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Commentary: Can We Talk? About Food and Drug Regulation and the First Amendment

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I. INTRODUCTION

There has been no shortage of speech lately about the applicability of the First Amendment to regulation by the Food and Drug Administration (FDA). For much of the past decade, FDA has been forced to defend its statutes and regulations against legal challenges based upon the First Amendment, and it has lost several high-profile cases. In a response to the litigation that may be without precedent in regulatory circles, FDA invited comment about the implications of First Amendment jurisprudence on other aspects of its statutes and policies. In essence, FDA asked the public to identify which other of its regulations should be modified or repealed because of First Amendment concerns. About 775 comments were received in the First Amendment docket. While many were from ordinary citizens responding in brief via an electronic form, others, lengthy and analytical, were unsurprisingly from regulated industry and its representatives. Citizen groups from both sides of the political spectrum also participated.

When the Food and Drug Law Institute (FDLI) decided to provide a forum in these pages for academic discussion of this topic (devoting all of the Food and Drug Law Journal’s Vol. 58, No. 3 to it), its invitation to produce an article for publication, under significant deadline pressure, was unsurprisingly accepted disproportionately by representatives of regulated industry. With some trepidation, as one whose field is food and drug law and not constituent

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** Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942 (May 16, 2002). Whether FDA’s approach is unprecedented is unclear; there is no simple method to search for comparable situations where a regulatory agency has asked for comment on whether some aspects of its operations are unconstitutional.

The comments may be read at http://www.fda.gov/ohrms/dockets/dockets/02n0209/02n0209.doc (last visited Nov. 10, 2003).

Of the ten Food and Drug Law Journal Vol. 58, No. 3 articles concerning American regulation, four were authored by attorneys in private practice who represent the drug industry; one by house counsel for a drug company; one by counsel for an industry trade association; and one by an attorney for the Washington Legal Foundation, plaintiff in a series of cases (see supra note 1) challenging FDA regulation on First Amendment grounds. The other three were authored by an academic, a member of Congress, and an attorney when she was a law student. Some, and probably many, of these authors prepared comments submitted to FDA’s First Amendment docket.
tional law, this author accepted the invitation to comment in reply to the First Amendment symposium, to suggest a different perspective on some of the issues.

The subject is vast; even the entire issue of this journal left many aspects virtually unmentioned, with drugs and medical devices getting the lion’s share of attention. This reply, too, is of necessity very selective. First, it focuses on the appropriate role of FDA in responding to First Amendment challenges to its authority. Second, it urges a more careful look by the courts at when FDA-regulated speech “would concern unlawful conduct and therefore be constitutionally unprotected” under the important precedent of Central Hudson Gas & Electric Corp. v. Public Service Commission of New York. Third, with a focus on drug-creation under the mantle of the practice of pharmacy, it considers the role of speech as evidence of crossing a regulatory boundary. Fourth, inspired by advice offered to drug manufacturers by symposium authors Blackwell and Beck—that they best beware a Pyrrhic victory in their First Amendment battles—this article suggests some alternatives to speech regulation that FDA might wish to consider champion.

II. THE ROLE OF THE FOOD AND DRUG ADMINISTRATION

It is FDA’s obligation to defend vigorously the regulatory choices made by the U.S. Congress. The agency has not done nearly enough to muster its defenses. Under the Supreme Court’s Central Hudson decision, even when commercial speech is involved, the government must justify regulatory requirements that can be viewed as speech restrictions with “concrete, credible evidence.” It is never sufficient simply to argue, at the time of challenge, that such restrictions are necessary to advance important government interests and that no less-restrictive alternatives are available. The judiciary repeatedly has found such an approach unconvincing. Consequently, to demonstrate the importance of regulatory restrictions in the context of consumer protection, FDA must gather data. In its First Amendment docket, FDA inquired about empirical evi-

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8 The Supreme Court continues to utilize the four-part analysis set out in Central Hudson to test the constitutionality of regulatory intrusions on commercial speech. The Court set forth its test as follows: At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest.
Central Hudson, 447 U.S. at 566.
11 FDA does engage in some such empirical research. In early 2003, for example, it released preliminary results of empirical research involving direct-to-consumer prescription drug advertising. See Margaret Gilhooley, The Supreme Court Checks Out Drug Promotion Restrictions, 58 Food & Drug L.J. 347, 351 & n.25 (2003). Litigation to which this research would have been directly relevant had begun eight years earlier. See Washington Legal Foundation litigation, supra note 1. FDA has supported proposals, such as those on uniform labeling formats, with research. Evans & Friede, supra note 5, at 397 & n.205.
In the Pearson litigation, FDA lost its legal argument concerning disclaimers, and apparently offered no empirical evidence at all in support of its contention that consumers would be unable to comprehend qualified health claims in conjunction with disclaimers. Pearson v. Shalala, 164 F.3d at 656. While the court added that it was “skeptical that the government could demonstrate with empirical evidence that disclaimers...would bewilder consumers and fail to correct for deceptiveness,” it did not “rule out that possibility.” Id. at 659-60. Neither the judge’s skepticism nor the FDA’s bare contention is an appropriate basis for sound public policy or constitutional judgment. In the absence of empirical evidence, rhetoric unfortunately was a significant basis for decision. Id. at 655.
dence to support various propositions. For example, the agency asked what an administrative record must contain to sustain a position that certain promotional speech about drugs, not in compliance with FDA requirements, is inherently misleading, or to sustain or deny claims on food labels. It asked whether the agency’s position on direct-to-consumer advertising is consistent with empirical research on the effects of such advertisements, and whether there is social science evidence to support distinguishing between claims made in advertisements and those made on labels.12

There is nothing inappropriate about making such inquiries, but it is not a very useful means to ferret out valid evidence. Industry can afford empirical research, but unless the results support its perspective, it would have no inclination to share them with FDA. Individual citizens and citizen groups are unlikely to be able to afford empirical research. If the agency has not yet begun to engage in a vigorous program of consumer studies, focus groups, and the like to test the empirical basis for various speech-related restrictions found in FDA statutes and regulations, it ought to do so immediately.

