematic *qua* fact-finding, is at best as strained judicial construction.

There is one additional element to prong one, which deals with the reading of "conceded" rather than "advertisement." The pamphlets in *Bolger* were not found to be advertisements, they were "*conceded* to be advertisements."[40] The defendant manufacturer in *Bolger* thought that all three types of its unsolicited, mass-mailing, direct advertising pamphlets were protected speech *and* advertisements; the Court agreed.[41] The plaintiff in WLF conceded no such thing regarding enduring materials and was right not to do so.[42]

IV. *NIKE* AND MIDDLE GROUND

Contemporary commercial speech doctrine has emerged over the past thirty years.[43] Clear in the doctrine is that "commercial speech is protected by the First Amendment,"[44] and that "the Constitution accords less protection to commercial speech than to other constitutionally safeguarded forms of expression."[45] Still, the boundary between commercial and noncommercial speech is not entirely clear. For example, economic motivation alone is insufficient to establish speech as commercial;[46] in that, the doctrine is at least sensible because economic motivation is ubiquitous whereas, presumably, commercial speech is not. Thus far, this article has argued that *WLF* was in error in certain regards. *WLF* was in error in its reading of *Bolger*. Consequently, *WLF* was in error in its reading of the Court's commercial speech jurisprudence and unjustified in its finding that enduring materials are clear examples of commercial, and not scientific, speech. This article stops short of arguing that enduring materials are not commercial speech at all.

There are reasons, however, to think that the Court would view this as, at least, an open question. The nondecision in *Nike* may be of some help in seeing what those

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[38] *Id.*

[39] *Id.*

[40] *Id.* at 64 (emphasis added).

[41] The Court found them all to be protected commercial speech and upheld the lower court's finding that the statute prohibiting the unsolicited mailing of contraceptive advertisements was violative of the First Amendment's protection of commercial speech.

[42] *Id.* at 75.

[43] *See* Bigelow v. Virginia, 421 U.S. 809 (1975) (extending First Amendment protection to commercial speech); Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976).

[44] *Western States*, 535 U.S. at 367, 122 S. Ct. at 1503**.**

[45] *Bolger,* 463 U.S. at 64-65.

[46] *See, e.g.*, *id.* at 67.

reasons are.[47] *Nike* promised to visit diverse public statements, by a corporate speaker, on matters of both public and private, business-related concern; across those diverse statements, the Court would parse the commercial/noncommercial speech distinction. The Court granted *certiorari*

> to decide two questions: (1) whether a corporation participating in a public debate may "e subjected to liability for factual inaccuracies on the theory that its statements are 'commercial speech' because they might affect consumers' opinions about the business as a good corporate citizen and thereby affect their purchasing decisions"; and (2) even assuming the California Supreme Court properly characterized such statements as commercial speech, whether the "First Amendment . . . permit[s] subjecting speakers to the legal regime approved by that court below."[48]

If there is an open question as to whether Nike's corporate letters were commercial speech, surely there is an open question as to whether reprints of peer-reviewed scientific articles are commercial speech whenever a corporate entity distributes them; or, in the alternative, they cannot be commercial speech at all.

Subsequent to granting the writ, the Court dismissed it as improvidently granted. The Court's dismissal of the writ did not appear to hinge, however, on any sort of conclusion that the boundaries of the commercial speech doctrine were clear enough after all. To the contrary, at least three Justices, in concurring with the dismissal, remarked on the "novelty and importance of the constitutional questions presented in this case."[49] Moreover, they made it clear, the "speech at issue represents a blending of commercial speech, noncommercial speech and debate on an issue of public importance."[50] If that is right, then *WLF* must be wrong in supposing that the presence of a financial motivation in product-related speech requires a finding that the speech is commercial, and only commercial, in nature.

It seems that at least five Justices on the Court think so. In addition to the concurring opinion above, it should be noted that, writing for the dissent, and joined by Justice O'Connor, Justice Breyer made clear his view that "a true reversal [of the California Supreme Court] is a highly realistic possibility."[51] Indeed, Justice Breyer would not be inclined to apply the "commercial speech" principle at all,[52] rather he appears to view the commercial speech doctrine—applied in formulaic manner in *WLF*—as inadequate to speech that involves a "mixture of commercial and noncommercial" elements.[53] To that end, he contrasts the protection of "only *truthful* commercial speech" with the protection afforded speech "on matters of public concern."[54] Such speech, he says, "needs 'breathing space'—potentially incorporating certain false or misleading speech

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[47] To be sure, the concurring and dissenting opinions accompanying the dismissal of the writ ought not to be confused with precedent. Nonetheless, they may be illustrative of current Court thinking on commercial speech and the First Amendment.

