

FDA Marketing v. First Amendment: Washington Legal Foundation Legal Challenges to Off-Label Policies May Force Unprecedented Changes at FDA

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I. INTRODUCTION

Years from now, when scholars examine the history of the Food and Drug Administration's (FDA's) marketing policy, Washington Legal Foundation's (WLF's) challenges under the First Amendment may be identified as the pivotal cases influencing the evolution of FDA's approach to marketing.

Assuming the primary holdings of the U.S. District Court for the District of Columbia are reaffirmed on appeal, virtually every FDA marketing decision will be subject to First Amendment analysis and review. FDA will have to consider First Amendment implications every time its commissioner or a senior staff member proposes to censor the speech of a regulated company.

This article reviews Judge Royce Lamberth's decisions invalidating certain FDA policies on First Amendment grounds. A key point is that the First Amendment standards are not just esoteric, academic, or legal ideas, but common sense policy principles. These principles are stated in the language of the courts, and are neither radical nor revolutionary in modern America. They arise from the basic First Amendment principles now routinely applied by the Supreme Court to determine the validity of speech restrictions imposed by federal, state, and local governments. If Judge Lamberth's decisions stand on appeal, the principles of free speech protected elsewhere in society will now be applicable to FDA. Modern First Amendment law will be given a new venue, and FDA will be compelled to move in a new direction.

The WLF decisions considered two important questions. First, the court considered whether an industry "pervasively regulated" by the federal government is entitled to First Amendment protection. The court unequivocally answered yes to that question. Given that the First Amendment does apply, the second question is, which test should be used. The court could apply either: 1) the "strict scrutiny" test, which pertains to political and other forms of speech with profound social and political importance; or 2) the "commercial speech" test, which applies to advertising and other forms of speech that propose a commercial transaction. In the *WLF* decisions, Judge Lamberth found that the "commercial speech" test applied, and that the "off-label" restrictions violated even these lesser protections afforded by the court's "commercial speech" test. He, however, rejected the argument that the higher standard was appropriate.

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II. BACKGROUND

A. *Jurisprudential Background*

In the 1976 *Virginia Pharmacy* case,¹ the Supreme Court recognized that commercial speech, namely advertising and promotion, was entitled to constitutional protection. That case involved a challenge to a law prohibiting licensed pharmacists from advertising the prices for which they sold prescription drugs. The Supreme Court invalidated the ban, recognizing that people were interested in information such as the price of pharmaceuticals. The Court also rejected paternalism as a justification, writing that "people 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."²

In 1980, the Supreme Court elaborated, and in the process significantly diminished the extent of the constitutional protection it appeared to furnish commercial speech in *Virginia Pharmacy*. In *Central Hudson*,³ the Court adopted a balancing test which, in theory, gives the government the opportunity to justify restrictions on commercial speech even if that speech is truthful and not deceptive. Under that balancing test, a court must determine whether: 1) the commercial speech concerns a lawful activity and is not misleading; 2) the government interest asserted to justify the regulation is substantial; 3) the regulation directly advances the government's interest; and 4) the regulation is no more extensive than necessary to serve that interest.⁴

The *Central Hudson* test can be restated in the plain language of four questions. First, is the underlying activity legal and the communication about it true and not misleading? If so, the Supreme Court expects the government to prove the next three. Second, does the government have clear authority and serious reason to regulate this speech? Third, does the speech restriction lead to a resolution of the problem? Fourth, are there other ways to solve the problem with less or no restrictions on speech? In nearly every case of this kind, the issue does not get to court unless the first two questions have been answered in the affirmative. The outcome, therefore, generally turns on the government's ability to prove that the restrictions actually work and that there are no reasonable, less restrictive alternatives.

Often categorized as "intermediate First Amendment scrutiny," this balancing test has the problem of providing the courts with enormous discretion. To illustrate, the Supreme Court used this test in *Posadas de Puerto Rico*⁵ to uphold a paternalistic restriction on casino advertising directed at anyone but tourists. The Court advanced the widely-criticized argument that "the greater power to completely ban casino gambling necessarily includes the lesser power to ban advertising of casino gambling."⁶ Modern-day state legislatures arguably have the power to outlaw almost any product or service. Thus, if taken seriously, this notion that the "greater-includes-the-lesser" essentially would eliminate protection for commercial speech about any product or service other than those that are constitutionally protected, such as books and movies.