The consumer’s view of the product label, for example, ought to be the subject of FDA study. While consumers in our society surely are cognizant of the role of advertising and the need to maintain an attitude of healthy skepticism about claims it might contain, their view of labels may well be quite different. To what extent do consumers believe that labels are a regulated space upon which they may rely for accurate, government-approved information? Unfortunately, consumers’ views on the reliability of label claims may be quite different now than they would have been if surveyed prior to the time FDA became embroiled in the Pearson litigation that had such a dramatic impact on the product label.14 If consumers nevertheless still believe labels are in some way regulated, how do they respond to disclaimers on product labels?15 Can disclaimers effectively convey the fact that the information preceding them is entitled only to the credibility afforded other types of unreviewed promotional materials? How would consumers respond to a warning that a drug “had not undergone FDA testing and that its risks were unknown”?16

How objective (on paper and in practice) are educational materials and programs on prescription drugs that are financially provided or supported by pharmaceutical companies?17 How do these materials and programs compare, in terms of airing all perspec-

12 Request for Comment on First Amendment Issues, 67 Fed. Reg. at 34,943-44.
15 FDA is now doing research to determine if, and when, potentially misleading health claims can be cured by disclaimers, but has no such data in respect to foods or dietary supplements. Research will be completed within a year. Food Labeling: Health Claims; Dietary Guidance, 68 Fed. Reg. 66,040 (Nov. 25, 2003).
16 Western States, 535 U.S. at 376. Gilhooley, supra note 11, at 350-51, expresses appropriate skepticism about the effectiveness of disclaimers in the context of off-label use and physicians. Rep. Waxman, supra note 14, at 306-10, presents evidence—historical and contemporary—to support the inherently misleading nature of drug company promotional claims as viewed by both physicians and consumers.
17 Chen notes that FDA’s suspicions of industry intentions are based on the manufacturers’ “interest in casting their own products in a favorable light and thereby increasing sales.” Peggy Chen, Education or Promotion?: Industry-Sponsored Continuing Medical Education (CME) as a Center for the Core/Commercial Speech Debate, 58 Food & Drug L.J. 473 (2003).
tives on a product's safety and efficacy, to programs produced without pharmaceutical company support?18

Answers to these crucial questions, among others, would help FDA (and Congress) formulate appropriate public policy and address the judicial concern that restrictions on commercial speech be "not more extensive than is necessary"19 to serve the government's interest. FDA's failure to gather and offer such evidence in prior cases has surely contributed to its inability to convince the courts of its positions. It may be necessary for Congress to demand that FDA devote sufficient resources to this effort, because the agency may be disinclined to counter First Amendment attacks with vigor.20 If Congress and FDA have taken the position that public protection requires such restrictions on speech as are found in current statutes and regulations, the agency should act vigorously to defend its position, not capitulate to opposing views.

III. "LAWFUL ACTIVITY": ANSWERING THE THRESHOLD QUESTION

Much of the speech that is the subject of the debates concerning FDA regulation and the First Amendment is concededly commercial speech, and thus subject to the four-pronged test set forth in the Central Hudson21 case. "The threshold analytical question," as Evans and Friede point out, "is whether the speech concerns 'lawful activity' and is not misleading."22 Evans and Friede then skip over the "lawful activity" issue, and focus solely on the question of "misleading."23 Analytical confusion about when lawful activity is involved is found also in the case law.24 The lawful activity issue is not necessarily simple, and demands close analysis. What is, and what is not, legal conduct by certain types of speakers does (and should) affect the outcome of these cases.

18 Chen, supra note 17, at 496. Chen criticizes WLF I, 13 F. Supp. 2d 51, for concluding without support that physicians are capable of critical evaluation of drug information. Her observation underscores the importance of factually-based evidence, rather than allegations and assumptions, in litigation of these cases.

19 Central Hudson, 447 U.S. at 573.


21 Central Hudson, 447 U.S. at 566; see supra note 8.

22 Evans & Friede, supra note 5, at 383 (citing Central Hudson, 447 U.S. at 566).

23 Id. Samp, supra note 10, at 319 n.37, also dismisses the "illegal transaction" concern without considering the contrast between the behavior of the manufacturers, which is the concern of FDA, and the behavior of physicians, whose prescribing practices (except for controlled substances, for which all prescribers require DEA registration (21 C.F.R. § 1306.03(a)), are unregulated under federal law.

Jonathan S. Kahan & Jeffrey K. Shapiro, The First Amendment and the Food and Drug Administration's Regulation of Labeling and Advertising: Three Proposed Reforms, 58 Food & Drug L.J. 353, 360 (2003), dismiss the unlawful activity element when the speech restriction concerns investigational use of devices. But drugs and devices "intended solely for investigational use" (21 U.S.C. § 355(i)(1)) are illegal to distribute in any way outside of this limited exception, so a restriction on their being promoted (21 C.F.R. § 812.7(a)) seems well within the "illegal transaction" framework. Kahan and Shapiro urge a regulatory change involving scientific speech, rather than commercial speech, so a different, more speech-protective standard would apply. See infra text accompanying notes 45-46.

24 See, e.g., WLF I, 13 F. Supp. at 59 ("there is little question that the relevant 'conduct' is the off-label prescription of drugs by physicians" (emphasis added)).
The issue of legality is a critical threshold question in respect to promotion of “off-label” uses of approved drugs. It is illegal, under federal law, to ship a new drug interstate unless it is the subject of an approved new drug application. A new drug is one “not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling.” It is undisputed that if Compound X has been approved in a 100 mg. dose, four times a day, for headache, it is illegal to ship Compound X in a 200 mg. dose, or for use six times a day, or for nausea. A drug may be proven safe and effective for one use, but be neither safe nor effective for another. Different uses are simply not interchangeable. Approval for shipment under the Federal Food, Drug, and Cosmetic Act (FDCA) is limited to the intended uses approved by FDA. As Kahan and Shapiro correctly remind us, “intended uses” are found “in labeling, advertising, promotional material, or oral statements by the manufacturer or its representatives,” in whatever context or medium. Shipment for an unapproved use is, from the perspective of the drug manufacturer governed by federal law, illegal.