[48] *Nike, Inc.*, slip opinion at 2-3 (Stevens, J., concurring). That decision regarded a suit, under California's Unfair Competition Law and False Advertising Law, alleging unfair and deceptive practices and false statements and/or material omissions of fact respectively.

[49] *Id.* at 9.

[50] *Id.*

[51] *Id.* at 12 (Breyer, J., dissenting).

[52] *Id.* at 13.

[53] *Id.*

[54] *Id.* at 12 (citing, e.g., Consolidated Edison Co. of N.Y. v. Public Serv. Comm'n of N.Y., 447 U.S. 530, 534 (1980) and New York Times Co. v. Sullivan, 376 U.S. 254 (1964)).

in order to survive."[55] According to Justice Breyer, "a proper resolution here favors application of the last mentioned public-speech principle, rather than the first mentioned commercial speech principle. Consequently, I would apply a form of heightened scrutiny to the speech regulations in question, and I believe those regulations cannot survive that scrutiny."[56]

To be sure, the concurring and dissenting opinions accompanying the dismissal of the writ ought not to be confused with precedent. But at least five Justices of the Supreme Court appear to think that significant admixtures of commercial and noncommercial speech present important and difficult Constitutional issues. If that is so for Nike's communications regarding the Asian manufacture of its sneakers, then it must be so for scientific speech that is disseminated by Nike's corporate counterparts in the pharmaceutical and biotechnology industries. Or rather, it cannot be that scientific speech, even if confounded by commercial attributes, deserves only the lesser protection afforded commercial speech. It is well settled that scientific speech merits "the highest degree of constitutional protection. Scientific and academic speech reside at the core of the First Amendment."[57] Certainly, scientific speech requires "breathing room" as much as any other.

If this analysis is correct, enduring materials—at least most enduring materials—deserve a very high level of Constitutional protection. Certainly, peer-reviewed journal articles, letters, notes, and abstracts deserve a high level of protection, independent of the question whether they are circulated by commercially-motivated parties. For one thing, *ad hoc* agency regulation is liable to restrict a significant body of beneficial speech, as harried practitioners may value highly diverse routes to published, refereed literature. That argument may apply equally to CME presentations, which for many physicians may be a critical first look at cutting-edge developments in clinical (and clinically relevant) science.[58]

Second, unlike the advertisements in *Western States* or *WLF*, the beneficial speech at issue is not originally drafted or vetted with primarily commercial ends in mind. Again, that is so especially for peer-reviewed scientific publications, and is likely substantially true for a large body of CME materials that FDA might otherwise chose to inspect for, e.g., balance.

Third, the beneficial speech being restricted is being filtered through an expert, critical audience, which should be acutely aware of the limitations in preliminary clinical results, just as it should be especially able to seek out contrary or qualifying findings. Moreover, that learned audience stands between patients—the ultimate consumers—and prescription drugs intended for off-label (or any other) use.[59]

V. CONCLUSION: NO RESTRICTION IS A GOOD RESTRICTION

To the extent *Nike* raises serious Constitutional questions about the hybrid or borderline speech at issue in that case, it raises questions also about the federal regulation

[55] *Id.* (citing *New York Times Co.*, 376 U.S. at 272; Gertz v. Robert Welch, Inc., 418 U.S. 323, 340 (1974); Time, Inc. v. Hill, 385 U.S. 374, 388-89 (1967)).

[56] *Nike, Inc.,* slip opinion at 13 (Breyer, J., dissenting).

[57] *WLF v. Friedman*, 13 F. Supp. 2d at 62 (citing Keyshian v. Board of Regents, 385 U.S. 589, 603, 87 S. Ct. 675 (1967); Board of Trustees of Leland Standford Junior Univ. v. Sullivan, 773 F. Supp. 472, 474 (D.D.C. 1991)).