The situation changed in the 1990s, beginning with the *Discovery Network* case.⁷ The Court struck down a city ban that prohibited newsracks on public property if the

¹ *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

² *Id.* at 770.

³ *Central Hudson Gas & Elec. Co. v. Public Serv. Comm'n of New York*, 447 U.S. 557 (1980).

⁴ *See id.*

⁵ *Posadas de Puerto Rico Ass'n v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986).

⁶ *Id.* at 345-46.

⁷ *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993).

racks were used to distribute “commercial handbills,” as opposed to newspapers. In the process, the Court clarified that a challenger could defeat a commercial speech restriction if it showed that there were numerous and obvious less restrictive alternatives to the restriction on speech.⁸

In two cases coming out of Florida’s strict regulation of accountants, the Court affirmed that the government bore a heavy burden in justifying regulations of commercial speech and that “mere speculation and conjecture” were not enough.⁹ In *United States v. Edge Broadcasting*,¹⁰ the Court upheld a ban on a North Carolina broadcaster carrying advertisements for the Virginia state lottery. That case was explainable, however, by the fact that it involved a product or service that was unlawful in the licensed state, and that it involved broadcasting, an area that traditionally has been accorded a lower level of First Amendment protection.¹¹

In 1996, the Court unanimously invalidated a Rhode Island restriction on advertising the price of alcohol.¹² This decision also witnessed Justice Thomas’ emergence as the new champion of commercial speech, a position previously filled by Justice Blackmun. Justice Thomas argued that truthful commercial speech about a lawful product or service ought not to be treated to any lesser scrutiny than, for example, political or artistic speech.¹³ More important, however, was Justice Stevens’ plurality opinion that assailed restrictions on commercial speech for paternalistic purposes,¹⁴ and Justice O’Connor’s opinion that spelled out the easy availability of less restrictive, non-speech related alternatives.¹⁵

Thus, the principle that has emerged during the last decade is that the Supreme Court looks askance at restrictions on commercial speech imposed for paternalistic purposes. The advertising may be regulated if the product or service is unlawful, and the Court still seems to be giving a wide berth to the government to ensure that people are not misled, as *Florida Bar v. Went for It*¹⁶ suggests. In that case, the Court upheld a Florida bar restriction on the solicitation of clients by lawyers for thirty days after an accident. Overall, though, the Court is quite protective of commercial speech.

B. *Background of the WLF Cases*

WLF challenged FDA guidance documents and subsequent statutory provisions restricting pharmaceutical company distribution of off-label information to medical professionals.¹⁷ Specifically, the cases challenged on First Amendment grounds restrictions on drug company distribution of reprints of medical textbooks and peer-reviewed medical journal articles, and the sponsorship of continuing medical education (CME) seminars.¹⁸

⁸ *Id.* at 418, n.13.

⁹ *Edenfield v. Fane*, 507 U.S. 761 (1993) (striking down restriction prohibiting certified public accountants from making uninvited visits or telephone calls to potential clients); *Ibanez v. Florida Dept. of Bus. and Prof’l Regulation*, 512 U.S. 136 (1994) (invalidating ban on use of certain credentials in advertising).

¹⁰ 509 U.S. 418 (1993).

¹¹ *Red Lion Broad. v. Federal Communications Comm’n*, 395 U.S. 367 (1969).

¹² 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996).

¹³ *Id.* at 518 (Thomas, J., concurring in part and concurring in the judgment).

¹⁴ *Id.* at 507 (principal opinion of Stevens, J., joined by Kennedy & Ginsburg, J.) (discussing a number of policy reasons for applying a higher level of scrutiny to bans on truthful, nonmisleading commercial speech).

¹⁵ *Id.* at 528-30 (O’Connor, J., concurring in the judgment, joined by Rehnquist, C.J., Souter, J., and Breyer, J.).

¹⁶ 515 U.S. 618 (1995).

¹⁷ The Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified at 21 U.S.C. §§ 360.999, 403 (1998)).

¹⁸ Final Guidance On Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,074 (Dec. 3, 1997), 61 Fed. Reg. 52,800 (Oct. 8, 1996).