When drugs reach the market, however, they are no longer governed solely by the perspective either of federal law or of drug manufacturers. Drugs are prescribed by physicians and other prescribers, all of whom are licensed under state—not federal—

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21 An “off-label” use is one that has not been approved by FDA, and thus is not on the product label. Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices, 63 Fed. Reg. 31,143 (June 8, 1998).
23 Id. § 321(p)(1) (emphasis added).
24 Evans & Friede, supra note 5, at 435, incorrectly argue that the “prior safety approval of drugs used off-label” vitiate any safety concern about off-label uses (although they concede “some off-label uses may not be effective,” id. at 431, 435). A drug found safe and approved for one purpose is not thereby “safe” for all purposes. “Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk. Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use.” United States v. Rutherford, 442 U.S. 544, 555 (1979). A drug that effectively treats a deadly disease or a condition for which no other therapy is available may be approved as “safe” notwithstanding significant side effects, although the same drug would be rejected as unsafe to treat a minor symptom or a condition for which there were safer alternatives. Thus, it cannot be concluded that prior approval of a drug vitiates safety concerns about its off-label use. See Comments of Public Citizen in response to Request for Comment on First Amendment Issues, Dkt. No. 02N-0209 (anti-arrhythmic drugs increased mortality when used in post-heart attack patients), available at http://www.fda.gov/ohrms/dockets/dockets/02n0209/02N-0209_emc-000212-01.doc (last visited Nov. 28, 2003). See generally How Safe Is Safe? The Design of Policy on Drugs and Food Additives 27-29 (Nat’l Acad. of Sci. 1974).
25 Daniel J. Gilman, Protecting Protected Speech: First Amendment Taxonomy and the Food and Drug Administration’s Regulation of “Enduring Materials,” 58 Food & Drug L.J. 463, 465 (2003), proclaims, without citation to authority, that “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.” This proposition seems doubtful. Shipment for unapproved uses is unlawful. 21 U.S.C. § 355. Most distribution, in any case, is not to physicians, but to wholesalers who sell to pharmacies that fill physician prescriptions. Consider this hypothetical case: suppose a manufacturer is certain that a physician wants free samples entirely for off-label uses. Should the request for samples be denied? Straightforward application of the law suggests they should be, although undoubtedly the official policy is something akin to “don’t ask, don’t tell.” Of course, FDA officially recognizes the existence of off-label use, as well as its particular importance to some medical specialists. See, e.g., Guidance for Institutional Review Boards and Clinical Investigators: 1998 Update, “Off-Label” and Investigational Use of Marketed Drugs, Biologics, and Medical Devices, available at http://www.fda.gov/oc/ohrt/irbs/offlabel.html (last visited Nov. 28, 2003).
26 Kahan & Shapiro, supra note 23, at 355 (citing Action on Smoking and Health v. Harris, 655 F.2d 236, 239 (D.C. Cir. 1980)).
27 Physicians are legal prescribers in all states. Other healthcare licensees have prescribing privileges; these vary from state to state. In California, for example, prescribers include dentists, optometrists, podiatrists, and veterinarians. Cal. Bus. & Prof. Code § 4040(a)(2) (Deering 2003). In various states, other mid-level practitioners (e.g., physician assistants, nurse practitioners, and certified nurse-midwives) and healthcare providers (e.g., pharmacists, chiropractors, and physical therapists) have what appear to be prescribing privileges, albeit limited by requirements of supervision and protocols and sometimes called by another name. William L. Marcus & Marsha N. Cohen, Pharmacy Law for California Pharmacists 129-33 (4th ed. 2002). For ease of reference, this article uses “physician” and “prescriber” interchangeably.
law. State licensure or other regulatory control over the professions predate the federal law that gave FDA the authority to require premarketing approval of drugs shipped interstate. The result is no more a “regulatory paradox” than are endless other regulatory situations in which federal and state law share authority, sometimes in a confusing manner. The U.S. Supreme Court referred to FDA’s jurisdiction over off-label uses of approved drugs as a “thorny question” in Heckler v. Chaney. In that case, opponents of capital punishment sought an order requiring FDA to prevent the (presumably prescribed) off-label use of prescription drugs for lethal injection. The Court did not reach the issue, however, because it held FDA had the discretion, in any case, not to exercise its enforcement authority, even if there were a violation. When “a drug has been approved by the FDA for marketing for any use, the actual prescription choices regarding those drugs are left to the discretion of the physician.”

FDA has always respected its own lack of authority over the practice of medicine, as Gibbs, Ferrari, and Murphy concede. They note that FDA has no jurisdiction to control physician discretion in prescribing. In contrast, state medical boards have the authority to control physicians’ prescribing behavior when it reflects on their competence to practice medicine. So, while selling or promoting the sale of Compound X other than for headache would be illegal under federal law, physicians may prescribe Compound X for other purposes, or under different dosing schedules than set forth in the labeling, as long as such conduct is not prohibited by the medical practice act under which they are licensed. FDA has power to control only the conduct of the drug seller, not the drug prescriber. Speech by the seller encouraging the sale of the drug for unapproved uses proposes an illegal commercial transaction under the relevant federal law. Promotion of

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32 State-licensed prescribers require federal registration to prescribe controlled substances. See supra note 23.

33 Kahan & Shapiro, supra note 23, at 355. Chen, supra note 17, at 478, refers to the “asymmetry” between what can be marketed and what can be prescribed.


35 Id. at 832. The somewhat-ironic argument of the plaintiffs was that the drugs had not been demonstrated to be safe and effective for use in executions.

36 WLF I, 13 F. Supp. 2d at 55 (emphasis added). As the court in WLF I notes, “it appears to be an open question as to whether the FDA could currently regulate this aspect of the practice of medicine if it wished to do so.” Id. at 56. Later in its opinion, the court in WLF I confuses the conduct of physicians in prescribing drugs for off-label uses (which is legal) with the conduct of manufacturers in selling drugs for off-label uses (which is not legal). The difference is critical because, as that court notes, “The First Amendment does not protect commercial speech about unlawful activities.” Id. at 66 (citing 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 497 n.7 (1996)).


38 FDAMA amended the FDCA to add that FDA has no authority to interfere with the prescription of “any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship,” while not limiting FDA’s authority to establish and enforce restrictions on sale or distribution, or changing “any existing prohibition on the promotion of unapproved uses of legally marketed devices.” 21 U.S.C. § 396. See generally Buckman Co. v. Plaintiffs’ Legal Committee, 531 U.S. 341, 351 n.5 (2001).