[58] The argument is perhaps less strong in the case of textbook materials, which also have been regulated as enduring materials

[59] This is central: the argument is not that the peer-review system is objective, much less flawless. Rather, it is that 1) the system works reasonably well; 2) it is part of the nature of science that the systems' outputs—refereed publications—are to be received critically; and 3) *ad hoc* agency intervention in this system is liable to be extremely problematic. *See, e.g.*, 1 NATIONAL ACADEMY OF SCIENCE, NATIONAL ACADEMY OF ENGINEERING, INSTITUTE OF MEDICINE, RESPONSIBLE SCIENCE: ENSURING THE INTEGRITY OF THE RESEARCH PROCESS (1992) (remarking on the critical nature of science and on the general effectiveness of, and concerns about, peer review).

of enduring materials and CME presentations. Such speech likely will be viewed either as pure scientific speech or as a *Nike*-like hybrid, entitled at least to have its restriction subject to a very high level of scrutiny.

Even if that argument is rejected, and science is transformed into the merely commercial act of mailing, such speech deserves significant constitutional protection. In either case, FDA would do well to restrain itself from any restrictions on the dissemination of such speech. At the least, such restrictions would routinely risk running afoul of the First Amendment's protection of commercial speech—the unmistakable conclusion of the district court in *WLF*. Although that conclusion was vacated in part, on justiciability grounds, the court of appeals took pains to avoid criticizing "the reasoning or conclusions of the district court."[60] At most, restrictions such as those that *were* provided in FDA's enduring materials guidance would directly contravene the very core of the First Amendment's protection of free speech. Perhaps, as *Nike* may suggest, the truth lies in the middle.

On any reading, restrictions on enduring materials—regarding off-label uses or not—are liable to be constitutionally suspect. FDA would do best to avoid that liability altogether, especially as it is difficult to envision candidate rules where basic issues of constitutional compliance would not hinge on arbitrary issues of enforcement. The better regulatory task by far would be to parse a realm of protected scientific speech—including partly commercial speech—from labeling proper. There is probably little to win here otherwise. No one capable of reading a reprint—certainly not licensed physicians—could fail to understand certain basic limitations inherent in the enduring materials at issue. Whatever their discipline and background, physicians should understand, for example, that an isolated clinical case report cannot represent the final empirical word on a topic. Policing the completeness of literature files or stickering reprints with warnings of possible imbalance or future refutation seem worse than pointless.

FDA's mission to ensure the safety of medicines by ensuring accurate labeling is critical to the public health. But the importance of that mission, as well as its statutory basis *and* its constitutional license, becomes increasingly murky as the agency reaches for more and more tangential senses of "labeling."[61] The sense in which enduring materials properly may be viewed as labeling or advertising seems to be highly qualified; the regulation of enduring materials is correspondingly difficult to justify. FDA should memorialize in the *Federal Register* what it conceded in *Washington Legal Foundation v. Henney*: FDA will not regard the distribution of scientific literature as violative of the Federal Food, Drug, and Cosmetic Act in general or as promoting off-label uses in particular; and FDA will not base an enforcement action wholly or in part on a manufacturer's distribution of enduring materials.

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[60] *WLF v. Henney*, 202 F.3d at 337 n.7.

[61] *Kordel v. United States*, 335 U.S. 345 (1948) generally is cited to support a broad reading of "accompanying" and hence of FDA's statutory mandate to regulate product labeling. Note two things: first, the issue of statutory construction addressed in *Kordel* does not speak to the scope of First Amendment protection; and second, *Kordel* does not suggest that the proper statutory sense of "accompanying" is unbounded. The *Kordel* Court regarded promotional pamphlets that were designed to be distributed to consumers of drug products, together with the products. *See id.* at 346. Some of the promotional materials were shipped from the manufacturer to vendors together with the drugs (in the same cartons) and some were not. *Id.* Where "the drugs and literature had a common origin and a common destination," and where the literature was an "essential supplement to the label attached to the package," the Supreme Court did not regard the question whether "the literature had been shipped in the same container" as dispositive of the question of misbranding. *Id.* FDA has appeared sometimes to read this decision as suggesting that *any* manufacturer speech about a regulated product may be viewed as labeling but that may be overly ambitious, even on statutory grounds.