When FDA approves a drug, it does so for the uses specified in the FDA product labeling. FDA then limits drug company communication about the use of the drug to the approved labeling unless modifications to such labeling have been approved specifically by FDA pursuant to a supplemental drug review and approval. Once a drug has been granted FDA approval, however, a physician may prescribe that drug for any use, both on- and off-label.¹⁹

Off-label use is allowed for several reasons. Technically, FDA has no statutory authority to control physician practice in this area. Moreover, FDA and the medical community long have recognized that for many medical conditions, clinical practice has proven that many drugs have value beyond the narrow labeling for which they were approved initially. In fact, off-label use often is the standard of care in medical practice. Not using an off-label drug in some instances could be medical malpractice. The General Accounting Office has estimated that twenty-five percent of anticancer drugs are prescribed off-label and that fifty-six percent of cancer patients have been given at least one off-label drug.²⁰ Further, for many conditions the small size of the patient population makes FDA approval prohibitively expensive and unnecessary. Therefore, even FDA acknowledges that the public benefits from off-label use.²¹

Drug companies, on the other hand, are permitted only to promote the on-label, FDA-approved uses of their drugs.²² It is considered to be "misbranding," a criminal offense, for a drug company to promote non-approved uses of FDA approved drugs.²³ Because pharmaceutical companies are not allowed to promote off-label uses, but physicians write more than one million prescriptions each year for off-label uses, it is clear that physicians are learning about these new medical developments from a variety of sources.

The issue took on regulatory significance in the early 1990s when, under the leadership of then-Commissioner David Kessler, FDA expressed concern that drug companies were becoming an important source of off-label information through the distribution of journal articles, medical textbooks, and presentations at company sponsored CME sessions. FDA asserted increased interest in controlling company distribution. Recognizing the sensitivity of the medical community to any restrictions on the dissemination of research information, the agency spent more than four years working on the Guidance Documents that provided the basis for the WLF First Amendment challenge. Interested parties, including doctors, pharmaceutical companies, trade, and consumer groups, filed written comments with FDA expressing concern about this proposed expansion of its marketing restrictions.²⁴

WLF first challenged FDA's guidance documents in 1994. While that challenge was pending, the issue of off-label use came to the attention of Congress, which passed the Food and Drug Administration Modernization Act (FDAMA) in 1997.²⁵ FDAMA modified, but perpetuated, most of the provisions of the Guidance Documents. Judge Lamberth's decision in *Washington Legal Foundation v. Friedman*²⁶ addressed the constitutionality of

¹⁹ Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, 59 Fed. Reg. 59,820 (Nov. 18, 1994).

²⁰ U.S. General Accounting Office, *Off-Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies*, Pub. No. GAO/PEMD 91-14, at 4 (1991).

²¹ *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 55 (D.D.C. 1998).

²² 21 U.S.C. § 352 (1994).

²³ *Id.*

²⁴ Draft Policy Statement on Industry-Supported Scientific and Educational Activities, 57 Fed. Reg. 56,412 (Nov. 27, 1992).

²⁵ Pub. L. No. 105-115, 111 Stat. at 2296.

²⁶ *Friedman*, 13 F. Supp. 2d at 55.

the FDA Guidance Documents. The second decision, *Washington Legal Foundation v. Henney*,²⁷ addressed the constitutionality of the associated FDAMA provisions.

III. THE DISTRICT COURT DECISIONS

The primary issue in the *WLF* cases was whether the First Amendment applied to FDA, and if so, whether FDA had violated the law by placing restrictions on manufacturers' dissemination of certain information about off-label uses.²⁸ In each decision, the court found that the First Amendment did apply and that the restrictions were "more extensive than necessary to serve the asserted government interest and that they unduly burden important speech."²⁹ The court limited enforcement of the off-label restrictions, allowing company communication so long as drug companies made certain disclosures.³⁰

Initially, FDA tried to avoid First Amendment scrutiny by asserting that the distribution of journal articles and textbooks and the sponsorship of CME seminars should be classified as conduct, not speech. Not surprisingly, the court viewed this argument with a good deal of skepticism and dismissed it, setting up the First Amendment analysis.³¹

A. *The First Amendment Applies to FDA Marketing Restrictions*

FDA's critics claim that the agency believes its mission to be so important that it is exempt from the protections guaranteed speakers by the First Amendment's free speech clause.³² FDA's first argument in defense of its guidance documents support this criticism. The agency essentially claimed that because it had been given the statutory authority to regulate the pharmaceutical industry, any infringements on the First Amendment that occurred due to its policies were permissible.³³ FDA claimed that the expansion of its marketing restrictions to include the distribution of research involving off-label uses independent of any input by drug companies was a natural extension of its regulatory mission.³⁴ Judge Lamberth disagreed.