39 See, e.g., CAL. BUS. & PROF. CODE § 2234(d).

40 Gibbs, Ferrari & Murphy, supra note 37, at 338, complain that FDA restrictions on dissemination of information on off-label uses are “based on who disseminates the materials.” That result, of course, is logical. FDA’s jurisdiction is limited to those disseminators over whom it has regulatory authority. Furthermore, manufacturers, who are subject to FDA jurisdiction, are providing information as a means of marketing their drugs for off-label uses, whereas others disseminating information about off-label uses are engaging in noncommercial speech, not subject to similar restrictions even if FDA had jurisdiction. The distinction is based on commercialization, not on content. Bolger v. Youngs Drug Products Corp., 463 U.S. 60 (1983) (cited by Gibbs, Ferrari & Murphy, supra note 37, at 339) is distinguishable because the contraceptive products that were the subject of the mailed information in that case were entirely legal for sale.
off-label uses of approved drugs is thus no different from promotion of drugs that are not legal to sell for any purpose.\(^4\)

That FDA has taken no action to restrict prescribing for off-label uses or to restrict their promotion by third parties, as Blackwell and Beck note,\(^4\) is thus irrelevant to First Amendment analysis pertaining to manufacturers. Even if FDA were to believe that all promotion of off-label uses is a threat to the public health, it has no regulatory power over other speakers.\(^4\)

The illegality analysis in respect to off-label uses is no different when drug manufacturers’ promotional activities take the form of continuing medical education. Similarly, promotion of drugs “in the pipeline” proposes an illegal transaction. As Samp notes, the \textit{WLF I} court pointed to the fact that “a manufacturer virtually always acts with the long-term goal of selling more of its products.”\(^4\) Nevertheless, a line must be drawn allowing behavior of manufacturers with little near-term or direct promotional potential (such as participation in, and financial support of, scientific meetings about the early development of classes of pharmaceuticals) to be entitled to the full protection of the First Amendment. The position of commercial speech “at the blurry crossroads of expressive and economic activity”\(^4\) is especially evident in considering drug manufacturers’ educational activities. Given the blur, courts should give significant deference to Congress’ attempt to draw the line in regard to promotional material, as it recently did in FDAMA.\(^4\)

“Off-label” use of drugs is in fact widespread. Existing limitations by FDA on manufacturer promotion have not seemed to stem the growth of off-label prescribing. According to an investigation published in November 2003 by the Knight Ridder newspapers, “[o]ver the last year, 115 million such prescriptions were written, nearly double the

\(^{41}\) Evans \& Friede, \textit{supra} note 5, at 401, concede FDA’s “constitutional authority to bar a manufacturer from promoting and selling a product for use as a drug where the agency has not approved that product to be marketed as a drug.” Because drug approval is \textit{for a specific use}, rather than \textit{for a specific compound}, their concession that commercial speech concerning unlawful conduct is constitutionally unprotected should apply equally to promotion of off-label uses.

\(^{42}\) Blackwell \& Beck, \textit{supra} note 7, at 444.

\(^{43}\) Blackwell \& Beck, \textit{id.} at 451, argue that because FDA allows third-party speech about off-label uses—“a variety of speech that poses the same risks as the speech sought to be prohibited”—its policies restricting manufacturer speech about off-label drugs cannot survive the third prong of \textit{Central Hudson}, that the regulation effectively advances the agency’s asserted interests. Even if we overlook the considerable problem of FDA’s lack of jurisdiction over other speakers (that is, it cannot do anything but “allow” their speech), FDA’s position is fully supportable. Manufacturers have a financial stake in off-label prescribing and thus are more likely than others to spend the money that widespread speech costs. Only manufacturers send “speakers”—their many detailers—to physicians’ offices. There are 94,000 such manufacturers’ representatives, one for every seven physicians in the country. Chris Adams \& Alison Young, \textit{Drugmakers Pushing Risky Off-Label Uses on Physicians}, DETROIT FREE PRESS, Nov. 4, 2003, at A1, also posted, but retitled as \textit{Drug-makers’ Promotions Boost Off-Label Use By Doctors}, at http://www.realcities.com/ml/krwashingon/news/special_packages/riskyrs/ (last visited Dec. 11, 2003). In addition, only manufacturers have a financial incentive for their speech to exaggerate the benefits and minimize the risks of their products. Chen, \textit{supra} note 17, at 473. Thus, regulating manufacturers’ speech, even without the ability (or desire) to regulate the speech of others on the same topic, can directly advance the state interest and alleviate the harm to a material degree.


\(^{45}\) Stern, \textit{supra} note 9, at 146 \& n.599 (citing Laurence H. Tribe, \textit{American Constitutional Law} 903 (2d ed. 1988) (“The entire commercial speech doctrine, after all, represents an accommodation between the right to speak and hear expression about goods and services and the right of government to regulate the sales of such goods and services.”)).

\(^{46}\) FDAMA, Pub. L. No. 105-115, § 401(a), added sections 360aaa-360aaa-6 to title 21 of the \textit{U.S. Code}, authorizing the dissemination, under specified conditions, of treatment information not described in the approved labeling (i.e., about off-label uses).
number of five years ago." While some of that use is essential to the public health, and is even the standard of care, the study’s authors estimate that “at least 8,000 people became seriously ill last year after taking some of the nation’s most popular drugs off-label.” Epilepsy drugs are widely used for depression, hot flashes, and weight loss; antidepressants to treat premature ejaculation and pain; and antipsychotics for insomnia and attention deficit disorder. In one extreme example, the drug thalidomide is approved only for a leprosy-related skin condition rarely found in the United States; only one percent of its use is for that condition, and the rest is off-label. The authors conclude that off-label prescribing “often is driven by questionable research, aggressive drug-company marketing and cavalier doctors, and condoned by tepid regulators.” Drug manufacturers, the authors conclude, “often had no incentive to evaluate the merits of off-label prescribing because they might discover that their drugs didn’t work when prescribed off-label and sales would suffer.” These findings parallel those cited by Representative Waxman as evidence that the promotional restrictions on drug manufacturers in the FDCA do not run afoul of the First Amendment.

IV. SPEECH AS A BOUNDARY MARKER BETWEEN LEGAL AND ILLEGAL

When Congress passed section 503A of the Food and Drug Administration Modernization Act of 1997 (FDAMA), it was concerned about preventing the illegal sale of

47 Alison Young & Chris Adams, Prescription for Trouble: Approved Medicine Is Being Used For the Wrong Purpose, DETROIT FREE PRESS, Nov. 3, 2003, at A1, available at http://www.freep.com/news/health/drugs3_20031103.htm (last visited Dec. 19, 2003). Exactly how widespread is unclear. The court in WLF I, 13 F. Supp. 2d at 56, cited for the low estimate of frequency of off-label use a study concluding from two to almost five percent of the prescriptions for the most frequently-prescribed drugs were off-label, and for the high estimate a study concluding 25% of prescriptions for anticancer drugs were off-label. Blackwell & Beck, supra note 7, at 440, cite estimates of between 25% and 60% of all prescriptions as off-label. While the high percentages are credible in respect to certain patient populations (id. at 440 n.7), they seem very unlikely in respect to the overall market. Retail pharmacies filled 2.9 billion prescriptions in 2000. Robert Pear, Spending on Prescription Drugs Increases by Almost 19 Percent, N.Y. TIMES, May 8, 2001, at A1. If the Knight Ridder study’s number (115 million off-label prescriptions) for 2002 is compared with the number of prescriptions filled in 2000 (2.9 billion), a rough guess is that about four percent of prescriptions are off-label.

48 Pediatricians, for example, routinely prescribe drugs for which there is no approved pediatric dosage in the labeling. Oncologists, faced with a fatal disease, frequently prescribe drugs off-label when they have exhausted other therapies or when there is scientific evidence, not yet reflected in labeling, that a drug might be effective. See James O’Reilly & Amy Dalal, Off-Label or Out of Bounds?, Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs, 12 ANN. HEALTH L. 295, 298 (2003); Veronica Henry, Off-Label Prescribing: Legal Implications, 20 J. LEGAL MED. 365(1999).

49 Chen, supra note 17, at 478.

50 Young & Adams, supra note 47.


52 See Comments of Public Citizen, supra note 28, at 1 (citing David Kessler, Addressing the Problem of Misleading Advertising, 116 ANN. INTERN. MED. 950-51 (1992)).

53 Young & Adams, supra note 47.

54 Id.

55 Waxman, supra note 14, passim. Congressman Waxman’s article gathers considerable evidence from the records of Congress that FDA could use to support Congressional and agency decisions to restrict commercial speech concerning off-label uses of drugs. He cogently argues the case that disclaimers, even where directed to prescribing physicians, would be inadequate to provide the type of information physicians need to make prescribing decisions—and that Congress has required as a precondition to drug approval. Id. at 311-12.

56 Section 503A (codified as 21 U.S.C. § 353a) exempted from the adulteration, misbranding, and new drug approval sections of the FDCA any drug “if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient,” and subject to various restrictions concerning the ingredients in the drug product and the licensure of the compounding pharmacist or physician. 21 U.S.C. § 353a(a).
unapproved drugs, while recognizing the traditional practice of pharmacy\textsuperscript{37} compounding. Since the passage of the FDCA, it has been illegal to ship an unapproved drug interstate—whether for one person or a thousand.\textsuperscript{58} However, federal controls over drug approval and manufacture have always existed in tension with traditional drug-creation by pharmacists, who are governed by state laws.

Virtually all drug preparation once was done by pharmacists (who more often were called druggists or apothecaries). Today, all drug making is considered manufacturing. Under federal law, anyone who engages in the manufacture, preparation, propagation, compounding, or processing of drugs or devices is deemed a manufacturer and subject to registration and other requirements.\textsuperscript{59} The states also regulate drug manufacturing. For example, under California law, manufacturing includes preparing, compounding, propagating, processing, or fabricating any drug or device.\textsuperscript{60} Pharmacy compounding thus is, in essence, manufacturing, as the definitions specifically recognize. Pharmacists, however, have been exempted from manufacturing regulations as long as their compounding has fallen within the traditional practice of pharmacy. As the FDCA section on registration of drug manufacturers provides,

[This] section shall not apply to—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.\textsuperscript{61}

This statutory exception of course begs the question of when a pharmacy is engaged in dispensing, and when it has crossed the line into manufacturing.\textsuperscript{62} Manufacturers are regulated stringently to ensure the safety and security of drugs. The risks to public health from the manufacturing process itself are not merely theoretical; deaths and other significant harms have resulted from drugs created in the less-regulated

\textsuperscript{37} Physicians also may compound, and their compounding was contemplated by the terms of the federal compounding statute. 21 U.S.C. § 353a(a)(1)(B). For simplicity, this article will henceforth refer only to pharmacies and pharmacists as compounders.

\textsuperscript{58} 21 U.S.C. § 353(a). See also Western States, 535 U.S. at 361-65 (providing background on the passage of the federal pharmacy compounding statute).

\textsuperscript{59} 21 U.S.C. § 360(c).


\textsuperscript{61} 21 U.S.C. § 360(g)(1).

\textsuperscript{62} The Court recognized the necessity of drawing the line in its Western States opinion, 535 U.S. at 370. Discussions of Western States can become mired in confusion in respect to this categorization problem. Gilman, supra note 29, at 465, exhibited confusion when he stated, "At issue in Western States was truthful speech about compounding services from legitimate (nonmanufacturing) pharmacies to physicians serving patients with special needs (citation omitted)." First, neither federal nor any state law has ever prohibited speech about compounding services, only about compounded \textit{products}. Second, while all the pharmacy plaintiffs in Western States were "legitimate"—presumably they all were duly licensed pharmacies—the very point of the statute at issue was to draw the line between compounding and manufacturing. Western States actually is silent about whether or not these particular pharmacies crossed that line; at issue was only whether the statute could use speech (in the form of promotion of compounded drugs) as a factor in making the judgment.
environment of a pharmacy.\textsuperscript{63} In addition, federal law requires premarket demonstration of the safety and efficacy of each new drug for the protection of public health. Compounds prepared by pharmacies are subject neither to the stringent safety regulations mandated for other manufacturers nor to the premarket approval process of the FDCA.

Until the passage of section 503A of FDAMA, federal law essentially was silent about the interstate shipment of compounded drugs. Five years earlier, in 1992, FDA had adopted a Compliance Policy Guideline defining the line between traditional pharmacy compounding and drug manufacturing—a line that state regulators had struggled to define for years.\textsuperscript{64} Prior to the 1990s, however, most pharmacy practice had remained largely within state borders, sufficiently governed by state laws. As mail-order and then Internet pharmacy became increasingly prevalent, and prescriptions regularly crossed state lines, the issue became a more critical one for federal regulation.