At first glance, the argument that a worthy regulatory mission trumps the First Amendment sweeps too far, too quickly. If the theory of the argument held, it would give the government the right to sweep away constitutional rights wherever there was a legitimate grant of state power. Regardless, FDA defended its claim by citing instances in which other federal agencies appeared to avoid First Amendment challenges due to the importance of their work.³⁵ In rejecting FDA's claim, Judge Lamberth concluded that these cases either had been superseded by recent Supreme Court decisions³⁶ or had been decided appropriately under commercial speech principles.³⁷

²⁷ 56 F. Supp. 2d 81 (D.D.C. 1999).

²⁸ *Friedman*, 13 F. Supp. 2d at 62.

²⁹ *Id.* at 54.

³⁰ *Id.* at 72.

³¹ *Id.* at 59. ("[T]he activities at issue in this case are only 'conduct' to the extent that affixing a stamp and distributing information through the mails is 'conduct.'").

³² See, e.g., Lars Noah & Barbara Noah, *Liberating Commercial Speech: Product Label Controls and the First Amendment*, 47 FLA. L. REV. 63 (1995); I. Scott Bass, Paul E. Kalb, M.D. & Bradford A. Berenson, *Off-Label Promotion: Is FDA's Final Guidance on Industry-Supported Scientific and Educational Programs Enforceable?*, 53 FOOD & DRUG L.J. 194 (1998).

³³ *Friedman*, 13 F. Supp. 2d at 60.

³⁴ *Id.* at 62.

³⁵ *Securities & Exch. Comm'n v. Wall St. Publ'g Inst., Inc.*, 851 F.2d 365 (D.C. Cir. 1988).

³⁶ 44 *Liquormart Inc.*, 517 U.S. at 512 ("Speech restrictions cannot be treated as simply another means that the government may use to achieve its ends.").

³⁷ *Friedman*, 13 F. Supp. 2d at 62.

B. *Commercial Speech Review*

Once the court decided that the First Amendment applied, it needed to decide which level of scrutiny to apply. The district court could have avoided the dilemma on the grounds that, because FDA rules violated the less restrictive “commercial speech” protections, it would not have to consider whether the more exacting “pure speech” rules would have been applied. Instead, it found that the lesser speech test developed in *Central Hudson* applied and considered each of its four questions.³⁸

1. *Is the Commercial Speech Unlawful, Untruthful, or Inherently Misleading?*

FDA acknowledged that physicians may prescribe approved drugs for off-label use,³⁹ but asked the court instead to look at the activity of drug companies’ distribution of off-label information. Under FDAMA, the agency claimed such action is misbranding and a crime.⁴⁰ Recognizing the tautology, Judge Lamberth rejected the argument. Further, FDA asserted that company control of label communication is “inherently misleading” because it is not approved by FDA. Again, the court recognized the tautology and remarked that, by making the argument, FDA had “exaggerated its place in the universe.”⁴¹

The court determined that the appropriate questions were whether the underlying information was useful to doctors and whether the speech was “more likely to deceive the public than inform it.”⁴² The court answered the latter in *Friedman* by saying:

The conclusions reached by a laboratory scientist or university academic and presented in a peer-reviewed journal or textbook, or the findings presented by a physician at a CME seminar are not “untruthful” or “inherently misleading” merely because the FDA has not yet had the opportunity to evaluate the claim.⁴³

When Judge Lamberth addressed the same issue a year later in *Henney*, he had the benefit of another Supreme Court decision invalidating restrictions on commercial speech.⁴⁴ Stressing the similarities of the cases, Judge Lamberth noted that FDA had allowed the same off-label information to be disseminated freely by all but the drug companies themselves. He continued:

Only when the manufacturer initiates the exchange does FDA choose to label the speech false or inherently misleading. The Supreme Court has recently addressed this situation with the following observation: “[e]ven under the degree of scrutiny that we have applied in commercial speech cases, decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment.”⁴⁵

³⁸ *Central Hudson*, 447 U.S. at 557.