Compounding is done extemporaneously, pursuant to a “prescription for an individually identified patient from a licensed practitioner.”\textsuperscript{65} The traditional path to a compounded drug begins in the prescriber’s office, when a patient’s care is found to require a therapy not commercially available, whether because of allergy to an inactive ingredient (perhaps a flavoring or a color additive) or an inability to use the dosage form (e.g., to swallow a pill). The prescriber then seeks out a pharmacy to mimic a commercially-available (and approved) drug, but to leave out the offending ingredient, or to turn pills into a liquid suspension or put their ingredients into a capsule. Other physicians may request that a pharmacy prepare a particular compound from available pharmaceutical ingredients to their specifications for a particular patient. Historically, the most frequent prescribers of compounded drugs were dermatologists. In recent years, compounded drugs have become more widely prescribed in such specialties as cardiology, rheumatology, pain management, bariatric medicine, oncology, endocrinology, pediatrics, and geriatrics.\textsuperscript{66}

California’s line-drawing between compounding and manufacturing was not atypical.\textsuperscript{67} To remain within the confines of the practice of pharmacy, a pharmacist could compound pursuant to a prescription for an individual patient, or in a reasonable quantity in anticipation of receiving prescriptions based upon an existing practitioner, patient, and pharmacist relationship.\textsuperscript{68} Pharmacy inspectors were to consider a number of factors to determine if the line had been crossed, including whether the pharmacy

\textsuperscript{63} Safety risks can be significant. Three patients died in 2001 in Walnut Creek, California, and one in North Carolina after receiving injected drugs prepared in pharmacies. See Sabin Russell, \textit{Tainted Shot May Have Killed Woman; N.C. Death Like Cases in Walnut Creek}, S.F. CHRON., Oct. 2, 2002, at A3. The extent of problems caused by compounded drugs is not known, because there is no federal law requiring reports of adverse consequences. At a recent congressional hearing, Sen. Kit Bond indicated that there have been 200 “adverse events” reported since 1990, involving 70 products, but noted that that is only an estimate. See Edward Epstein, \textit{Warning Issued on Preparation of Drugs; Senator Says Pharmacies Must Improve Safety of Hand-Mixed Prescription Medicines}, S.F. CHRON., Oct. 24, 2003, at A3. See \textit{Western States}, 535 U.S. at 382-83 (Breyer, J., dissenting).

\textsuperscript{64} Id. (quoting FDA Compliance Policy Guide 7132.16 (1992)).

\textsuperscript{65} Telephone interview with Dr. Joanne Whitney, Director of Drug Product Services Laboratory and Associate Clinical Professor, University of California at San Francisco, School of Pharmacy (Dec. 1, 2003).

\textsuperscript{66} See \textit{Western States}, 535 U.S. at 381-82 (Breyer, J., dissenting) (listing statutes and regulations of thirteen states and the model Good Compounding Practices of the National Association of Boards of Pharmacy).

\textsuperscript{67} \textsc{Cal. Bus. \\& Prof. Code} § 4052(a)(1); \textsc{Cal. Code Regs. tit. 21, §§ 1716.1,1716.2; The Script, Summer 1995, at 16-17 (newsletter of the California State Board of Pharmacy).
“solicits or advertises for business from any practitioner or other entity for specific products which the pharmacy compounds.”

FDA’s 1992 Compliance Policy Guide also attempted to draw a line between the practice of pharmacy and “the kinds of concerns normally associated with a manufacturer.” Like California, FDA did so by outlining a group of factors that suggested the line had been crossed, to be considered by FDA in determining whether to challenge the practice as illegal manufacturing. In 1997, FDA’s policy was largely incorporated into section 503A of FDAMA, when Congress for the first time specifically recognized the pharmacy compounding exception.

Under the new statute, a pharmacist was compounding—and exempt from regulation as a manufacturer—if the drug product was “compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient.” The law set forth factors to distinguish allowable compounding from manufacturing, including the existence of an established relationship between the compounding pharmacist and either the patient or the prescriber, in which the prescriber initiates the demand (“the unsolicited receipt of a valid prescription”) for the compounded product. Federal law restricted the quantity of compounded drugs that could be shipped interstate. Most critically, Congress included a limitation that allowed compounding only if the pharmacy did “not advertise or promote the compounding of any particular drug, class of drug, or type of drug.” This is the provision that caused the Supreme Court, by a 5-4 vote, to declare the statute unconstitutional in Thompson v. Western States Medical Center as a violation of the free speech rights of pharmacies.

Like the state legislators and pharmacy regulators who had earlier considered this issue, Congress recognized that a certain amount of flexibility to individualize drugs, in

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69 THE SCRIPT, supra note 68, at 17. Those factors were:
1. A professional relationship does not exist among the prescriber, patient, and pharmacist who compounds and dispenses the drug product.
2. The pharmacy solicits or advertises for business from any practitioner or other entity for specific products which the pharmacy compounds.
3. The pharmacy is compounding products which are essentially generic copies of FDA-approved products which are commercially available.
4. The pharmacy is receiving and using drug substances or components without obtaining and retaining appropriate evidence of source or method of preparation.
5. The pharmacy is compounding drugs in anticipation of receiving prescriptions, as opposed to in response to individual prescriptions. The volume of such drugs compounded by the pharmacy is high when compared to the volume of prescriptions actually received for such drugs.
6. A significant amount of compounded drugs is distributed to patients or customers outside the pharmacy’s normal trade area or across state lines.
7. Drugs are compounded by one pharmacy and dispensed by another pharmacy.
8. The pharmacy is not in general compliance with state or federal requirements for the production, preparation and maintenance of safe and effective drug products (for example, [CAL. BUS. & PROF. CODE § 4342; CAL. HEALTH & SAFETY CODE] §109875 and following).

Id.

70 Western States, 535 U.S. at 362 (citing FDA Compliance Policy Guide 7132.16).
71 Id. at 363.
73 Id. § 353a(a)(2).
74 A number of additional requirements focused upon the safety of the compounding, such as requiring the use of bulk drug substances that comply with various standards and are manufactured by establishments registered with FDA, and forbidding the compounding of drugs withdrawn from the market as unsafe or ineffective. Id. § 353a(b).
75 Id. § 353a(b)(3)(B)(i), (ii).
76 Id. § 353a(c).
77 535 U.S. 357.
response to unique consumer needs, contributes to the public health. On the other hand, the sale of drugs outside the systems created to ensure that they are safe and effective for their intended purposes (premarket approval) and produced under safe and sanitary conditions by personnel adequately trained to do so (good manufacturing practices regulation) poses significant risks to public health. In drawing the line between acceptable compounding and manufacturing, Congress had used speech as one factor to demarcate the boundary.

Speech as an indicator of a boundary that, when crossed, requires the speaker to comply with a particular set of regulatory requirements is not uncommon in regulatory law. One major instance of the speech-boundary concept is integral to the regulation of drugs. Under the FDCA, it is crucial to determine when a substance is in fact a drug rather than, for example, a food, a cosmetic, or something else not subject to the same—or to any—regulation. One of the definitions of a drug is an article “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.” Intent is determined in significant part by the advertising and promotion done by the seller. The drug-defining statute does not forbid any speech, but through speech a speaker may position its product as a drug, thus subjecting it to a complex regulatory scheme. Evans and Friede, in an extended analysis, conclude that “imposing certain consequences on a manufacturer depending upon what it says about its products . . . is sustainable under the First Amendment.”