³⁹ *Friedman*, 13 F. Supp. 2d at 66.

⁴⁰ 62 Fed. Reg. at 64,079.

⁴¹ *Friedman*, 13 F. Supp. 2d at 67.

⁴² *Id.* (citing *Central Hudson*, 447 U.S. at 563).

⁴³ *Id.*

⁴⁴ *Greater New Orleans Broadcasters Ass’n v. Federal Communications Comm’n*, 119 S. Ct. 1923 (1999).

⁴⁵ *Henney*, 56 F. Supp. 2d at 85 (citing *Greater New Orleans*, 119 S. Ct. at 1923).

2. *Is the Government's Purported Interest in the Challenged Restriction Substantial?*

Few doubt the substantiality of FDA's interest in promoting public health and safety by protecting the integrity of its drug approval process.⁴⁶ Nonetheless, Judge Lamberth narrowed this inquiry to two interests: 1) ensuring that physicians receive accurate and unbiased information relevant to prescription decisions; and 2) encouraging drug manufacturers to seek supplemental drug approvals for off-label uses.⁴⁷

In *Friedman*, the court categorically rejected FDA's assertion that the guidance documents were necessary to protect physicians from misusing information regarding off-label treatments.⁴⁸ The court noted that the restricted communication was being distributed to physicians with the ability to evaluate the information regardless of its source,⁴⁹ and highlighted that FDA had restricted only the distribution of the information by drug manufacturers.⁵⁰ The court not only reiterated this finding in *Henney*, but also used it to dismiss all the restrictions in FDAMA aimed at the "inherently false and misleading" elements of the materials at issue.⁵¹

In both decisions, the district court accepted the legitimacy of FDA and congressional interest in encouraging supplemental drug approvals. Hence, as the court moved to the third and fourth elements of *Central Hudson*, it categorically rejected restrictions based on any "inherently misleading" theory, and only considered them in light of the need to encourage supplemental drug approvals.

3. *Does the Challenged Restriction Directly Advance the Substantial Governmental Interest?*

Judge Lamberth was satisfied that the government met its burden in both cases on this question. In *Friedman*, the district court concluded that the guidance documents appropriately provide an incentive for drug manufacturers to seek FDA approval for off-label treatments.⁵² Likewise, in *Henney*, the court identified three requirements of FDAMA that not only encourage, but often require, new drug applications. Specifically, FDAMA required that before a company could distribute these off-label materials, it either must: 1) submit a supplemental application; 2) certify one is forthcoming; or 3) receive a certificate of exemption from FDA.⁵³

4. *Is the Challenged Restriction More Extensive Than Necessary to Serve the Governmental Interest?*

The government failed to meet its burden regarding this question in both cases. In *Friedman*, the court found that "there exists a less-burdensome alternative to this restriction on commercial speech."⁵⁴ In fact, the judge specified four such conditions

⁴⁶ *Friedman*, 13 F. Supp. 2d at 69.

⁴⁷ *Id.*

⁴⁸ *Id.* at 70 ("To endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection . . . is practically an engraved invitation to have the restriction struck.").

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Henney*, 56 F. Supp. 2d at 85.

⁵² *Friedman*, 13 F. Supp. 2d at 72.

⁵³ *Henney*, 56 F. Supp. 2d at 87.

⁵⁴ *Friedman*, 13 F. Supp. 2d at 51.

that FDA could impose without violating the First Amendment. FDA could: 1) require conspicuous notifications that the uses discussed were not approved by the agency; 2) require that the articles and textbook reprints come from peer reviewed journals and bona fide independent publishers; 3) require that the sponsor of CME seminars be “independent program providers”; and 4) require authors and manufacturers to disclose their financial interests.⁵⁵ The court found that these would address all of FDA’s concerns regarding deception of physicians or avoidance of the approval process without unnecessarily restricting the dissemination of scientific research.

In *Henney*, Judge Lamberth was critical of FDAMA’s three-part requirement on supplemental applications. The problem, he said, was not its effectiveness but its means. “The supplemental application requirement of the act amounts to a kind of constitutional blackmail — comply with the statute or sacrifice your First Amendment rights. It should go without saying that this tactic cannot survive judicial scrutiny.”⁵⁶

To highlight the court’s finding that the restrictions were more extensive than necessary, Judge Lamberth listed several less restrictive alternatives. Specifically, he noted that the government had chosen neither to ban off-label prescriptions, to prohibit off-label profit by manufacturers, nor to fine manufacturers for failing to file supplemental applications.⁵⁷ Further, he noted that many existing measures already encourage such applications.⁵⁸

Perhaps the best summary of the issue was made by Judge Lamberth in his conclusion in *Friedman*:

Off-label prescriptions, presently legal, do constitute the most effective treatment available for some conditions. Through the government’s well-intentioned efforts to prevent misleading information from being communicated, a great deal of truthful information will also be embargoed. In this case, the truthful information may be lifesaving information, or information that makes a life with a debilitating condition more comfortable.⁵⁹

IV. THE COURT SHOULD HAVE EMPLOYED HEIGHTENED SCRUTINY IN ASSESSING THE RESTRICTIONS AT ISSUE

The *WLF* cases exemplify the value of First Amendment protections in our society. Despite their best intentions and justifications, FDA and Congress developed policies and laws that interfered with the policy of encouraging and protecting scientific discussion.⁶⁰ For reasons having little to do with the truth of the underlying information, the restrictions blocked the provision of valuable medical information from drug companies to physicians. In many instances, drug companies are the best source of information about the uses of their own drugs and have the greatest incentive to distribute that information.

In *Friedman*, the district court acknowledged that the question of which level of First Amendment protection applied was a difficult one.⁶¹ In the end, the court applied the lesser commercial speech standard, noting the significant marketing resources of

⁵⁵ *Id.*

⁵⁶ *Henney*, 56 F. Supp. 2d at 87.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Friedman*, 13 F. Supp. 2d at 73.

⁶⁰ *Keyishian v. Board of Regents of the Univ. of the State of New York*, 385 U.S. 589, 603 (1967).

⁶¹ *Friedman*, 13 F. Supp. 2d at 62.

drug companies and the legitimate government interest in protecting consumers from misleading or deceptive sales practices.⁶² In *Henney*, the court moved directly to analyze the FDAMA restrictions without considering this question.

The court should have employed a different test — the “close scrutiny” test applied to political and pure speech cases. As long as the First Amendment is not an absolute right, the test that will be used essentially will balance the risks involved in suppressing speech against the risks of not suppressing speech. Where science and medical practice information is involved, the most exacting test is appropriate. In this case, the potential harm of censoring speech is huge because it would limit information that doctors could receive about the beneficial uses of drugs. Meanwhile, the potential harm of allowing the speech is minimal. The information has been vetted already in the scientific community, and it is offered only to people with the expertise to evaluate it.

Speech with scientific or academic value is at the core of the communications protected by the First Amendment.⁶³ “The Supreme Court has said that the First Amendment protects scientific expression and debate as well as political and artistic expression.”⁶⁴ The otherwise fully protected speech at issue in *Friedman* and *Henney* should not be treated as “only” commercial speech by virtue of the fact that a manufacturer paying to disseminate the speech has an economic interest in the product under discussion. To the contrary, the fact that the manufacturer “has an economic motivation” to support distribution of the information “would clearly be insufficient by itself to turn the materials into commercial speech.”⁶⁵

Moreover, aside from the case law establishing that scientific speech is protected fully, the speech in these cases exhibits none of the characteristics that would make it commercial speech. The Supreme Court has “characteriz[ed] the proposal of a commercial transaction as ‘the test for identifying commercial speech.’”⁶⁶ The activities at issue — e.g., mailing a textbook or an article reprint, or presenting data at a symposium — do not propose a commercial transaction. Thus, under the governing standard, the speech should not be commercial.