Similarly, speech is regularly a factor in defining who is subject to professional licensure requirements. Persons who give legal “counsel and advice,” even if not connected to a judicial or other proceeding, cross over the boundary into the practice of law, which may be done only by those licensed as attorneys. Merely “advertising or holding one’s self out” as an attorney constitutes the practice of law. A typical medical practice act forbids, among other things, the diagnosis of disease by anyone not licensed as a physician, and similarly prohibits advertising or holding one’s self out as a physician, even though some significant aspects of the practice of medicine (such as diagnosis) can be accomplished entirely through speech. While speech about legal problems and medical diagnosis is constitutionally protected when directed generally to the public, as by an author of a self-help book, the same speech directed to an individual to deal with his or her legal or medical problem would be deemed to cross the boundary line, and would require the speaker to obtain a license.

Just as a manufacturer’s speech about a substance can cause it to be regulated as a drug, compounding pharmacists’ speech about their products can be a legitimate reflec-
tion of their intent to act as drug manufacturers. The speech itself is not forbidden, but engaging in it may change the categorization of the product and of the speaker, such that the speaker must obtain the licenses and approvals required for the product’s sale. To protect public health and safety, Congress (and state legislatures and regulatory bodies before it) carved out a narrow legal exception to manufacturing based upon responsive behavior. That is, pharmacies were allowed to fill prescriber requests for compounded medications for individual patients, but could not promote the sale of compounded medications in the hope of receiving future physician requests. The latter behavior was determined to be a characteristic of drug manufacturers, and those who engaged in it would need to be licensed as such.

The Western States Court’s concern that the advertising restriction would prevent pharmacists “from telling . . . children’s doctors about a new development in compounding that allowed a drug that was previously available only in pill form to be administered another way . . . [and] from posting a notice informing customers that if their children refuse to take medications because of the taste, the pharmacist could change the flavor . . .” was to some extent misplaced. The federal compounding law specifically allowed the advertising and promotion of compounding service. Certainly a notice that reads, “Parents: does your child reject a prescribed medication because of its taste? Your physician may ask this pharmacy to change its flavor,” promotes compounding service, rather than any particular drug.

In contrast, the statement, “Because of a new technological development in compounding, Drug X, previously available only in pill form, can now be transformed into a liquid,” was covered by the prohibition in section 503A against the advertising or promotion of “the compounding of any particular drug, class of drug, or type of drug.” However, if the statement were drafted more broadly (e.g., “drugs previously available only in pill form”), it might be outside the prohibition. The federal prohibition admittedly was more broadly worded than, for example, the California guideline, which forbade only soliciting or advertising for business “for specific products which the pharmacy compounds.” The government interest in ensuring the safety and efficacy of all drug products is more directly affected by the promotion of particular products than by discussion of types of products that might be available through compounding. A more narrowly-drafted statute could reduce the “amount of beneficial speech” forbidden, while still enabling the use of a narrowed category of speech as a partial boundary marker between manufacturers and compounding pharmacists. In addition, a litigation record that more fully explains public health concerns about increasing population exposure to drugs not subjected to premarket testing, and made under conditions not as stringently controlled as those governing manufacturers, could dispel the notion that the government’s concern is only about people making “bad decisions” with truthful information.

83 Western States, 535 U.S. at 377.
84 21 U.S.C. § 353a(c) (“The pharmacy . . . may advertise and promote the compounding service . . . .”).
85 Id.
86 See supra note 69 (emphasis added).
87 Western States, 535 U.S. at 376.
88 The government conceded in Western States that the prohibited advertisements would not be about unlawful activity. 535 U.S. at 368. This concession likely was unwise, as an argument could be made (see Section III, supra) that all compounded drugs shipped interstate are in fact illegal prior to the receipt of a prescription for a particular patient, with the exception of limited quantities made based on the history of receipt of valid prescriptions for that particular product, within a valid compounding/patient/prescriber relationship. 21 U.S.C. § 353a(a)(2). Timing, in the compounding exception, is everything, because the receipt of a prescription makes legal a product that, prior to the existence of that prescription, was not legal.
89 Western States, 535 U.S. at 374.
It is more than a bit ironic that the Western States Court majority relied so heavily on the Virginia Board of Pharmacy\textsuperscript{90} case to support its position concerning “fear” of information. The Virginia Board of Pharmacy plaintiffs were consumers who wanted to wrest price information, and the competition that would arise from its availability, from a regulatory body controlled by members of the profession who feared that competition.\textsuperscript{91} In significant contrast, the Western States litigation was brought by sellers seeking to expand their markets under what the government intended to be a narrow exception to consumer protection requirements ensuring the safety and efficacy of new drugs. As Justice Breyer noted in his dissent in Western States, overly-rigid interpretation of the commercial speech doctrine transformed a legislative/regulatory decision “about the best way to protect the health and safety of the American public into a constitutional decision prohibiting . . . necessary protections.”\textsuperscript{92}

Now that the decision in Western States leaves federal law silent on pharmacy compounding,\textsuperscript{93} however, all compounded drugs that cross state lines are in violation of the FDCA, as unapproved drugs shipped interstate, and subject to seizure.\textsuperscript{94} It could therefore be argued (see section III, supra) that advertising of such unapproved drugs, like advertising of off-label uses, by their commercial sellers is speech concerning an unlawful activity and is subject to regulation.

V. THE PYRRHIC VICTORY

To the extent they are forced to eliminate regulatory restrictions interpreted as unconstitutional limitations on speech, the Congress and FDA will need to consider how to implement preferred public policy in the food and drug arena through restrictions on conduct. As Blackwell and Beck suggest, industry may rue the day it challenged speech restrictions.\textsuperscript{95} It is interesting to contemplate alternative routes to some of FDA’s regulatory goals.

As noted above, with federal law now silent on pharmacy compounding, there is no remaining statutory “safe harbor” for interstate sales of drugs created by pharmacists. The simplest conduct-based approach FDA could take to pharmacy compounding would be to declare all compounded drugs crossing state lines subject to seizure. While such


\textsuperscript{91} Id. at 754.

\textsuperscript{92} Western States, 535 U.S. at 389 (Breyer, J., dissenting).

\textsuperscript{93} In response to the decision in Western States, FDA modified its compliance policy guideline on pharmacy compounding, § 460.200, retaining all the factors to distinguish manufacturing from traditional compounding except the speech-related factor declared unconstitutional. FDA is considering the implications of Western States and “how it intends to regulate pharmacy compounding in the long term.” See http://www.uspharmd.com/pharmacy_compounding.htm#INTRODUCTION (May 29, 2002) (last visited Nov. 23, 2003). FDA appears to be exercising enforcement discretion in respect to these interstate sales. See also Epstein, supra note 63 (an October 23, 2003 hearing of the Senate Health, Education, Labor and Pensions Committee signals congressional interest in the subject).

\textsuperscript{94} The transcript of the oral argument before the Supreme Court in Western States includes the following question asked by an unidentified Justice to counsel for the Government: It seems to me that you still can enforce—I would have thought the parties to be arguing the opposite sides of this case, to tell you the truth. It seemed to me the statute actually helps the compounders, because it makes legal something that is otherwise illegal, and if the statute’s knocked out, you have all your enforcement mechanisms to prevent them from doing the mass marketing, don’t you? Western States, Transcript of Oral Argument, available at http://a257.g.akamaitech.net/7/257/2422/11mar20020920/www.supremecourts.gov/oral_arguments/ argument_transcripts/01-344.pdf (01-344, Feb. 26, 2002) (last visited Nov. 10, 2003).

\textsuperscript{95} Blackwell & Beck, supra note 7, at 439.
a policy would pose little difficulty in large states, where the services of compounding pharmacists playing their traditional role would remain available to the citizenry, it could have negative consequences elsewhere. A less drastic alternative would be for FDA to define with specificity the types of situations in which pharmacy compounding would be tolerated notwithstanding the federal new drug and manufacturing laws. For example, FDA could allow pharmacists to change the dosage form of a manufactured drug (e.g., making a pill into a capsule or liquid); add flavoring to, or change the flavor of, a manufactured drug; or create a duplicate of an approved drug without an ingredient a particular patient could not tolerate; and it could declare all other compounding to be manufacturing. If it had the resources to do so, the agency could indicate it would exercise its enforcement discretion not to seize other products compounded at the request of a prescriber who registers the order for a particular patient with the FDA, under conditions that FDA could develop. Those conditions might involve a statement of necessity and limitations on volume, for example. States could create parallel restrictions. Such compounding limitations would, as Blackwell and Beck warned, make Western States into a Pyrrhic victory.

Blackwell and Beck themselves offer interesting suggestions for limiting off-label drug use. FDA “could require manufacturers to seek FDA approval of off-label uses if such uses reach specified statistical thresholds—either by pure volume of off-label prescriptions or by off-label use as a percentage of total product sales.” 96 If a new indication were sought and denied as not safe and effective, and FDA were aware of significant use for this indication, it could mandate labeling to that effect. 97 Such labeling would not eliminate off-label use for that indication, but the enhanced risk of malpractice suits against physicians ignoring the mandated labeling would likely diminish its use.

The First Amendment likely would bar significant FDA restrictions on direct-to-consumer advertising of prescription drugs, as long as the promotional materials avoid misleading consumers. If the government decides that direct-to-consumer advertising of prescription drugs is bad public policy, either because it increases the costs of drugs or exposes consumers to additional drug risks when alternative therapies (or none) might be a more reasonable choice, it nevertheless has some options available. 98 The anticipated increase in government support of prescription drug costs through Medicare 99 provides additional rationale for government action. Even if it cannot prevent advertising and promotion, Congress could change the tax laws to remove the government subsidy of such activities. While it would need to avoid singling out speech, Congress could eliminate the business-expense deduction for all promotional expenses incurred by sellers of prescription drugs. 100 Such expenses would include dollars-off coupons, free samples intended to be provided to patients, payroll expenses for detailers, support for medical conferences, and educational materials, as well as traditional advertising. Promotion could continue, but the costs would be borne entirely by the company and its stockholders, rather than being shared by taxpayers. A similar approach could

96 Id. at 459.
97 As part of a broader scheme of regulation, not solely involving mandated speech, such required labeling would not violate the First Amendment. See United States v. United Foods, 533 U.S. 405 (2001).
98 Gilhooley, supra note 11, at 352.
100 No doubt the statute would meet with a First Amendment challenge. If it is broad in scope, covering more than just speech-related expenditures, such a change in the tax code should pass muster. It will obtain the support of Justice Scalia and Chief Justice Rehnquist, dissenters in Arkansas Writers' Project v. Ragland, 481 U.S. 221 (1987) (striking down Arkansas sales tax that exempted certain specialty magazines from taxation while taxing others). Justice Scalia stated in dissent, "[D]enial of participation in a tax exemption or other subsidy scheme does not necessarily 'infringe' a fundamental right [because] . . . such a denial does not, as a general rule, have any significant coercive effect." Arkansas Writers' Project, 481 U.S. at 237.
be taken in respect to continuing medical education expenses, and to prescription drugs created under the compounding exception. By definition, it also would cover promotion of off-label uses.  

With judicial decisions enabling claims on dietary supplement labels based on progressively-reduced levels of scientific confidence, policy makers in Congress and at FDA need to give serious consideration to an alternative method of regulation. Most logical would be to create a legislative scheme for the approval of marketing of dietary supplements, on a generic (substance-by-substance) basis. These substances, no less than over-the-counter drugs and food additives, could be required to be demonstrated to be safe at a particular dosage level for a particular purpose, and effective for that purpose—even if the legislative scheme requires proof on a less stringent basis than the controlled clinical studies required for new drugs. Once sales are restricted to products meeting a government-set standard, manufacturer claims outside the bounds of that marketing permission will be subject to control.

VI. CONCLUSION

By developing data to demonstrate how communications are received by consumers, as well as by vigorous and careful advocacy, FDA should defend those aspects of its laws and regulations that, while affecting speech, are important to public protection. Both FDA and Congress should consider alternative means to achieve the same goals. Abandoning public protection to the whims of the marketplace is not an appropriate alternative.

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101 The extension of such a concept to other FDA-regulated commodities—such as food and dietary supplements—would likely have many proponents.

102 The latest is Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002) (one-third of the scientific studies reviewed by FDA supported the claim).

103 A process to review products currently on the market (and a long lead time for the review) would be required. Traditional vitamin/mineral supplements, at dosage levels long recommended, could be approved quickly for continued sale. In light of the current marketplace, the German Commission E model certainly deserves a careful look. See, e.g., Cary Zak, Herbal Remedies Are Not Dietary Supplements: A Proposal for Regulatory Reform, 11 Hastings Women's L.J. 29, 53 (2000); Margaret Gilhooley, Herbal Remedies and Dietary Supplements: The Boundaries of Drug Claims and Freedom of Choice, 49 Fla. L. Rev. 665, 710-11 (1997).