Additionally, the speech here does not reflect any of the related characteristics that the Supreme Court also has used in identifying commercial speech.⁶⁷ For example, none of the parameters traditionally employed to classify speech as commercial is applicable to this type of speech.⁶⁸ The textbooks, article reprints, and symposia support are not “advertisements” in the common understanding of the term; even if they were, that would be insufficient to “compel the conclusion that they are commer-

⁶² *Id.* at 65.

⁶³ *See, e.g., Keyishian*, 385 U.S. at 589 (academic freedom is “a special concern of the First Amendment”); *Miller v. California*, 413 U.S. 15, 34 (1973) (First Amendment protection extends to works with “scientific value”).

⁶⁴ *Board of Trustees of Leland Stanford Junior Univ. v. Sullivan*, 773 F. Supp. 472, 474 (D.D.C. 1991).

⁶⁵ *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60, 67 (1983); *cf. New York Times Co. v. Sullivan*, 376 U.S. 254, 266 (1964) (“[t]o avoid placing . . . a handicap upon the freedoms of expression, we hold that if the . . . statements would otherwise be constitutionally protected . . . , they do not forfeit that protection because they were published in the form of a paid advertisement”) (assessing protected status of allegedly libelous statement).

⁶⁶ *Discovery Network*, 507 U.S. at 423 (emphasis in the original) (quoting *Board of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 473-74 (1989)).

⁶⁷ The Court has been careful to maintain a definition that does not sweep too broadly in order “to ensure that speech deserving of greater constitutional protection is not inadvertently suppressed.” *Discovery Network*, 507 U.S. at 423 (quoting *Bolger*, 463 U.S. at 66); *see also Central Hudson*, 447 U.S. at 579 (Stevens, J., concurring) (“[I]t is important that the commercial speech concept not be defined too broadly lest speech deserving of greater constitutional protection be inadvertently suppressed.”).

⁶⁸ *See Bolger*, 463 U.S. at 66-67.

cial speech.”⁶⁹ Nor does the reference to a specific product in textbooks, article reprints, or symposia presentations “by itself render [the communication] commercial speech.”⁷⁰ Thus, the speech at issue here is not commercial.

Even if the speech here could be deemed a hybrid, including commercial and noncommercial aspects, whatever elements of the latter may exist are intertwined inextricably with the fully protected non-commercial elements which require application of the strictest standard of First Amendment scrutiny.⁷¹ “[W]here, as here, the component parts of a single speech are inextricably intertwined,”⁷² courts cannot parcel out the speech, applying one test to one phrase and another test to another phrase. Such an endeavor would be both artificial and impractical.

Moreover, FDA’s restrictions should be subject to heightened scrutiny for another, independent reason — namely that they are content- and speaker-based. The regulatory scheme restricting the dissemination of independently generated, peer-reviewed information to physicians incorporates many elements disfavored under First Amendment precedent. As discussed above, both FDAMA and the Guidance Documents concern off-label uses of a manufacturer’s products. FDA bears a heavy burden in justifying any proscriptive ban on speech; the constitutionally preferred remedy is vigorous, after-the-fact enforcement in the event of a specific violation.⁷³ It is longstanding First Amendment doctrine that blanket speech bans are disfavored unless the government demonstrates that no other means can serve its legitimate goals. “Broad prophylactic rules in the area of free expression are suspect . . . precision of regulation must be the touchstone.”⁷⁴

Furthermore, FDA’s policies rest on two suspect distinctions: they restrict both “the subjects about which persons may speak *and* the speakers who may address a public issue.”⁷⁵ FDA’s restrictions, which are triggered, *inter alia*, by a “significant focus” on off-label uses,⁷⁶ are categorized properly as content-based rules “by any commonsense understanding of the term.”⁷⁷ Accordingly, the highest degree of First Amendment scrutiny should have been applied.⁷⁸

The restrictions also should be subject to strict scrutiny as speaker-based rules. According to the Supreme Court, speaker-based restrictions constitutionally are suspect when the restrictions are “concerned with the communicative impact of the regulated speech.”⁷⁹ FDA has made clear that the purpose of the restrictions at issue in *Friedman* and *Henney* is to prevent manufacturers, but not other speakers, from communicating information regarding off-label uses of the manufacturer’s products to physicians and other health care professionals. Such “differential treatment . . . suggests that the goal of the regulation is not unrelated to suppression of expression, and

⁶⁹ *Id.* at 66.

⁷⁰ *Id.*; see also *Wall St. Publ’g Inst.*, 851 F.2d at 372.

⁷¹ *Riley v. National Fed’n of the Blind*, 487 U.S. 781, 796 (1988); *Fox*, 492 U.S. at 474-75 (FDA regulations here do not merely restrict sales pitches that happen to include protected speech, such as the home products demonstrations at issue in *Fox*. Rather, FDA’s restrictions here have demonstrably “prevent[ed] the speaker from conveying, or the audience from hearing, the [] noncommercial messages.”).

⁷² *Riley*, 487 U.S. at 796 (applying highest level of First Amendment review to arguably commercial elements of charitable solicitation).

⁷³ See, e.g., *Boos v. Barry*, 485 U.S. 312 (1988).

⁷⁴ *NAACP v. Button*, 371 U.S. 415, 438 (1963).

⁷⁵ *First Nat’l Bank of Boston v. Bellotti*, 435 U.S. 765, 785 (1978) (acknowledging corporation’s free speech rights) (emphasis added).

⁷⁶ 62 Fed. Reg. 52,800 (Oct. 8, 1996).

⁷⁷ *Discovery Network*, 507 U.S. at 426-29.

⁷⁸ *Sable Communications of California v. Federal Communications Comm’n*, 492 U.S. 115, 126 (1989).

⁷⁹ *Turner Broad. Sys. v. Federal Communications Comm’n*, 512 U.S. 622, 658 (1994).

such a goal is presumptively unconstitutional.”⁸⁰ Thus, because the regulations “reflect the Government’s . . . aversion to what the disfavored speakers have to say,” strict scrutiny is appropriate.⁸¹

There is no doubt that, standing alone, scientific and medical research is entitled to the highest level of First Amendment protection. Similarly, courts should refuse to allow the government to make distinctions between the research itself and any economically motivated dissemination of that research. The research either is sound and valuable to the research and clinical communities, or it is not. Commercial status and commercial motivations should not alter the analysis.

V. SPEECH RESTRICTIONS ARE BAD POLICY

Although these two cases are written and analyzed in the parlance of the First Amendment protections of free speech, the result derives as much from common sense as from abstract legal theory. Good public policy demands that the medical community operate in an environment where free speech is protected, just as it is elsewhere in our society.

Sound social policy demands that restraints on the dissemination of medical research always be subject to exacting judicial scrutiny. The potential for harmful government intervention is very high. Consider the facts of the *WLF* cases. Essentially, FDA asserted that it was necessary to block *all* drug company dissemination of off-label information in light of its need to protect public health and safety. On this theory, any government entity could justify almost any restriction on the dissemination of truthful information in the name of protecting public health and safety. Not until Judge Lamberth carefully applied the third and fourth prongs of the *Central Hudson* test was it clear that the restrictions simply went too far in seeking to override the needs of patients and the medical community.

Other unfortunate examples of unwarranted state power are not difficult to imagine. For example, certain types of medical research could be seen as inherently detrimental to vulnerable members of society, such as teens pursuing high-profile cosmetic surgery. The Department of Health and Human Services could then assert a substantial interest in curbing the distribution of certain cosmetic surgery information.

Another possible effect of FDA’s guidance documents and the FDAMA restriction is isolation of scientists and medical researchers from one another. Company experts were given second-class status in research and clinical communities. Free exchange of medical research enhances efficiency, however, thus avoiding unnecessary duplication and maximizing the interplay of diverse ideas. These benefits cannot be achieved fully unless the distribution of new scientific information is left unrestricted by the government.

VI. CONCLUSION

The *WLF* decision and the principles discussed put FDA at a crossroad. How the agency interprets the district court decision in *Henney* largely will define its future credibility. FDA can view the *WLF* decisions as either a curse or a gift. It can resist the common sense instructions of the cases, or use these decisions as an opportunity to design more transparent and accessible approaches to its statutory duties. The latter is the more sensible course.

⁸⁰ *Minneapolis Star & Tribune Co. v. Minnesota Comm’r of Revenue*, 460 U.S. 575, 585 (1983).

⁸¹ *Turner Broad.*, 512 U.S. at 658.

